

US3312605 (Prod: Johnson County Clin-Trials)

Generated By: (b) (6)

Generated On: 26 Nov 2020 10:55:55

All time stamps listed in this document are displayed in GMT

**US3312605**

**Form: Participant Creation**

**Generated On: 26 Nov 2020 10:55:55**

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[Participant ID](#)

US3312605

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

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US3312605

Folder: Screening

Form: Visit Date

Generated On: 26 Nov 2020 10:55:55

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	10 SEP 2020
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	SCRN

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Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 10:55:55

Date of Birth (MMM yyyy)	(b) (6) 1996
Age	24
Age Units	YEARS
Age (Derived)	24
Sex	Female <input type="radio"/> Male <input checked="" type="radio"/>
Ethnicity	Hispanic or Latino <input type="radio"/> Not Hispanic or Latino <input checked="" type="radio"/> Not Reported <input type="radio"/> Unknown <input type="radio"/>
Race (Check All That Apply)	
White	True
Black	False
Asian	False
American Indian or Alaska Native	False
Native Hawaiian or other Pacific Islander	False
Other	False
If race is Other, specify _____	
Unknown	False
Not reported	False

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Folder: Screening

Form: Enrollment

Generated On: 26 Nov 2020 10:55:55

Date of Informed Consent ( <i>dd MMM yyyy</i> )	10 SEP 2020
Month and Year of Informed Consent (derived)	SEP 2020
Year of Informed Consent (derived)	2020
Protocol Version	Amendment 1 <input type="radio"/>
	Amendment 2 <input type="radio"/>
	Amendment 3 <input checked="" type="radio"/>
	Amendment 4 <input type="radio"/>
	Amendment 5 <input type="radio"/>
Was participant enrolled in the study?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
If No, indicate reason for screen fail	Withdrew Consent <input type="radio"/>
	Inclusion/Exclusion <input type="radio"/>
	Cohort Full <input type="radio"/>
	Other <input type="radio"/>
If reason for screen fail is Other, specify	
Was this participant screened previously?	Yes <input type="radio"/>
	No <input checked="" type="radio"/>
If Yes, previous participant number	
Enrollment Trigger	1

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Folder: Screening

Form: Inclusion/Exclusion Criteria Summary

Generated On: 26 Nov 2020 10:55:55

Did the participant meet all eligibility criteria?

Yes ☒

No ☐

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Folder: Screening

Form: Medical History Summary

Generated On: 26 Nov 2020 10:55:55

Were any significant conditions reported?

Yes ☒

No ☐

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Folder: Screening

Form: Medical History (1)

Generated On: 26 Nov 2020 10:55:55

Condition	DEPRESSION
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)	



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Folder: Screening

Form: Medical History (2)

Generated On: 26 Nov 2020 10:55:55

Condition	ANXIETY
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)	_____

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Folder: Screening

Form: Medical History (3)

Generated On: 26 Nov 2020 10:55:55

Condition	ATTENTION DEFICIT HYPERACTIVITY DISORDER
Start date (dd MMM yyyy)	UN UNK 2011
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 2011
Start Year (derived)	2011
Stop Month and Year (derived)	
Stop Year (derived)	

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Folder: Screening

Form: Medical History (4)

Generated On: 26 Nov 2020 10:55:55

Condition	EXCESSIVE HAIR LOSS
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)	

US3312605

Folder: Screening

Form: Medical History (5)

Generated On: 26 Nov 2020 10:55:55

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

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Folder: Screening

Form: Medical History (6)

Generated On: 26 Nov 2020 10:55:55

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

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Folder: Screening

Form: Medical History (7)

Generated On: 26 Nov 2020 10:55:55

Condition	RECURRENT TONSILLITIS
Start date (dd MMM yyyy)	UN UNK 2000
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 2001
Stop date completely unknown	False
Start Month and Year (derived)	JAN 2000
Start Year (derived)	2000
Stop Month and Year (derived)	JAN 2001
Stop Year (derived)	2001

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Folder: Screening

Form: Medical History (8)

Generated On: 26 Nov 2020 10:55:55

Condition	TONSILLECTOMY
Start date (dd MMM yyyy)	UN UNK 2001
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 2001
Stop date completely unknown	False
Start Month and Year (derived)	JAN 2001
Start Year (derived)	2001
Stop Month and Year (derived)	JAN 2001
Stop Year (derived)	2001

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Folder: Screening

Form: Medical History (9)

Generated On: 26 Nov 2020 10:55:55

Condition	RECURRENT NEPHROLITHIASIS
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)	



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Folder: Screening

Form: Medical History (10)

Generated On: 26 Nov 2020 10:55:55

Condition	NOSE FRACTURE
Start date (dd MMM yyyy)	UN UNK 2010
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 2010
Stop date completely unknown	False
Start Month and Year (derived)	JAN 2010
Start Year (derived)	2010
Stop Month and Year (derived)	JAN 2010
Stop Year (derived)	2010

US3312605

Folder: Screening

Form: Medical History (11)

Generated On: 26 Nov 2020 10:55:55

Condition	RECONSTRUCTIVE NASAL SURGERY
Start date (dd MMM yyyy)	UN UNK 2010
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 2010
Stop date completely unknown	False
Start Month and Year (derived)	JAN 2010
Start Year (derived)	2010
Stop Month and Year (derived)	JAN 2010
Stop Year (derived)	2010

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Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 10:55:55

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment ( <i>dd MMM yyyy</i> )	10 SEP 2020
Time of assessment ( <i>00:00-23:59</i> )	13:54 (24 HR)
Vital Signs Date and Time (derived)	10 SEP 2020 13:54
Height ( <i>xxx.x</i> )	72.0 in
Weight ( <i>xxx.x</i> )	209.6 lb
BMI ( <i>xxx.x</i> )	28.48631 kg/m <sup>2</sup>
BMI units	KG/M2
Temperature ( <i>xxx.x</i> )	ND - Not Done
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse ( <i>xxx</i> )	ND - Not Done
Pulse units	BPM
Respiratory Rate ( <i>xxx</i> )	ND - Not Done
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure ( <i>xxx</i> )	ND - Not Done
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure ( <i>xxx</i> )	ND - Not Done
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

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Folder: Screening

Form: Physical Examination

Generated On: 26 Nov 2020 10:55:55

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

10 SEP 2020

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

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Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 10:55:55

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**Occupational Risk**

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

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

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

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

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

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

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

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

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

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

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

**Other** Yes ☐ No ☐

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**Specify**

---

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

**No Risk Identified** False

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

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

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Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 10:55:55

<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)	False
<b>Other</b>	True
<b>Specify</b>	RESIDES IN COMMUNITY WITH ONGOING PERSON TO PERSON TRANSMISSION

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Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 26 Nov 2020 10:55:55

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	10 SEP 2020
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	VISIT1

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Folder: Visit 1 Day 1

Form: Randomization

Generated On: 26 Nov 2020 10:55:55

What was the date of randomization? (dd MMM yyyy) 10 SEP 2020

What was the participant's randomization number? 113213

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 ☒



**US3312605**

**Folder: Visit 1 Day 1**

**Form: Vital Signs - Dosing**

**Generated On: 26 Nov 2020 10:55:55**

Height	ND - Not Done
Weight	ND - Not Done

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 10:55:55

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)	10 SEP 2020
Time of assessment (00:00-23:59)	13:54 (24 HR)
Vital Signs Date and Time (derived)	10 SEP 2020 13:54
Temperature (xxx.x)	97.9 F
Route of measurement	Oral <input checked="" type="radio"/> Axillary <input type="radio"/> Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	67 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	137 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	82 mmHg
Diastolic Blood Pressure units	MMHG

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 10:55:55

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)	10 SEP 2020
Time of assessment (00:00-23:59)	15:25 (24 HR)
Vital Signs Date and Time (derived)	10 SEP 2020 15:25
Temperature (xxx.x)	98.6 F
Route of measurement	Oral <input checked="" type="radio"/> Axillary <input type="radio"/> Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	67 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	137 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	74 mmHg
Diastolic Blood Pressure units	MMHG

US3312605

Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 26 Nov 2020 10:55:55

Was the physical examination performed?

Yes ☐

No ☒

Date of examination (dd MMM yyyy)

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

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Folder: Visit 1 Day 1

Form: Exposure

Generated On: 26 Nov 2020 10:55:55

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) 10 SEP 2020

What was the treatment time? (00:00-23:59) 14:54 (24 HR)

Treatment Date and Time (derived) 10 SEP 2020 14:54

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

US3312605

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 10:55:55

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

US3312605

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 26 Nov 2020 10:55:55

Collection date ( <i>dd MMM yyyy</i> )			10 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	14:15	10 SEP 2020 14:15
Nasopharyngeal Swab 2	No		

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Folder: Visit 1 Day 1

Form: Continuing

Generated On: 26 Nov 2020 10:55:55

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1



US3312605

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/1)

Generated On: 26 Nov 2020 10:55:55

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**TIMEPOINT**

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

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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):

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PC Time Stamp

10 SEP 2020 15:25

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PC Open Date & Time

10 SEP 2020 15:14

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PC Close Date & Time

10 SEP 2020 17:44

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US3312605

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/2)

Generated On: 26 Nov 2020 10:55:55

**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 98.5 °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	11 SEP 2020 09:12
PC Open Date & Time	10 SEP 2020 18:39
PC Close Date & Time	11 SEP 2020 11:59

US3312605

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(2)

Generated On: 26 Nov 2020 10:55:55

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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

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

12 SEP 2020 11:06

PC Open Date & Time

11 SEP 2020 12:00

PC Close Date & Time

12 SEP 2020 11:59

US3312605

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(3)

Generated On: 26 Nov 2020 10:55:55

**TIMEPOINT**

DAY 3

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

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

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

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

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

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

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

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

Please record your **TEMPERATURE in °F**

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

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

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

To **PREVENT** pain or fever from occurring

PC Time Stamp

PC Open Date & Time 12 SEP 2020 12:00

PC Close Date & Time 13 SEP 2020 11:59

US3312605

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(4)

Generated On: 26 Nov 2020 10:55:55

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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

98.6 °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

13 SEP 2020 21:01

PC Open Date & Time

13 SEP 2020 12:00

PC Close Date & Time

14 SEP 2020 11:59

US3312605

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(5)

Generated On: 26 Nov 2020 10:55:55

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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

98.6 °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

15 SEP 2020 09:35

PC Open Date & Time

14 SEP 2020 12:00

PC Close Date & Time

15 SEP 2020 11:59

US3312605

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(6)

Generated On: 26 Nov 2020 10:55:55

---

**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

98.6 °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 SEP 2020 09:16

PC Open Date & Time

15 SEP 2020 12:00

PC Close Date & Time

16 SEP 2020 11:59

US3312605

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(7)

Generated On: 26 Nov 2020 10:55:55

---

**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

98.6 °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

17 SEP 2020 09:39

---

PC Open Date & Time

16 SEP 2020 12:00

---

PC Close Date & Time

17 SEP 2020 11:59

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US3312605

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 26 Nov 2020 10:55:55

**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

10 SEP 2020 15:26

PC Open Date & Time

10 SEP 2020 15:14

PC Close Date & Time

10 SEP 2020 17:44

US3312605

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 26 Nov 2020 10:55:55

**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 09:13

PC Open Date & Time

10 SEP 2020 18:39

PC Close Date & Time

11 SEP 2020 11:59

US3312605

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 26 Nov 2020 10:55:55

**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 11:06

PC Open Date & Time

11 SEP 2020 12:00

PC Close Date & Time

12 SEP 2020 11:59

US3312605

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 26 Nov 2020 10:55:55

**TIMEPOINT**

DAY 3

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

None ☐

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

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

Yes ☐

No ☐

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

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

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

Yes ☐

No ☐

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

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

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

None ☐

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

PC Time Stamp

PC Open Date & Time

12 SEP 2020 12:00

PC Close Date & Time

13 SEP 2020 11:59

US3312605

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 26 Nov 2020 10:55:55

**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

13 SEP 2020 21:01

PC Open Date & Time

13 SEP 2020 12:00

PC Close Date & Time

14 SEP 2020 11:59

US3312605

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 26 Nov 2020 10:55:55

**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 09:35

PC Open Date & Time

14 SEP 2020 12:00

PC Close Date & Time

15 SEP 2020 11:59

US3312605

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(6)

Generated On: 26 Nov 2020 10:55:55

**TIMEPOINT**

DAY 6

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

PC Time Stamp

16 SEP 2020 09:16

PC Open Date & Time

15 SEP 2020 12:00

PC Close Date & Time

16 SEP 2020 11:59

US3312605

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 26 Nov 2020 10:55:55

**TIMEPOINT**

DAY 7

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

PC Time Stamp

17 SEP 2020 09:39

PC Open Date & Time

16 SEP 2020 12:00

PC Close Date & Time

17 SEP 2020 11:59



US3312605

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 26 Nov 2020 10:55:55

**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 ☐

US3312605

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 26 Nov 2020 10:55:55

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

No ☒

Yes ☐

PC Time stamp	10 SEP 2020 15:26
PC Open Date & Time	10 SEP 2020 15:14
PC Close Date & Time	10 SEP 2020 17:44

US3312605

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 26 Nov 2020 10:55:55

**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 ☐

US3312605

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 26 Nov 2020 10:55:55

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

No ☒

Yes ☐

PC Time stamp	11 SEP 2020 09:17
PC Open Date & Time	10 SEP 2020 18:39
PC Close Date & Time	11 SEP 2020 11:59

US3312605

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 26 Nov 2020 10:55:55

**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 ☒

US3312605

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 26 Nov 2020 10:55:55

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

US3312605

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 26 Nov 2020 10:55:55

**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 ☐

US3312605

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 26 Nov 2020 10:55:55

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



US3312605

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 26 Nov 2020 10:55:55

**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 ☒

US3312605

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 26 Nov 2020 10:55:55

Yes <input type="checkbox"/>	
PC Time stamp	14 SEP 2020 09:47
PC Open Date & Time	13 SEP 2020 12:00
PC Close Date & Time	14 SEP 2020 11:59

US3312605

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 26 Nov 2020 10:55:55

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 ☒

US3312605

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 26 Nov 2020 10:55:55

Yes <input type="checkbox"/>	
PC Time stamp	15 SEP 2020 09:35
PC Open Date & Time	14 SEP 2020 12:00
PC Close Date & Time	15 SEP 2020 11:59

US3312605

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 26 Nov 2020 10:55:55

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 ☒

US3312605

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 26 Nov 2020 10:55:55

Yes <input type="checkbox"/>	
PC Time stamp	16 SEP 2020 09:17
PC Open Date & Time	15 SEP 2020 12:00
PC Close Date & Time	16 SEP 2020 11:59

US3312605

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 26 Nov 2020 10:55:55

**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 ☒

US3312605

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 26 Nov 2020 10:55:55

Yes <input type="checkbox"/>	
PC Time stamp	17 SEP 2020 09:39
PC Open Date & Time	16 SEP 2020 12:00
PC Close Date & Time	17 SEP 2020 11:59



US3312605

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 26 Nov 2020 10:55:55

Was Contact Attempted?

Yes ☒

No ☐

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

18 SEP 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

*If Contact Not Made, please provide Comments*

US3312605

Folder: Safety Call Day 8 (1)

Form: Continuing

Generated On: 26 Nov 2020 10:55:55

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3312605

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 26 Nov 2020 10:55:55

Was Contact Attempted?

Yes ☒

No ☐

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

24 SEP 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

*If Contact Not Made, please provide Comments*

US3312605

Folder: Safety Call Day 15 (1)

Form: Continuing

Generated On: 26 Nov 2020 10:55:55

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3312605

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 26 Nov 2020 10:55:55

Was Contact Attempted?

Yes ☒

No ☐

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

01 OCT 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

*If Contact Not Made, please provide Comments*

US3312605

Folder: Safety Call Day 22 (1)

Form: Continuing

Generated On: 26 Nov 2020 10:55:55

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3312605

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 26 Nov 2020 10:55:55

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	8 OCT 2020
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	VISIT2

US3312605

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 10:55:55

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)	8 OCT 2020
Time of assessment (00:00-23:59)	13:41 (24 HR)
Vital Signs Date and Time (derived)	8 OCT 2020 13:41
Temperature (xxx.x)	98.2 F
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	67 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	12 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	129 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	69 mmHg
Diastolic Blood Pressure units	MMHG



US3312605

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 10:55:55

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)	8 OCT 2020
Time of assessment (00:00-23:59)	15:00 (24 HR)
Vital Signs Date and Time (derived)	8 OCT 2020 15:00
Temperature (xxx.x)	97.9 F
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	83 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	131 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	69 mmHg
Diastolic Blood Pressure units	MMHG

US3312605

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Generated On: 26 Nov 2020 10:55:55

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

8 OCT 2020

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

US3312605

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 26 Nov 2020 10:55:55

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) 08 OCT 2020

What was the treatment time? (00:00-23:59) 14:29 (24 HR)

Treatment Date and Time (derived) 08 OCT 2020 14:29

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

US3312605

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 10:55:55

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date ( <i>dd MMM yyyy</i> )	8 OCT 2020
Collection time ( <i>00:00-23:59</i> )	13:53 (24 HR)
Collection date and time (derived)	8 OCT 2020 13:53

US3312605

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 26 Nov 2020 10:55:55

Collection date ( <i>dd MMM yyyy</i> )			8 OCT 2020
Lab Test	Was the sample collected?	Collection time ( <i>00:00 - 23:59</i> )	Collection date and time (derived)
Nasopharyngeal Swab 1	Yes	13:50	8 OCT 2020 13:50
Nasopharyngeal Swab 2	No		

US3312605

Folder: Visit 2 Day 29 (1)

Form: Continuing

Generated On: 26 Nov 2020 10:55:55

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3312605

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/1)

Generated On: 26 Nov 2020 10:55:55

**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

08 OCT 2020 15:01

PC Open Date & Time

08 OCT 2020 14:49

PC Close Date & Time

08 OCT 2020 17:19

US3312605

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/2)

Generated On: 26 Nov 2020 10:55:55

**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 96.8 °F

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

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

PC Time Stamp	09 OCT 2020 09:37
PC Open Date & Time	08 OCT 2020 18:14
PC Close Date & Time	09 OCT 2020 11:59



US3312605

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(2)

Generated On: 26 Nov 2020 10:55:55

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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

97.8 °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

10 OCT 2020 00:11

---

PC Open Date & Time

09 OCT 2020 12:00

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PC Close Date & Time

10 OCT 2020 11:59

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US3312605

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(3)

Generated On: 26 Nov 2020 10:55:55

**TIMEPOINT**

DAY 3

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

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

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

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

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

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

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

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

Please record your **TEMPERATURE in °F**

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

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

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

To **PREVENT** pain or fever from occurring

PC Time Stamp

PC Open Date & Time 10 OCT 2020 12:00

PC Close Date & Time 11 OCT 2020 11:59

US3312605

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(4)

Generated On: 26 Nov 2020 10:55:55

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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

98.6 °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

12 OCT 2020 08:40

---

PC Open Date & Time

11 OCT 2020 12:00

---

PC Close Date & Time

12 OCT 2020 11:59

---

US3312605

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(5)

Generated On: 26 Nov 2020 10:55:55

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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

99.0 °F

---

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

Yes ☐

No ☒

---

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

---

PC Time Stamp

12 OCT 2020 12:34

---

PC Open Date & Time

12 OCT 2020 12:00

---

PC Close Date & Time

13 OCT 2020 11:59

---

US3312605

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(6)

Generated On: 26 Nov 2020 10:55:55

**TIMEPOINT**

DAY 6

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

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

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

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

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

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

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

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

Please record your **TEMPERATURE in °F**

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

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

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

To **PREVENT** pain or fever from occurring

PC Time Stamp

PC Open Date & Time 13 OCT 2020 12:00

PC Close Date & Time 14 OCT 2020 11:59

US3312605

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(7)

Generated On: 26 Nov 2020 10:55:55

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**TIMEPOINT**

DAY 7

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

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

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

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

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

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

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

---

Was **TEMPERATURE** taken?

Yes ☒

No ☐

---

Please record your **TEMPERATURE** in °F

97.0 °F

---

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

Yes ☐

No ☒

---

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

---

PC Time Stamp

14 OCT 2020 12:00

---

PC Open Date & Time

14 OCT 2020 12:00

---

PC Close Date & Time

15 OCT 2020 11:59

---

US3312605

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/1)

Generated On: 26 Nov 2020 10:55:55

**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

08 OCT 2020 15:02

PC Open Date & Time

08 OCT 2020 14:49

PC Close Date & Time

08 OCT 2020 17:19

US3312605

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/2)

Generated On: 26 Nov 2020 10:55:55

**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

09 OCT 2020 09:37

PC Open Date & Time

08 OCT 2020 18:14

PC Close Date & Time

09 OCT 2020 11:59



US3312605

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(2)

Generated On: 26 Nov 2020 10:55:55

**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

10 OCT 2020 00:11

PC Open Date & Time

09 OCT 2020 12:00

PC Close Date & Time

10 OCT 2020 11:59

US3312605

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(3)

Generated On: 26 Nov 2020 10:55:55

**TIMEPOINT**

DAY 3

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

None ☐

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

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

Yes ☐

No ☐

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

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

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

Yes ☐

No ☐

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

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

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

None ☐

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

PC Time Stamp

PC Open Date & Time

10 OCT 2020 12:00

PC Close Date & Time

11 OCT 2020 11:59

US3312605

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(4)

Generated On: 26 Nov 2020 10:55:55

**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

12 OCT 2020 08:40

PC Open Date & Time

11 OCT 2020 12:00

PC Close Date & Time

12 OCT 2020 11:59

US3312605

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(5)

Generated On: 26 Nov 2020 10:55:55

**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

12 OCT 2020 12:34

PC Open Date & Time

12 OCT 2020 12:00

PC Close Date & Time

13 OCT 2020 11:59

US3312605

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(6)

Generated On: 26 Nov 2020 10:55:55

**TIMEPOINT**

DAY 6

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

None ☐

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

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

Yes ☐

No ☐

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

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

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

Yes ☐

No ☐

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

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

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

None ☐

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

PC Time Stamp

PC Open Date & Time

13 OCT 2020 12:00

PC Close Date & Time

14 OCT 2020 11:59

US3312605

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(7)

Generated On: 26 Nov 2020 10:55:55

**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

14 OCT 2020 12:00

PC Open Date & Time

14 OCT 2020 12:00

PC Close Date & Time

15 OCT 2020 11:59

US3312605

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 26 Nov 2020 10:55:55

**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 ☐

US3312605

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 26 Nov 2020 10:55:55

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

No ☒

Yes ☐

PC Time stamp	08 OCT 2020 15:02
PC Open Date & Time	08 OCT 2020 14:49
PC Close Date & Time	08 OCT 2020 17:19



US3312605

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 26 Nov 2020 10:55:55

**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 ☐

US3312605

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 26 Nov 2020 10:55:55

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

No ☒

Yes ☐

PC Time stamp	09 OCT 2020 09:38
PC Open Date & Time	08 OCT 2020 18:14
PC Close Date & Time	09 OCT 2020 11:59

US3312605

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 26 Nov 2020 10:55:55

**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 ☒

US3312605

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 26 Nov 2020 10:55:55

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

US3312605

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 26 Nov 2020 10:55:55

**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 ☐

US3312605

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 26 Nov 2020 10:55:55

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

US3312605

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 26 Nov 2020 10:55:55

**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 ☒

US3312605

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 26 Nov 2020 10:55:55

Yes <input type="checkbox"/>	
PC Time stamp	12 OCT 2020 08:40
PC Open Date & Time	11 OCT 2020 12:00
PC Close Date & Time	12 OCT 2020 11:59



US3312605

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 26 Nov 2020 10:55:55

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 ☒

US3312605

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 26 Nov 2020 10:55:55

Yes <input type="checkbox"/>	
PC Time stamp	12 OCT 2020 12:34
PC Open Date & Time	12 OCT 2020 12:00
PC Close Date & Time	13 OCT 2020 11:59

US3312605

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 26 Nov 2020 10:55:55

**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 ☐

US3312605

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 26 Nov 2020 10:55:55

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

US3312605

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 26 Nov 2020 10:55:55

**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 ☒

US3312605

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 26 Nov 2020 10:55:55

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

US3312605

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 26 Nov 2020 10:55:55

Was Contact Attempted?

Yes ☒

No ☐

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

15 OCT 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

*If Contact Not Made, please provide Comments*

US3312605

Folder: Safety Call Day 36 (1)

Form: Continuing

Generated On: 26 Nov 2020 10:55:55

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1



US3312605

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 26 Nov 2020 10:55:55

Was Contact Attempted?

Yes ☒

No ☐

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

22 OCT 2020

Please select one status for the follow-up contact

Contact Made ☐

Contact Not Made ☒

Comments

UNABLE TO REACH SUBJECT.  
PROTOCOL DEVIATION NOTED.  
NOT REPORABLE TO IRB

*If Contact Not Made, please provide Comments*

US3312605

Folder: Safety Call Day 43 (1)

Form: Continuing

Generated On: 26 Nov 2020 10:55:55

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3312605

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 26 Nov 2020 10:55:55

Was Contact Attempted?

Yes ☒

No ☐

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

29 OCT 2020

Please select one status for the follow-up contact

Contact Made ☐

Contact Not Made ☒

Comments

UNABLE TO REACH SUBJECT.  
PROTOCOL DEVIATION NOTED.  
NOT REPORABLE TO IRB.

*If Contact Not Made, please provide Comments*

US3312605

Folder: Safety Call Day 50 (1)

Form: Continuing

Generated On: 26 Nov 2020 10:55:55

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3312605

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 26 Nov 2020 10:55:55

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	04 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	VISIT3

US3312605

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 10:55:55

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment ( <i>dd MMM yyyy</i> )	04 NOV 2020
Time of assessment ( <i>00:00-23:59</i> )	14:29 (24 HR)
Vital Signs Date and Time (derived)	04 NOV 2020 14:29
Temperature ( <i>xxx.x</i> )	98.7 F
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse ( <i>xxx</i> )	74 beats/min
Pulse units	BPM
Respiratory Rate ( <i>xxx</i> )	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure ( <i>xxx</i> )	129 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure ( <i>xxx</i> )	69 mmHg
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

US3312605

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Generated On: 26 Nov 2020 10:55:55

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

04 NOV 2020

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

US3312605

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 10:55:55

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date ( <i>dd MMM yyyy</i> )	04 NOV 2020
Collection time ( <i>00:00-23:59</i> )	14:53 (24 HR)
Collection date and time (derived)	04 NOV 2020 14:53



US3312605

Folder: Visit 3 Day 57 (1)

Form: Continuing

Generated On: 26 Nov 2020 10:55:55

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3312605

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:55:55

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"/>

**US3312605**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:55:55**

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

07 NOV 2020 00:01

[Patient Cloud Close Date & Time](#)

11 NOV 2020 23:59

US3312605

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:55:55

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="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"/>

**US3312605**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:55:55**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm 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 NOV 2020 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	18 NOV 2020 23:59

US3312605

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:55:55

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"/>

**US3312605**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:55:55**

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

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[Patient Cloud Close Date & Time](#)

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25 NOV 2020 23:59

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US3312605

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:55:55

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"/>



**US3312605**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:55:55**

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

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[Patient Cloud Close Date & Time](#)

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02 DEC 2020 23:59

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US3312605

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:55:55

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"/>

**US3312605**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:55:55**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm 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>	05 DEC 2020 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	09 DEC 2020 23:59

US3312605

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:55:55

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="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"/>

**US3312605**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:55:55**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm 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 2020 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	16 DEC 2020 23:59

US3312605

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:55:55

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

**US3312605**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:55:55**

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

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[Patient Cloud Close Date & Time](#)

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23 DEC 2020 23:59

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US3312605

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:55:55

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"/>



**US3312605**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:55:55**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm 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 2020 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	30 DEC 2020 23:59

US3312605

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:55:55

TIMEPOINT	DAY 117
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$ )	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>

**US3312605**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:55:55**

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

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[Patient Cloud Close Date & Time](#)

06 JAN 2021 23:59

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US3312605

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:55:55

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

**US3312605**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:55:55**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

09 JAN 2021 00:01

[Patient Cloud Close Date & Time](#)

13 JAN 2021 23:59

US3312605

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:55:55

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

**US3312605**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:55:55**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm 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>	16 JAN 2021 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	20 JAN 2021 23:59

US3312605

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:55:55

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 <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"/>



**US3312605**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:55:55**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

23 JAN 2021 00:01

[Patient Cloud Close Date & Time](#)

27 JAN 2021 23:59

US3312605

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:55:55

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

**US3312605**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:55:55**

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

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[Patient Cloud Close Date & Time](#)

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03 FEB 2021 23:59

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US3312605

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:55:55

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"/>

**US3312605**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:55:55**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm 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 FEB 2021 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	10 FEB 2021 23:59

US3312605

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:55:55

TIMEPOINT	DAY 159
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$ )	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>

**US3312605**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:55:55**

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

13 FEB 2021 00:01

[Patient Cloud Close Date & Time](#)

17 FEB 2021 23:59

US3312605

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:55:55

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"/>



**US3312605**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:55:55**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm 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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20 FEB 2021 00:01

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[Patient Cloud Close Date & Time](#)

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24 FEB 2021 23:59

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US3312605

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:55:55

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 <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"/>

**US3312605**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:55:55**

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

27 FEB 2021 00:01

[Patient Cloud Close Date & Time](#)

03 MAR 2021 23:59

US3312605

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:55:55

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"/>

**US3312605**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:55:55**

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

[Patient Cloud Close Date & Time](#)

10 MAR 2021 23:59

US3312605

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:55:55

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

**US3312605**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:55:55**

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

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[Patient Cloud Close Date & Time](#)

17 MAR 2021 23:59

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US3312605

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:55:55

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"/>



**US3312605**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:55:55**

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

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[Patient Cloud Close Date & Time](#)

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24 MAR 2021 23:59

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US3312605

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:55:55

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"/>

**US3312605**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:55:55**

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

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[Patient Cloud Close Date & Time](#)

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31 MAR 2021 23:59

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US3312605

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:55:55

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 <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"/>

**US3312605**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:55:55**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

03 APR 2021 00:01

[Patient Cloud Close Date & Time](#)

07 APR 2021 23:59

US3312605

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:55:55

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"/>

**US3312605**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:55:55**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm 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 APR 2021 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	14 APR 2021 23:59

US3312605

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:55:55

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"/>



**US3312605**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:55:55**

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

17 APR 2021 00:01

[Patient Cloud Close Date & Time](#)

21 APR 2021 23:59

US3312605

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:55:55

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

**US3312605**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:55:55**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

24 APR 2021 00:01

[Patient Cloud Close Date & Time](#)

28 APR 2021 23:59

US3312605

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:55:55

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"/>

**US3312605**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:55:55**

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

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[Patient Cloud Close Date & Time](#)

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05 MAY 2021 23:59

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US3312605

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:55:55

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"/>

**US3312605**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:55:55**

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

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[Patient Cloud Close Date & Time](#)

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12 MAY 2021 23:59

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US3312605

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:55:55

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"/>



**US3312605**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:55:55**

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

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[Patient Cloud Close Date & Time](#)

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19 MAY 2021 23:59

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US3312605

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:55:55

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 ☐

**US3312605**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:55:55**

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

22 MAY 2021 00:01

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[Patient Cloud Close Date & Time](#)

26 MAY 2021 23:59

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US3312605

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:55:55

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"/>

**US3312605**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:55:55**

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

[Patient Cloud Close Date & Time](#)

02 JUN 2021 23:59

US3312605

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:55:55

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

**US3312605**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:55:55**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

05 JUN 2021 00:01

[Patient Cloud Close Date & Time](#)

09 JUN 2021 23:59

US3312605

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:55:55

TIMEPOINT	DAY 278
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$ )	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>



**US3312605**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:55:55**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm 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 JUN 2021 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	16 JUN 2021 23:59

US3312605

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:55:55

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"/>

**US3312605**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:55:55**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

19 JUN 2021 00:01

[Patient Cloud Close Date & Time](#)

23 JUN 2021 23:59

US3312605

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:55:55

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

**US3312605**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:55:55**

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

[Patient Cloud Close Date & Time](#)

30 JUN 2021 23:59

US3312605

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:55:55

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"/>

**US3312605**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:55:55**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

03 JUL 2021 00:01

[Patient Cloud Close Date & Time](#)

07 JUL 2021 23:59

US3312605

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:55:55

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"/>



**US3312605**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:55:55**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm 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 2021 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	14 JUL 2021 23:59

US3312605

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:55:55

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="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"/>

**US3312605**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:55:55**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm 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 2021 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	21 JUL 2021 23:59

US3312605

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:55:55

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"/>

**US3312605**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:55:55**

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

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[Patient Cloud Open Date & Time](#)

24 JUL 2021 00:01

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[Patient Cloud Close Date & Time](#)

28 JUL 2021 23:59

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US3312605

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:55:55

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="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"/>

**US3312605**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:55:55**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

31 JUL 2021 00:01

[Patient Cloud Close Date & Time](#)

04 AUG 2021 23:59

US3312605

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:55:55

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



**US3312605**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:55:55**

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

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[Patient Cloud Close Date & Time](#)

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11 AUG 2021 23:59

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US3312605

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:55:55

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

**US3312605**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:55:55**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

14 AUG 2021 00:01

[Patient Cloud Close Date & Time](#)

18 AUG 2021 23:59

US3312605

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:55:55

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"/>

**US3312605**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:55:55**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

21 AUG 2021 00:01

[Patient Cloud Close Date & Time](#)

25 AUG 2021 23:59

US3312605

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:55:55

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 ☐

**US3312605**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:55:55**

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

[Patient Cloud Close Date & Time](#)

01 SEP 2021 23:59

US3312605

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:55:55

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"/>



**US3312605**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:55:55**

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

[Patient Cloud Close Date & Time](#)

08 SEP 2021 23:59

US3312605

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:55:55

**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 ☐

**US3312605**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:55:55**

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

11 SEP 2021 00:01

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[Patient Cloud Close Date & Time](#)

15 SEP 2021 23:59

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US3312605

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:55:55

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 ☐

**US3312605**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:55:55**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

18 SEP 2021 00:01

[Patient Cloud Close Date & Time](#)

22 SEP 2021 23:59

US3312605

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:55:55

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

**US3312605**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:55:55**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm 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 SEP 2021 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	29 SEP 2021 23:59

US3312605

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:55:55

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"/>



**US3312605**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:55:55**

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

[Patient Cloud Close Date & Time](#)

06 OCT 2021 23:59

US3312605

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:55:55

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 ☐

**US3312605**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:55:55**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

09 OCT 2021 00:01

[Patient Cloud Close Date & Time](#)

13 OCT 2021 23:59

US3312605

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:55:55

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"/>

**US3312605**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:55:55**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm 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>	16 OCT 2021 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	20 OCT 2021 23:59

US3312605

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:55:55

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

**US3312605**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:55:55**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

23 OCT 2021 00:01

[Patient Cloud Close Date & Time](#)

27 OCT 2021 23:59

US3312605

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:55:55

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"/>



**US3312605**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:55:55**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

30 OCT 2021 00:01

[Patient Cloud Close Date & Time](#)

03 NOV 2021 23:59

US3312605

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:55:55

**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 ☐

**US3312605**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:55:55**

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

[Patient Cloud Close Date & Time](#)

10 NOV 2021 23:59

US3312605

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:55:55

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"/>

**US3312605**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:55:55**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm 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>	13 NOV 2021 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	17 NOV 2021 23:59

US3312605

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:55:55

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

**US3312605**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:55:55**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

20 NOV 2021 00:01

[Patient Cloud Close Date & Time](#)

24 NOV 2021 23:59

US3312605

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:55:55

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



**US3312605**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:55:55**

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

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[Patient Cloud Close Date & Time](#)

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01 DEC 2021 23:59

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US3312605

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:55:55

**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 ☐

**US3312605**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:55:55**

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

[Patient Cloud Close Date & Time](#)

08 DEC 2021 23:59

US3312605

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:55:55

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"/>

**US3312605**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:55:55**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm 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 DEC 2021 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	15 DEC 2021 23:59

US3312605

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:55:55

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="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"/>

**US3312605**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:55:55**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

18 DEC 2021 00:01

[Patient Cloud Close Date & Time](#)

22 DEC 2021 23:59

US3312605

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:55:55

TIMEPOINT	DAY 474
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$ )	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>



**US3312605**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:55:55**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm 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 DEC 2021 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	29 DEC 2021 23:59

US3312605

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:55:55

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

**US3312605**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:55:55**

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

[Patient Cloud Close Date & Time](#)

05 JAN 2022 23:59

US3312605

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:55:55

TIMEPOINT	DAY 488
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$ )	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>

**US3312605**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:55:55**

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

08 JAN 2022 00:01

[Patient Cloud Close Date & Time](#)

12 JAN 2022 23:59

US3312605

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:55:55

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

**US3312605**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:55:55**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm 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>	15 JAN 2022 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	19 JAN 2022 23:59

US3312605

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:55:55

TIMEPOINT	DAY 502
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="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"/>



**US3312605**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:55:55**

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

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[Patient Cloud Close Date & Time](#)

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26 JAN 2022 23:59

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US3312605

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:55:55

**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 ☐

**US3312605**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:55:55**

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

[Patient Cloud Close Date & Time](#)

02 FEB 2022 23:59

US3312605

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:55:55

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

**US3312605**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:55:55**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm 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>	05 FEB 2022 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	09 FEB 2022 23:59

US3312605

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:55:55

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 ☐

**US3312605**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:55:55**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm 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 FEB 2022 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	16 FEB 2022 23:59

US3312605

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:55:55

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



**US3312605**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:55:55**

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

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[Patient Cloud Close Date & Time](#)

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23 FEB 2022 23:59

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US3312605

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:55:55

**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 ☐

**US3312605**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:55:55**

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

[Patient Cloud Close Date & Time](#)

02 MAR 2022 23:59

US3312605

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:55:55

**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 ☐

**US3312605**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:55:55**

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

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[Patient Cloud Close Date & Time](#)

09 MAR 2022 23:59

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US3312605

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:55:55

TIMEPOINT	DAY 551
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="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"/>

**US3312605**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:55:55**

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

12 MAR 2022 00:01

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[Patient Cloud Close Date & Time](#)

16 MAR 2022 23:59

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US3312605

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:55:55

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 ☐



**US3312605**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:55:55**

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

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[Patient Cloud Close Date & Time](#)

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23 MAR 2022 23:59

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US3312605

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:55:55

**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 ☐

**US3312605**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:55:55**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm 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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26 MAR 2022 00:01

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[Patient Cloud Close Date & Time](#)

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30 MAR 2022 23:59

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US3312605

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:55:55

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 ☐

**US3312605**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:55:55**

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

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[Patient Cloud Close Date & Time](#)

06 APR 2022 23:59

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US3312605

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:55:55

**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 ☐

**US3312605**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:55:55**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

09 APR 2022 00:01

[Patient Cloud Close Date & Time](#)

13 APR 2022 23:59

US3312605

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:55:55

**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 ☐



**US3312605**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:55:55**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm 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>	16 APR 2022 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	20 APR 2022 23:59

US3312605

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:55:55

**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 ☐

**US3312605**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:55:55**

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

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[Patient Cloud Close Date & Time](#)

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27 APR 2022 23:59

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US3312605

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:55:55

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"/>

**US3312605**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:55:55**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

30 APR 2022 00:01

[Patient Cloud Close Date & Time](#)

04 MAY 2022 23:59

US3312605

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:55:55

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"/>

**US3312605**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:55:55**

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

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[Patient Cloud Close Date & Time](#)

11 MAY 2022 23:59

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US3312605

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:55:55

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"/>



**US3312605**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:55:55**

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

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[Patient Cloud Close Date & Time](#)

18 MAY 2022 23:59

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US3312605

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:55:55

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"/>

**US3312605**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:55:55**

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

US3312605

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:55:55

TIMEPOINT	DAY 628
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$ )	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

**US3312605**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:55:55**

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

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[Patient Cloud Close Date & Time](#)

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01 JUN 2022 23:59

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US3312605

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:55:55

TIMEPOINT	DAY 635
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="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"/>

**US3312605**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:55:55**

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

[Patient Cloud Close Date & Time](#)

08 JUN 2022 23:59

US3312605

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:55:55

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



**US3312605**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:55:55**

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

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[Patient Cloud Close Date & Time](#)

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15 JUN 2022 23:59

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US3312605

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:55:55

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

**US3312605**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:55:55**

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

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[Patient Cloud Close Date & Time](#)

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22 JUN 2022 23:59

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US3312605

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:55:55

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"/>

**US3312605**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:55:55**

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

[Patient Cloud Close Date & Time](#)

29 JUN 2022 23:59

US3312605

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:55:55

**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 ☐

**US3312605**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:55:55**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm 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>	02 JUL 2022 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	06 JUL 2022 23:59

US3312605

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:55:55

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



**US3312605**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:55:55**

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

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[Patient Cloud Close Date & Time](#)

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13 JUL 2022 23:59

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US3312605

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:55:55

TIMEPOINT	DAY 677
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="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"/>

**US3312605**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:55:55**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

16 JUL 2022 00:01

[Patient Cloud Close Date & Time](#)

20 JUL 2022 23:59

US3312605

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:55:55

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

**US3312605**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:55:55**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

23 JUL 2022 00:01

[Patient Cloud Close Date & Time](#)

27 JUL 2022 23:59

US3312605

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:55:55

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"/>

**US3312605**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:55:55**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

30 JUL 2022 00:01

[Patient Cloud Close Date & Time](#)

03 AUG 2022 23:59

US3312605

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:55:55

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"/>



**US3312605**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:55:55**

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

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[Patient Cloud Close Date & Time](#)

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10 AUG 2022 23:59

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US3312605

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:55:55

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"/>

**US3312605**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:55:55**

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

13 AUG 2022 00:01

[Patient Cloud Close Date & Time](#)

17 AUG 2022 23:59

US3312605

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:55:55

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"/>

**US3312605**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:55:55**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

20 AUG 2022 00:01

[Patient Cloud Close Date & Time](#)

24 AUG 2022 23:59

US3312605

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:55:55

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

**US3312605**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:55:55**

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

27 AUG 2022 00:01

[Patient Cloud Close Date & Time](#)

31 AUG 2022 23:59

US3312605

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:55:55

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



**US3312605**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:55:55**

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

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[Patient Cloud Close Date & Time](#)

07 SEP 2022 23:59

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US3312605

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:55:55

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

**US3312605**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:55:55**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm 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 SEP 2022 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	14 SEP 2022 23:59

US3312605

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:55:55

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

**US3312605**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:55:55**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm 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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17 SEP 2022 00:01

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[Patient Cloud Close Date & Time](#)

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21 SEP 2022 23:59

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US3312605

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:55:55

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

**US3312605**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:55:55**

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

[Patient Cloud Close Date & Time](#)

28 SEP 2022 23:59

US3312605

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:55:55

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



**US3312605**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:55:55**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm 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>	01 OCT 2022 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	05 OCT 2022 23:59

US3312605

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:55:55

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

**US3312605**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:55:55**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm 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>	08 OCT 2022 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	12 OCT 2022 23:59

US3312605

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:55:55

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"/>

**US3312605**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:55:55**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm 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>	15 OCT 2022 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	19 OCT 2022 23:59

US3312605

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:55:55

**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 ☐

**US3312605**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:55:55**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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>	22 OCT 2022 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	26 OCT 2022 23:59

US3312605

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:55:55

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



**US3312605**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:55:55**

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

[Patient Cloud Close Date & Time](#)

02 NOV 2022 23:59

US3312605

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:55:55

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

**US3312605**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:55:55**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm 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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05 NOV 2022 00:01

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[Patient Cloud Close Date & Time](#)

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09 NOV 2022 23:59

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US3312605

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:55:55

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"/>

**US3312605**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:55:55**

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

[Patient Cloud Close Date & Time](#)

16 NOV 2022 23:59

**US3312605**

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

**Form: Safety Call**

**Generated On: 26 Nov 2020 10:55:55**

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*

**US3312605**

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

**Form: Continuing**

**Generated On: 26 Nov 2020 10:55:55**

Is the participant continuing to the next visit?

Yes ☐

No ☐

Continuing Flag

US3312605

Folder: Covid-19 Assessment 04 Nov 2020

Form: COVID-19 Contact

Generated On: 26 Nov 2020 10:55:55

Date of Contact	04 NOV 2020
Time of Contact	14:20
Date and Time of Contact (derived)	04 NOV 2020 14:20
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"/>



US3312605

Folder: Covid-19 Assessment 04 Nov 2020

Form: Symptom Log (1)

Generated On: 26 Nov 2020 10:55:55

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"/>

US3312605

Folder: Covid-19 Assessment 04 Nov 2020

Form: Symptom Log (1)

Generated On: 26 Nov 2020 10:55:55

	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 OCT 2020	
Assessment Not Done	False	
O2 Saturation		
O2 Saturation Units		
Temperature		
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 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 type="radio"/>
v6.020 DTW (1102)	337 of 2379	

US3312605

Folder: Covid-19 Assessment 04 Nov 2020

Form: Symptom Log (1)

Generated On: 26 Nov 2020 10:55:55

	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 type="radio"/>
	Not Done	<input checked="" 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"/>

US3312605

Folder: Covid-19 Assessment 04 Nov 2020

Form: Symptom Log (1)

Generated On: 26 Nov 2020 10:55:55

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

US3312605

Folder: Covid-19 Assessment 04 Nov 2020

Form: Symptom Log (2)

Generated On: 26 Nov 2020 10:55:55

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"/>

US3312605

Folder: Covid-19 Assessment 04 Nov 2020

Form: Symptom Log (2)

Generated On: 26 Nov 2020 10:55:55

	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 OCT 2020	
Assessment Not Done	False	
O2 Saturation	<input type="text"/>	
O2 Saturation Units	<input type="text"/>	
Temperature	<input type="text"/>	
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 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 type="radio"/>
v6.020 DTW (1102)	341 of 2379	

US3312605

Folder: Covid-19 Assessment 04 Nov 2020

Form: Symptom Log (2)

Generated On: 26 Nov 2020 10:55:55

	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 checked="" 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"/>

US3312605

Folder: Covid-19 Assessment 04 Nov 2020

Form: Symptom Log (2)

Generated On: 26 Nov 2020 10:55:55

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



US3312605

Folder: Covid-19 Assessment 04 Nov 2020

Form: Symptom Log (3)

Generated On: 26 Nov 2020 10:55:55

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"/>

US3312605

Folder: Covid-19 Assessment 04 Nov 2020

Form: Symptom Log (3)

Generated On: 26 Nov 2020 10:55:55

	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 OCT 2020	
Assessment Not Done	False	
O2 Saturation		
O2 Saturation Units		
Temperature		
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 type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input checked="" type="checkbox"/>
	Not Done	<input type="checkbox"/>
Difficulty Breathing	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input checked="" type="checkbox"/>
	Not Done	<input type="checkbox"/>
Fatigue	None	<input type="checkbox"/>
v6.020 DTW (1102)	345 of 2379	

US3312605

Folder: Covid-19 Assessment 04 Nov 2020

Form: Symptom Log (3)

Generated On: 26 Nov 2020 10:55:55

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

US3312605

Folder: Covid-19 Assessment 04 Nov 2020

Form: Symptom Log (3)

Generated On: 26 Nov 2020 10:55:55

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

US3312605

Folder: Covid-19 Assessment 04 Nov 2020

Form: Symptom Log (4)

Generated On: 26 Nov 2020 10:55:55

Symptom Day

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

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Form: Symptom Log (4)

Generated On: 26 Nov 2020 10:55:55

	Day 34	<input type="checkbox"/>
	Day 35	<input type="checkbox"/>
	Day 36	<input type="checkbox"/>
	Day 37	<input type="checkbox"/>
	Day 38	<input type="checkbox"/>
	Day 39	<input type="checkbox"/>
	Day 40	<input type="checkbox"/>
Date	22 OCT 2020	
Assessment Not Done	False	
O2 Saturation	<hr/>	
O2 Saturation Units	<hr/>	
Temperature	<hr/>	
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 type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input checked="" type="checkbox"/>
	Not Done	<input type="checkbox"/>
Difficulty Breathing	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input checked="" type="checkbox"/>
	Not Done	<input type="checkbox"/>
Fatigue	None	<input type="checkbox"/>
v6.020 DTW (1102)	349 of 2379	

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Folder: Covid-19 Assessment 04 Nov 2020

Form: Symptom Log (4)

Generated On: 26 Nov 2020 10:55:55

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

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Form: Symptom Log (4)

Generated On: 26 Nov 2020 10:55:55

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



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Folder: Covid-19 Assessment 04 Nov 2020

Form: Symptom Log (5)

Generated On: 26 Nov 2020 10:55:55

Symptom Day

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

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Form: Symptom Log (5)

Generated On: 26 Nov 2020 10:55:55

	Day 34	<input type="checkbox"/>
	Day 35	<input type="checkbox"/>
	Day 36	<input type="checkbox"/>
	Day 37	<input type="checkbox"/>
	Day 38	<input type="checkbox"/>
	Day 39	<input type="checkbox"/>
	Day 40	<input type="checkbox"/>
Date	23 OCT 2020	
Assessment Not Done	False	
O2 Saturation	<input type="text"/>	
O2 Saturation Units	<input type="text"/>	
Temperature	<input type="text"/>	
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 type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input checked="" type="checkbox"/>
	Not Done	<input type="checkbox"/>
Difficulty Breathing	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input checked="" type="checkbox"/>
	Not Done	<input type="checkbox"/>
Fatigue	None	<input type="checkbox"/>
v6.020 DTW (1102)	353 of 2379	

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Form: Symptom Log (5)

Generated On: 26 Nov 2020 10:55:55

	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"/>

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Form: Symptom Log (5)

Generated On: 26 Nov 2020 10:55:55

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

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Folder: Covid-19 Assessment 04 Nov 2020

Form: Symptom Log (6)

Generated On: 26 Nov 2020 10:55:55

Symptom Day

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

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Form: Symptom Log (6)

Generated On: 26 Nov 2020 10:55:55

	Day 34	<input type="checkbox"/>
	Day 35	<input type="checkbox"/>
	Day 36	<input type="checkbox"/>
	Day 37	<input type="checkbox"/>
	Day 38	<input type="checkbox"/>
	Day 39	<input type="checkbox"/>
	Day 40	<input type="checkbox"/>
Date	24 OCT 2020	
Assessment Not Done	False	
O2 Saturation		
O2 Saturation Units		
Temperature		
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 type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input checked="" type="checkbox"/>
	Not Done	<input type="checkbox"/>
Difficulty Breathing	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input checked="" type="checkbox"/>
	Not Done	<input type="checkbox"/>
Fatigue	None	<input type="checkbox"/>
v6.020 DTW (1102)	357 of 2379	

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Form: Symptom Log (6)

Generated On: 26 Nov 2020 10:55:55

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

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Form: Symptom Log (6)

Generated On: 26 Nov 2020 10:55:55

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



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Form: Symptom Log (7)

Generated On: 26 Nov 2020 10:55:55

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"/>

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Form: Symptom Log (7)

Generated On: 26 Nov 2020 10:55:55

	Day 34	<input type="checkbox"/>
	Day 35	<input type="checkbox"/>
	Day 36	<input type="checkbox"/>
	Day 37	<input type="checkbox"/>
	Day 38	<input type="checkbox"/>
	Day 39	<input type="checkbox"/>
	Day 40	<input type="checkbox"/>
Date	25 OCT 2020	
Assessment Not Done	False	
O2 Saturation	<hr/>	
O2 Saturation Units	<hr/>	
Temperature	<hr/>	
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 type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input checked="" type="checkbox"/>
	Not Done	<input type="checkbox"/>
Difficulty Breathing	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input checked="" type="checkbox"/>
	Not Done	<input type="checkbox"/>
Fatigue	None	<input type="checkbox"/>
v6.020 DTW (1102)	361 of 2379	

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Form: Symptom Log (7)

Generated On: 26 Nov 2020 10:55:55

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

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Form: Symptom Log (7)

Generated On: 26 Nov 2020 10:55:55

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

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Form: Symptom Log (8)

Generated On: 26 Nov 2020 10:55:55

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"/>

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Form: Symptom Log (8)

Generated On: 26 Nov 2020 10:55:55

	Day 34	<input type="checkbox"/>
	Day 35	<input type="checkbox"/>
	Day 36	<input type="checkbox"/>
	Day 37	<input type="checkbox"/>
	Day 38	<input type="checkbox"/>
	Day 39	<input type="checkbox"/>
	Day 40	<input type="checkbox"/>
Date	26 OCT 2020	
Assessment Not Done	False	
O2 Saturation	<input type="text"/>	
O2 Saturation Units	<input type="text"/>	
Temperature	<input type="text"/>	
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 type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input checked="" type="checkbox"/>
	Not Done	<input type="checkbox"/>
Difficulty Breathing	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input checked="" type="checkbox"/>
	Not Done	<input type="checkbox"/>
Fatigue	None	<input type="checkbox"/>
v6.020 DTW (1102)	365 of 2379	

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Form: Symptom Log (8)

Generated On: 26 Nov 2020 10:55:55

	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 type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input checked="" type="radio"/>
	Not Done	<input type="radio"/>
<hr/>		
Body Aches	None	<input type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input checked="" type="radio"/>
	Not Done	<input type="radio"/>
<hr/>		
Headache	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 Taste	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 Smell	None	<input type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input checked="" type="radio"/>
	Not Done	<input type="radio"/>
<hr/>		
Nasal Congestion	None	<input type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>

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Form: Symptom Log (8)

Generated On: 26 Nov 2020 10:55:55

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



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Folder: Covid-19 Assessment 04 Nov 2020

Form: Symptom Log (9)

Generated On: 26 Nov 2020 10:55:55

Symptom Day

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

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Form: Symptom Log (9)

Generated On: 26 Nov 2020 10:55:55

	Day 34	<input type="checkbox"/>
	Day 35	<input type="checkbox"/>
	Day 36	<input type="checkbox"/>
	Day 37	<input type="checkbox"/>
	Day 38	<input type="checkbox"/>
	Day 39	<input type="checkbox"/>
	Day 40	<input type="checkbox"/>
Date	27 OCT 2020	
Assessment Not Done	False	
O2 Saturation	<input type="text"/>	
O2 Saturation Units	<input type="text"/>	
Temperature	<input type="text"/>	
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 type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input checked="" type="checkbox"/>
	Not Done	<input type="checkbox"/>
Difficulty Breathing	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input checked="" type="checkbox"/>
	Not Done	<input type="checkbox"/>
Fatigue	None	<input type="checkbox"/>
v6.020 DTW (1102)	369 of 2379	

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Form: Symptom Log (9)

Generated On: 26 Nov 2020 10:55:55

	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 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 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 type="radio"/>
	Moderate	<input type="radio"/>

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Form: Symptom Log (9)

Generated On: 26 Nov 2020 10:55:55

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

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Folder: Covid-19 Assessment 04 Nov 2020

Form: Symptom Log (10)

Generated On: 26 Nov 2020 10:55:55

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"/>

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Folder: Covid-19 Assessment 04 Nov 2020

Form: Symptom Log (10)

Generated On: 26 Nov 2020 10:55:55

	Day 34	<input type="checkbox"/>
	Day 35	<input type="checkbox"/>
	Day 36	<input type="checkbox"/>
	Day 37	<input type="checkbox"/>
	Day 38	<input type="checkbox"/>
	Day 39	<input type="checkbox"/>
	Day 40	<input type="checkbox"/>
Date	28 OCT 2020	
Assessment Not Done	False	
O2 Saturation		
O2 Saturation Units		
Temperature		
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 type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input checked="" type="checkbox"/>
	Not Done	<input type="checkbox"/>
Difficulty Breathing	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input checked="" type="checkbox"/>
	Not Done	<input type="checkbox"/>
Fatigue	None	<input type="checkbox"/>
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Form: Symptom Log (10)

Generated On: 26 Nov 2020 10:55:55

	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 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 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 type="radio"/>
	Moderate	<input type="radio"/>

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Folder: Covid-19 Assessment 04 Nov 2020

Form: Symptom Log (10)

Generated On: 26 Nov 2020 10:55:55

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



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Form: Symptom Log (11)

Generated On: 26 Nov 2020 10:55:55

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"/>

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Form: Symptom Log (11)

Generated On: 26 Nov 2020 10:55:55

	Day 34	<input type="checkbox"/>
	Day 35	<input type="checkbox"/>
	Day 36	<input type="checkbox"/>
	Day 37	<input type="checkbox"/>
	Day 38	<input type="checkbox"/>
	Day 39	<input type="checkbox"/>
	Day 40	<input type="checkbox"/>
Date	29 OCT 2020	
Assessment Not Done	False	
O2 Saturation	<hr/>	
O2 Saturation Units	<hr/>	
Temperature	<hr/>	
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 type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input checked="" type="checkbox"/>
	Not Done	<input type="checkbox"/>
Difficulty Breathing	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input checked="" type="checkbox"/>
	Not Done	<input type="checkbox"/>
Fatigue	None	<input type="checkbox"/>
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Form: Symptom Log (11)

Generated On: 26 Nov 2020 10:55:55

	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 type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input checked="" type="radio"/>
	Not Done	<input type="radio"/>
<hr/>		
Body Aches	None	<input type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input checked="" type="radio"/>
	Not Done	<input type="radio"/>
<hr/>		
Headache	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 Taste	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 Smell	None	<input type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input checked="" type="radio"/>
	Not Done	<input type="radio"/>
<hr/>		
Nasal Congestion	None	<input type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>

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Form: Symptom Log (11)

Generated On: 26 Nov 2020 10:55:55

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

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Form: Symptom Log (12)

Generated On: 26 Nov 2020 10:55:55

[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"/>

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Folder: Covid-19 Assessment 04 Nov 2020

Form: Symptom Log (12)

Generated On: 26 Nov 2020 10:55:55

	Day 34	<input type="checkbox"/>
	Day 35	<input type="checkbox"/>
	Day 36	<input type="checkbox"/>
	Day 37	<input type="checkbox"/>
	Day 38	<input type="checkbox"/>
	Day 39	<input type="checkbox"/>
	Day 40	<input type="checkbox"/>
Date	30 OCT 2020	
Assessment Not Done	False	
O2 Saturation	<input type="text"/>	
O2 Saturation Units	<input type="text"/>	
Temperature	<input type="text"/>	
Chills	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input 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 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 type="checkbox"/>
v6.020 DTW (1102)	381 of 2379	

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Form: Symptom Log (12)

Generated On: 26 Nov 2020 10:55:55

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

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Form: Symptom Log (12)

Generated On: 26 Nov 2020 10:55:55

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



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Folder: Covid-19 Assessment 04 Nov 2020

Form: Symptom Log (13)

Generated On: 26 Nov 2020 10:55:55

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"/>

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Form: Symptom Log (13)

Generated On: 26 Nov 2020 10:55:55

	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	01 NOV 2020	
Assessment Not Done	False	
O2 Saturation	<input type="text"/>	
O2 Saturation Units	<input type="text"/>	
Temperature	<input type="text"/>	
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"/>
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Folder: Covid-19 Assessment 04 Nov 2020

Form: Symptom Log (13)

Generated On: 26 Nov 2020 10:55:55

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

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Folder: Covid-19 Assessment 04 Nov 2020

Form: Symptom Log (13)

Generated On: 26 Nov 2020 10:55:55

	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"/>

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Folder: Covid-19 Assessment 04 Nov 2020

Form: COVID Diagnostic Test

Generated On: 26 Nov 2020 10:55:55

Date of Visit	27 OCT 2020
Was the Subject Tested For SARS-CoV-2 by RT-PCR?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Did Subject Test Positive For SARS-CoV-2 by RT-PCR?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Date of Test	27 OCT 2020
Type of Test Performed	Nasopharyngeal Swab <input checked="" type="radio"/> Nasal Swab <input type="radio"/> Saliva Test <input type="radio"/> Other <input type="radio"/>
Other, specify _____	
Was this diagnostic test performed at a lab other than the Study Central Lab?	Yes <input checked="" type="radio"/> No <input type="radio"/>
If yes, provide lab information below	
Lab/ Institution Test Performed	SAINT LUKE'S HOSPITAL
CLIA Certified?	Yes <input checked="" type="radio"/> No <input type="radio"/>
COVID-19 Positive (CSA Programming Field Only)	1

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Folder: Covid-19 Assessment 04 Nov 2020

Form: Covid-19 Severity Assessment

Generated On: 26 Nov 2020 10:55:55

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 27 OCT 2020

End Date 28 OCT 2020

Oxygen Saturation 85 %

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:

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Folder: Covid-19 Assessment 04 Nov 2020

Form: Covid-19 Severity Assessment

Generated On: 26 Nov 2020 10:55:55

**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 \_\_\_\_\_

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Folder: Covid-19 Assessment 04 Nov 2020

Form: Covid-19 Severity Assessment

Generated On: 26 Nov 2020 10:55:55

Neurologic Dysfunction? Yes ☐  
No ☒

Start Date

Evidence of Pneumonia:

Clinical Evidence Yes ☒  
No ☐

Date of Assessment 27 OCT 2020

Radiographical Evidence Yes ☒  
No ☐

Date of Assessment 27 OCT 2020

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

Start Date

End Date



**US3312605**

**Folder: Covid-19 Assessment 04 Nov 2020**

**Form: Generate Next COVID-19 Assessment**

**Generated On: 26 Nov 2020 10:55:55**

---

Generate Next COVID-19 Assessment

Yes ☐

No ☐

---

US3312605

Folder: Adverse Events

Form: Adverse Events Summary

Generated On: 26 Nov 2020 10:55:55

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Did the participant experience any adverse events?

Yes ☒

No ☐

---

If Yes, enter details on the Adverse Events form.

---

US3312605

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 10:55:55

AEID	USA-US300-2020-MRNA-1273-P30 1000009
Adverse event	SYMPTOMATIC COVID 19
Was this a medically-attended AE?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Was this a Solicited Adverse Reaction?	Yes <input type="radio"/> No <input checked="" type="radio"/>
Is this event a confirmed diagnosis of Symptomatic Covid-19?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Start date (dd MMM yyyy)	19 OCT 2020
Start time (00:00-23:59)	
AE start date and time (derived)	
Ongoing?	Yes <input type="radio"/> No <input checked="" type="radio"/>
If not Ongoing, end date (dd MMM yyyy)	02 NOV 2020
End time (00:00-23:59)	
AE End Date and Time (derived)	
Severity	Grade 1/Mild <input type="radio"/> Grade 2/Moderate <input type="radio"/> Grade 3/Severe <input checked="" type="radio"/> Grade 4 <input type="radio"/>
Is the adverse event serious?	Yes <input checked="" type="radio"/> No <input type="radio"/>
AE is serious due To (check all that apply)	
Death	False
Life threatening	False
Requires inpatient or prolongation of existing Hospitalization	True
Hospital Admission Date (dd MMM yyyy)	27 OCT 2020
Hospital Discharge Date (dd MMM yyyy)	29 OCT 2020
Admitted to ICU?	Yes <input type="radio"/> No <input checked="" type="radio"/> Unknown <input type="radio"/>
Number of Days in ICU	

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 10:55:55

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 checked="" type="radio"/> Recovered/Resolved with Sequelae <input type="radio"/> Recovering/Resolving <input type="radio"/> Unknown <input type="radio"/>
If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:	
Narrative	

US3312605

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 10:55:55

---

SUBJECT DEVELOPED COUGH,  
SORE THROAT, MYALGIAS,  
HEADACHE, FATIGUE, NAUSEA,  
EMESIS, ABDOMINAL  
DISCOMFORT & DIARRHEA  
19OCT2020 & STARTED CMS  
NOTED SUBJECT PROCURED  
COVID TEST 20OCT2020. ON  
21OCT2020, SYMPTOMS  
PROGRESSED TO FEVER 101.9,  
CHILLS, SOA, CHEST PRESSURE.  
COVID TEST REPORTED +  
22OCT2020 & STARTED  
ADDITIONAL CMS NOTED ON  
LOG NAUSEA, EMESIS,  
ABDOMINAL DISCOMFORT &  
DIARRHEA RESOLVED;  
SUBJECT STARTED  
ALBUTEROL INHALER.  
26OCT2020 LOSS OF TASTE AND  
SMELL. 27OCT2020 WORSENING  
OF SYMPTOMS: FATIGUE,  
SHORTNESS OF AIR, COUGH,  
DIFFICULTY CONCENTRATING.  
SUBJECT WENT TO HOSPITAL &  
ADMITTED FOR SATS DOWN  
TO 85% WHICH IMPROVED  
WITH IV HYDRATION.  
DIAGNOSED WITH COVID-19  
DISEASE. OTHER TREATMENT  
IN HOSPITAL ALBUTEROL AND  
TESSALON PERLES BUT  
REPORTEDLY NO OXYGEN. DCD  
TO HOME 29OCT2020 ON  
ALBUTEROL INHALER &  
CONTINUED VITAMINS,  
MELATONIN & FAMOTIDINE.

US3312605

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 10:55:55

---

STEADY IMPROVEMENT OF  
SYMPTOMS ENDED BY  
02NOV2020.SAT 98% AT SITE  
VISIT 04NOV2020 WITH  
NORMAL PE.DIDN'T REPORT  
SYMPTOMS TO SITE AT TIME  
OF ILLNESS DUE TO SEVERITY  
OF ILLNESS,STATED HE "FELT  
TOO BAD TO DO ANYTHING".  
MED RECS PENDING. FOLLOW  
UP:SUBJECT NOTIFIED SITE HE  
WISHES TO NO LONGER  
PARTICIPATE IN STUDY AND  
GAVE NO REASON. CANNOT  
CONFIRM HIS ACCOUNT OF  
COVID-19 ILLNESS, AS  
HOSPITAL WHICH HE  
REPORTED BEING ADMITTED  
HAS NO RECORD OF  
ADMISSION,& SUBJECT NEVER  
PRODUCED A COPY OF HIS  
INITIAL SARS-COV2 TEST AS HE  
STATED THAT HE WOULD  
QUICKLY DO.OF NOTE, IN HIS  
ACCOUNT OF  
HOSPITALIZATION,SUBJECT  
STATED THAT HE NEVER  
RECEIVED OXYGEN THERAPY  
EVEN THOUGH HE HAD O2SATS  
AS LOW AS 85%.THIS IS  
INCONSISTENT WITH  
STANDARD OF CARE AND I  
DOUBTED THE VERACITY OF  
IT, BUT THOUGHT IT MUST BE  
AN ERROR MADE BY THE  
SUBJECT THAT WOULD BE  
CLARIFIED BY MEDICAL

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 10:55:55

---

RECORDS. HAS HISTORY OF  
NONCOMPLIANCE WITH  
DIARIES AND  
INCONSISTENCIES IN HISTORY  
REPORTING TO DIFFERENT  
SITE STAFF THAT HAVE  
REQUIRED FURTHER  
CLARIFICATION FOR THE  
FINAL ACCOUNT.IN  
RETROSPECT, THE ACCURACY  
OF SUBJECT'S REPORTING IS  
SERIOUSLY IN DOUBT.PLEASE  
ADVISE BEST WAY TO CLOSE  
THIS SAE

---

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

---

US3312605

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Generated On: 26 Nov 2020 10:55:55

---

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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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 10:55:55

Name of Medication	ESCITALOPRAM
Prophylaxis	Yes <input type="radio"/> No <input checked="" type="radio"/>
Indication	DEPRESSION AND ANXIETY
Dose per administration	20
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 10:55:55

	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 2016	
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 10:55:55

Name of Medication	DESTROAMPHETAMINE-AMPHE TAMINE
Prophylaxis	Yes <input type="radio"/> No <input checked="" type="radio"/>
Indication	ATTENTION DEFICIT HYPERACTIVITY DISORDER
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 checked="" 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"/>

US3312605

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 10:55:55

	Intraocular	<input type="checkbox"/>
	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	UN	UNK 2011
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)	3	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 10:55:55

Name of Medication	FINASTERIDE
Prophylaxis	Yes <input type="radio"/> No <input checked="" type="radio"/>
Indication	EXCESSIVE HAIR LOSS
Dose per administration	1.25
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 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 (3)

Generated On: 26 Nov 2020 10:55:55

	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	UN	UNK 2019
Start date completely unknown		False
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)		1
Interval Dosage Unit Number (derived)		1
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 10:55:55

Name of Medication	POTASSIUM CITRATE
Prophylaxis	Yes <input type="radio"/> No <input checked="" type="radio"/>
Indication	NEPHROLITHIASIS
Dose per administration	10
Dose unit	mg <input type="radio"/> ug <input type="radio"/> mL <input type="radio"/> g <input type="radio"/> IU <input type="radio"/> tablet <input type="radio"/> capsule <input type="radio"/> puff <input type="radio"/> Other <input checked="" type="radio"/>
If dose unit is Other, specify	MILLIEQUIVALENTS
Frequency	once daily <input type="radio"/> twice daily <input type="radio"/> three times daily <input checked="" 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 (4)

Generated On: 26 Nov 2020 10:55:55

	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 2016
Start date completely unknown		False
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)		3
Interval Dosage Unit Number (derived)		1
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>



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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 10:55:55

Name of Medication	CETIRIZINE
Prophylaxis	Yes <input type="checkbox"/> No <input checked="" type="checkbox"/>
Indication	SEASONAL ALLERGIES
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"/> Intramuscular <input type="checkbox"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 10:55:55

	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 2010	
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 10:55:55

Name of Medication	ACETAMINOPHEN
Prophylaxis	Yes <input type="checkbox"/> No <input checked="" type="checkbox"/>
Indication	MILD OCCASIONAL HEADACHES
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 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"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 10:55:55

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)		UN UNK 2010
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"/>

US3312605

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 26 Nov 2020 10:55:55

Name of Medication	IBUPROFEN
Prophylaxis	Yes <input type="checkbox"/> No <input checked="" type="checkbox"/>
Indication	SYMPTOMATIC COVID-19
Dose per administration	400
Dose unit	mg <input checked="" type="checkbox"/> ug <input type="checkbox"/> mL <input type="checkbox"/> g <input type="checkbox"/> IU <input type="checkbox"/> tablet <input type="checkbox"/> capsule <input type="checkbox"/> puff <input type="checkbox"/> Other <input type="checkbox"/>
If dose unit is Other, specify	
Frequency	once daily <input type="checkbox"/> twice daily <input type="checkbox"/> three times daily <input type="checkbox"/> four times daily <input type="checkbox"/> every other day <input type="checkbox"/> every week <input type="checkbox"/> every month <input type="checkbox"/> as needed <input 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"/>

US3312605

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 26 Nov 2020 10:55:55

	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)		19 OCT 2020
Start date completely unknown		False
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)		19 OCT 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"/>

US3312605

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 26 Nov 2020 10:55:55

Name of Medication	ACETAMINOPHEN
Prophylaxis	Yes <input type="radio"/> No <input checked="" type="radio"/>
Indication	SYMPTOMATIC COVID-19
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 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"/>

US3312605

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 26 Nov 2020 10:55:55

	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> )		19 OCT 2020
Start date completely unknown		False
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
<hr/>		
If not Ongoing, End date ( <i>dd MMM yyyy</i> )		30 OCT 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"/>



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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 26 Nov 2020 10:55:55

Name of Medication	VITAMIN C
Prophylaxis	Yes <input type="checkbox"/> No <input checked="" type="checkbox"/>
Indication	SYMPTOMATIC COVID-19
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 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 checked="" type="checkbox"/> Topical <input type="checkbox"/> Subcutaneous <input type="checkbox"/> Transdermal <input type="checkbox"/> Intraocular <input type="checkbox"/> Intramuscular <input type="checkbox"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 26 Nov 2020 10:55:55

	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)		22 OCT 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)		2
Interval Dosage Unit Number (derived)		1
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>

US3312605

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 26 Nov 2020 10:55:55

Name of Medication	ZINC
Prophylaxis	Yes <input type="checkbox"/> No <input checked="" type="checkbox"/>
Indication	SYMPTOMATIC COVID-19
Dose per administration	75
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"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 26 Nov 2020 10:55:55

	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)		22 OCT 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"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 26 Nov 2020 10:55:55

Name of Medication	MELATONIN
Prophylaxis	Yes <input type="radio"/> No <input checked="" type="radio"/>
Indication	SYMPTOMATIC COVID-19
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 (11)

Generated On: 26 Nov 2020 10:55:55

	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)		22 OCT 2020
Start date completely unknown		False
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)		1
Interval Dosage Unit Number (derived)		1
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 26 Nov 2020 10:55:55

Name of Medication	FAMOTIDINE
Prophylaxis	Yes <input type="checkbox"/> No <input checked="" type="checkbox"/>
Indication	SYMPTOMATIC COVID-19
Dose per administration	20
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"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 26 Nov 2020 10:55:55

	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)		22 OCT 2020
Start date completely unknown		False
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)		1
Interval Dosage Unit Number (derived)		1
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>



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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 26 Nov 2020 10:55:55

Name of Medication	TESSALON PERLES BENZONATATE
Prophylaxis	Yes <input type="radio"/> No <input checked="" type="radio"/>
Indication	SYMPTOMATIC 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 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"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 26 Nov 2020 10:55:55

	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"/>
<hr/>		
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)		27 OCT 2020
Start date completely unknown		False
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
<hr/>		
If not Ongoing, End date (dd MMM yyyy)		29 OCT 2020
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
<hr/>		
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"/>

US3312605

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 26 Nov 2020 10:55:55

Name of Medication	ALBUTEROL NEBULIZER
Prophylaxis	Yes <input type="checkbox"/> No <input checked="" type="checkbox"/>
Indication	SYMPTOMATIC COVID-19
Dose per administration	2.5
Dose unit	mg <input checked="" type="checkbox"/> ug <input type="checkbox"/> mL <input type="checkbox"/> g <input type="checkbox"/> IU <input type="checkbox"/> tablet <input type="checkbox"/> capsule <input type="checkbox"/> puff <input type="checkbox"/> Other <input type="checkbox"/>
If dose unit is Other, specify	
Frequency	once daily <input type="checkbox"/> twice daily <input type="checkbox"/> three times daily <input type="checkbox"/> four times daily <input checked="" 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"/>

US3312605

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 26 Nov 2020 10:55:55

	Respiratory (Inhalation)	<input checked="" type="radio"/>
	Intralesional	<input type="radio"/>
	Intraperitoneal	<input type="radio"/>
	Nasal	<input type="radio"/>
	Vaginal	<input type="radio"/>
	Rectal	<input type="radio"/>
	Intravenous	<input type="radio"/>
	Intravenous Bolus	<input type="radio"/>
	Intravenous Drip	<input type="radio"/>
	Other	<input type="radio"/>
<hr/>		
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)		27 OCT 2020
Start date completely unknown		False
Ongoing?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
<hr/>		
If not Ongoing, End date (dd MMM yyyy)		29 OCT 2020
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
<hr/>		
Separate Dosage Number (derived)		4
Interval Dosage Unit Number (derived)		1
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>

US3312605

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 26 Nov 2020 10:55:55

Name of Medication	ALBUTEROL INHALER
Prophylaxis	Yes <input type="radio"/> No <input checked="" type="radio"/>
Indication	SYMPTOMATIC COVID-19
Dose per administration	200
Dose unit	mg <input type="radio"/> ug <input checked="" type="radio"/> mL <input type="radio"/> g <input type="radio"/> IU <input type="radio"/> tablet <input type="radio"/> capsule <input type="radio"/> puff <input type="radio"/> Other <input type="radio"/>
If dose unit is Other, specify	
Frequency	once daily <input 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 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 (15)

Generated On: 26 Nov 2020 10:55:55

	Respiratory (Inhalation)	<input checked="" type="radio"/>
	Intralesional	<input type="radio"/>
	Intraperitoneal	<input type="radio"/>
	Nasal	<input type="radio"/>
	Vaginal	<input type="radio"/>
	Rectal	<input type="radio"/>
	Intravenous	<input type="radio"/>
	Intravenous Bolus	<input type="radio"/>
	Intravenous Drip	<input type="radio"/>
	Other	<input type="radio"/>
<hr/>		
If route of administration is Other, specify <hr/>		
Start date (dd MMM yyyy)		25 OCT 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) <hr/>		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
<hr/>		
Separate Dosage Number (derived)		<hr/>
Interval Dosage Unit Number (derived)		<hr/>
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input type="radio"/>

US3312605

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 26 Nov 2020 10:55:55

Name of Medication DAYQUIL COLD & FLU  
(ACETAMINOPHEN  
325MG/PHENYLEPHRINE HCL  
5MG/DEXTROMETHORPHAN  
HBR 10MG)

Prophylaxis Yes ☐  
No ☒

Indication SYMPTOMATIC COVID-19

Dose per administration 2

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

If dose unit is Other, specify

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

If frequency is Other, specify

Route of administration Oral ☒  
Topical ☐  
Subcutaneous ☐

US3312605

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 26 Nov 2020 10:55:55

	Transdermal	<input type="checkbox"/>
	Intraocular	<input type="checkbox"/>
	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	19 OCT 2020	
Start date completely unknown	False	
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)		30 OCT 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"/>



US3312605

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 26 Nov 2020 10:55:55

Name of Medication NYQUIL COLD & FLU  
(ACETAMINOPHEN  
325MG/DEXTROMETHORPHAN  
15 MG/ DOXYLAMINE  
SUCCINATE 6.25MG)

Prophylaxis Yes ☐  
No ☒

Indication SYMPTOMATIC COVID-19

Dose per administration 2

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

If dose unit is Other, specify

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

If frequency is Other, specify

Route of administration Oral ☒  
Topical ☐  
Subcutaneous ☐

US3312605

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 26 Nov 2020 10:55:55

	Transdermal	<input type="checkbox"/>
	Intraocular	<input type="checkbox"/>
	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date ( <i>dd MMM yyyy</i> )	19 OCT 2020	
Start date completely unknown	False	
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date ( <i>dd MMM yyyy</i> )		30 OCT 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"/>

**US3312605**

**Folder: Concomitant Procedures (1)**

**Form: Concomitant Procedures Summary**

**Generated On: 26 Nov 2020 10:55:55**

---

Were any concomitant procedures performed?

Yes ☐

No ☐

---

**If yes, please complete Concomitant Procedures form.**

---

US3312605

Folder: COVID-19 Impact (1)

Form: COVID-19 Impact (1)

Generated On: 26 Nov 2020 10:55:55

Visit	Screening	<input type="checkbox"/>
	Visit 1 Day 1	<input type="checkbox"/>
	Visit 2 Day 29	<input type="checkbox"/>
	Visit 3 Day 57	<input type="checkbox"/>
	Visit 4 Day 209	<input type="checkbox"/>
	Visit 5 Day 394	<input type="checkbox"/>
	Visit 6 Day 759	<input type="checkbox"/>

**Case Report Form**

Visit Date	False
Demographics	False
Enrollment	False
Inclusion/Exclusion Criteria Summary	False
Inclusion/Exclusion Criteria	False
Medical History Summary	False
Medical History	False
Vital Signs	False
Vital Signs - Dosing	False
Physical Examination	False
Central Laboratory - Nasopharyngeal Swab	False
Childbearing Potential	False
Pregnancy Test	False
Randomization	False
Exposure	False
Immunogenicity Assessment	False
Saliva Collection	False
COVID Diagnostic Test	False
Symptom Log	False
Blood Sample Collection for Immunologic Assessment of SARS-CoV-2 Infection	False
COVID-19 Severity Assessment	False
COVID-19 Contact	False
Risk of Exposure	False
Safety Call	True
Dosing Discontinuation	False
End of Study / Study Discontinuation	False

US3312605

Folder: COVID-19 Impact (1)

Form: COVID-19 Impact (1)

Generated On: 26 Nov 2020 10:55:55

All	False
-----	-------

---

Date of missed or out of window visit or assessment	22 OCT 2020
---	-------------

---

**Category**

Inclusion criteria not met/Exclusion criteria met	False
Study Treatment not given	False
Missed Visit	False
Missed Assessment	True
Visit performed out of window	False
Assessment performed out of window	False
Scheduled clinical visit performed as home visit	False
Other	False
Other, specify	

---

**Description of Relationship to COVID-19**

Clinical site closed	False
Travel restrictions	False
Quarantine due to COVID-19	False
Possible exposure to COVID-19	False
Exposure to COVID-19	False
Presumption / confirmed COVID-19	True
Symptoms of COVID-19	False
Sponsor hold due to COVID-19	False
Participant decision	False

US3312605

Folder: COVID-19 Impact (1)

Form: COVID-19 Impact (2)

Generated On: 26 Nov 2020 10:55:55

Visit	Screening	<input type="checkbox"/>
	Visit 1 Day 1	<input type="checkbox"/>
	Visit 2 Day 29	<input type="checkbox"/>
	Visit 3 Day 57	<input type="checkbox"/>
	Visit 4 Day 209	<input type="checkbox"/>
	Visit 5 Day 394	<input type="checkbox"/>
	Visit 6 Day 759	<input type="checkbox"/>

### Case Report Form

Visit Date	False
Demographics	False
Enrollment	False
Inclusion/Exclusion Criteria Summary	False
Inclusion/Exclusion Criteria	False
Medical History Summary	False
Medical History	False
Vital Signs	False
Vital Signs - Dosing	False
Physical Examination	False
Central Laboratory - Nasopharyngeal Swab	False
Childbearing Potential	False
Pregnancy Test	False
Randomization	False
Exposure	False
Immunogenicity Assessment	False
Saliva Collection	False
COVID Diagnostic Test	False
Symptom Log	False
Blood Sample Collection for Immunologic Assessment of SARS-CoV-2 Infection	False
COVID-19 Severity Assessment	False
COVID-19 Contact	False
Risk of Exposure	False
Safety Call	True
Dosing Discontinuation	False
End of Study / Study Discontinuation	False

US3312605

Folder: COVID-19 Impact (1)

Form: COVID-19 Impact (2)

Generated On: 26 Nov 2020 10:55:55

All	False
Date of missed or out of window visit or assessment	29 OCT 2020
<b>Category</b>	
Inclusion criteria not met/Exclusion criteria met	False
Study Treatment not given	False
Missed Visit	False
Missed Assessment	True
Visit performed out of window	False
Assessment performed out of window	False
Scheduled clinical visit performed as home visit	False
Other	False
Other, specify	
<b>Description of Relationship to COVID-19</b>	
Clinical site closed	False
Travel restrictions	False
Quarantine due to COVID-19	False
Possible exposure to COVID-19	False
Exposure to COVID-19	False
Presumption / confirmed COVID-19	True
Symptoms of COVID-19	False
Sponsor hold due to COVID-19	False
Participant decision	False

US3312605

Folder: End of Study (1)

Form: Dosing Discontinuation

Generated On: 26 Nov 2020 10:55:55

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



US3312605

Folder: End of Study (1)

Form: End of Study / Study Discontinuation

Generated On: 26 Nov 2020 10:55:55

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 ☐

US3312605

Folder: SAE USA-US300-2020-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 26 Nov 2020 10:55:55

SAEID	USA-US300-2020-MRNA-1273-P301000009
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input type="radio"/> No <input checked="" type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input checked="" type="radio"/> No <input type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input type="radio"/> No <input checked="" type="radio"/>
Investigator's First Name	CARLOS
Investigator's Last Name	FIERRO
Site Address: Street	16300 COLLEGE BLVD
Site Address: City	SHAWNEE
Site Address: State	KS
Site Address: Postal Code	66219
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	3

US3312605

Folder: SAE USA-US300-2020-MRNA-1273-P301000009

Form: Safety Report Form (1)

Generated On: 26 Nov 2020 10:55:55

SAEID	USA-US300-2020-MRNA-1273-P301000009
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input type="radio"/> No <input checked="" type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input checked="" type="radio"/> No <input type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input type="radio"/> No <input checked="" type="radio"/>
Investigator's First Name	CARLOS
Investigator's Last Name	FIERRO
Site Address: Street	16300 COLLEGE BLVD
Site Address: City	SHAWNEE
Site Address: State	KS
Site Address: Postal Code	66219
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	3
Date of submission (Pre-filled from custom function)	05/NOV/2020 20:20
Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.	True

US3312605

Folder: SAE USA-US300-2020-MRNA-1273-P301000009

Form: Safety Report Form (2)

Generated On: 26 Nov 2020 10:55:55

SAEID	USA-US300-2020-MRNA-1273-P301000009
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input type="radio"/> No <input checked="" type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input checked="" type="radio"/> No <input type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input type="radio"/> No <input checked="" type="radio"/>
Investigator's First Name	CARLOS
Investigator's Last Name	FIERRO
Site Address: Street	16300 COLLEGE BLVD
Site Address: City	SHAWNEE
Site Address: State	KS
Site Address: Postal Code	66219
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	3
Date of submission (Pre-filled from custom function)	13/NOV/2020 08:05
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

US3312605

Folder: SAE USA-US300-2020-MRNA-1273-P301000009

Form: Safety Report Form (3)

Generated On: 26 Nov 2020 10:55:55

SAEID	USA-US300-2020-MRNA-1273-P301000009
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input type="radio"/> No <input checked="" type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input checked="" type="radio"/> No <input type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input type="radio"/> No <input checked="" type="radio"/>
Investigator's First Name	CARLOS
Investigator's Last Name	FIERRO
Site Address: Street	16300 COLLEGE BLVD
Site Address: City	SHAWNEE
Site Address: State	KS
Site Address: Postal Code	66219
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	3
Date of submission (Pre-filled from custom function)	16/NOV/2020 20:28
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

Audit

US3312605 (Prod: Johnson County Clin-Trials)

**US3312605**

**Form: Participant Creation**

**Generated On: 26 Nov 2020 10:55:55**

[Participant ID](#)

Audit	User	Time (GMT)
User entered 'US3312605'	RWS_ENDPOINT ENDPOINT (b) (4) <div></div>	10 Sep 2020 18:29:27

US3312605

Folder: Screening

Form: Visit Date

Generated On: 26 Nov 2020 10:55:55

[Was this visit performed?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Christa Estrada (b) (4) (b) (4)	10 Sep 2020 19:57:21



**US3312605**

**Folder: Screening**

**Form: Visit Date**

**Generated On: 26 Nov 2020 10:55:55**

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

Audit	User	Time (GMT)
User entered '10 SEP 2020'	RWS_ENDPOINT ENDPOINT (b) (4) <div></div>	10 Sep 2020 18:29:28

US3312605

Folder: Screening

Form: Visit Date

Generated On: 26 Nov 2020 10:55:55

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

Audit	User	Time (GMT)
User entered 'Clinic (Clinic)'	Christa Estrada (b) (4) (b) (4)	10 Sep 2020 19:57:21

**US3312605**

**Folder: Screening**

**Form: Visit Date**

**Generated On: 26 Nov 2020 10:55:55**

[Folder OID](#)

Audit	User	Time (GMT)
User entered 'SCRN'	System	10 Sep 2020 19:57:21

US3312605

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 10:55:55

Date of Birth (MMM yyyy)

Audit	User	Time (GMT)
User entered (b) (6) 1996'	RWS_ENDPOINT ENDPOINT (b) (4) [REDACTED]	10 Sep 2020 18:29:30

US3312605

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 10:55:55

[Age](#)

Audit	User	Time (GMT)
User entered '24'	Christa Estrada (b) (4) (b) (4)	10 Sep 2020 19:58:12

**US3312605**

**Folder: Screening**

**Form: Demographics**

**Generated On: 26 Nov 2020 10:55:55**

[Age Units](#)

Audit	User	Time (GMT)
User entered 'YEARS'	System	10 Sep 2020 19:58:12

**US3312605**

**Folder: Screening**

**Form: Demographics**

**Generated On: 26 Nov 2020 10:55:55**

[Age \(Derived\)](#)

Audit	User	Time (GMT)
User entered '24'	System	10 Sep 2020 19:58:40

US3312605

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 10:55:55

Sex

Audit	User	Time (GMT)
User entered 'Male (M)'	Christa Estrada (b) (4) (b) (4)	10 Sep 2020 19:58:12



US3312605

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 10:55:55

[Ethnicity](#)

Audit	User	Time (GMT)
User entered 'Not Hispanic or Latino (NOT HISPANIC OR LATINO)'	Christa Estrada (b) (4) (b) (4)	10 Sep 2020 19:58:12

**US3312605**

**Folder: Screening**

**Form: Demographics**

**Generated On: 26 Nov 2020 10:55:55**

[White](#)

Audit	User	Time (GMT)
User entered '1'	Christa Estrada (b) (4) (b) (4)	10 Sep 2020 19:58:12

**US3312605**

**Folder: Screening**

**Form: Demographics**

**Generated On: 26 Nov 2020 10:55:55**

[Black](#)

Audit	User	Time (GMT)
User entered '0'	Christa Estrada (b) (4) (b) (4)	10 Sep 2020 19:58:12

**US3312605**

**Folder: Screening**

**Form: Demographics**

**Generated On: 26 Nov 2020 10:55:55**

[Asian](#)

Audit	User	Time (GMT)
User entered '0'	Christa Estrada (b) (4) (b) (4)	10 Sep 2020 19:58:12

US3312605

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 10:55:55

[American Indian or Alaska Native](#)

Audit	User	Time (GMT)
User entered '0'	Christa Estrada (b) (4) (b) (4)	10 Sep 2020 19:58:12

**US3312605**

**Folder: Screening**

**Form: Demographics**

**Generated On: 26 Nov 2020 10:55:55**

[Native Hawaiian or other Pacific Islander](#)

Audit	User	Time (GMT)
User entered '0'	Christa Estrada (b) (4) (b) (4)	10 Sep 2020 19:58:12

**US3312605**

**Folder: Screening**

**Form: Demographics**

**Generated On: 26 Nov 2020 10:55:55**

[Other](#)

Audit	User	Time (GMT)
User entered '0'	Christa Estrada (b) (4) (b) (4)	10 Sep 2020 19:58:12

US3312605

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 10:55:55

If race is Other, specify

Audit	User	Time (GMT)
User entered empty.	Christa Estrada (b) (4) (b) (4)	10 Sep 2020 19:58:12



**US3312605**

**Folder: Screening**

**Form: Demographics**

**Generated On: 26 Nov 2020 10:55:55**

[Unknown](#)

Audit	User	Time (GMT)
User entered '0'	Christa Estrada (b) (4) (b) (4)	10 Sep 2020 19:58:12

**US3312605**

**Folder: Screening**

**Form: Demographics**

**Generated On: 26 Nov 2020 10:55:55**

[Not reported](#)

Audit	User	Time (GMT)
User entered '0'	Christa Estrada (b) (4) (b) (4)	10 Sep 2020 19:58:12

US3312605

Folder: Screening

Form: Enrollment

Generated On: 26 Nov 2020 10:55:55

Date of Informed Consent (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered '10 Sep 2020'	Christa Estrada (b) (4) (b) (4)	10 Sep 2020 19:58:40

**US3312605**

**Folder: Screening**

**Form: Enrollment**

**Generated On: 26 Nov 2020 10:55:55**

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

Audit	User	Time (GMT)
User entered 'Sep 2020'	System	10 Sep 2020 19:58:40

**US3312605**

**Folder: Screening**

**Form: Enrollment**

**Generated On: 26 Nov 2020 10:55:55**

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

Audit	User	Time (GMT)
User entered '2020'	System	10 Sep 2020 19:58:40

US3312605

Folder: Screening

Form: Enrollment

Generated On: 26 Nov 2020 10:55:55

[Protocol Version](#)

Audit	User	Time (GMT)
User entered 'Amendment 3 (3)'	Christa Estrada (b) (4) (b) (4)	10 Sep 2020 19:58:40

US3312605

Folder: Screening

Form: Enrollment

Generated On: 26 Nov 2020 10:55:55

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

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Christa Estrada (b) (4) (b) (4)	10 Sep 2020 19:58:40

**US3312605**

**Folder: Screening**

**Form: Enrollment**

**Generated On: 26 Nov 2020 10:55:55**

[If No, indicate reason for screen fail](#)

Audit	User	Time (GMT)
User entered empty.	Christa Estrada (b) (4) (b) (4)	10 Sep 2020 19:58:40



US3312605

Folder: Screening

Form: Enrollment

Generated On: 26 Nov 2020 10:55:55

If reason for screen fail is Other, specify

Audit	User	Time (GMT)
User entered empty.	Christa Estrada (b) (4) (b) (4)	10 Sep 2020 19:58:40

**US3312605**

**Folder: Screening**

**Form: Enrollment**

**Generated On: 26 Nov 2020 10:55:55**

[Was this participant screened previously?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Christa Estrada (b) (4) (b) (4)	10 Sep 2020 19:58:40

**US3312605**

**Folder: Screening**

**Form: Enrollment**

**Generated On: 26 Nov 2020 10:55:55**

[If Yes, previous participant number](#)

Audit	User	Time (GMT)
User entered empty.	RWS_ENDPOINT ENDPOINT (b) (4) [REDACTED]	10 Sep 2020 18:29:28

**US3312605**

**Folder: Screening**

**Form: Enrollment**

**Generated On: 26 Nov 2020 10:55:55**

[Enrollment Trigger](#)

Audit	User	Time (GMT)
User entered 'I'	System	10 Sep 2020 19:58:47

US3312605

Folder: Screening

Form: Inclusion/Exclusion Criteria Summary

Generated On: 26 Nov 2020 10:55:55

Did the participant meet all eligibility criteria?

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Christa Estrada (b) (4) (b) (4)	10 Sep 2020 19:58:47

US3312605

Folder: Screening

Form: Medical History Summary

Generated On: 26 Nov 2020 10:55:55

[Were any significant conditions reported?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Karol Moore (b) (4) (b) (4)	06 Oct 2020 20:32:06

US3312605

Folder: Screening

Form: Medical History (1)

Generated On: 26 Nov 2020 10:55:55

[Condition](#)

Audit	User	Time (GMT)
User coded data point as SOC: Psychiatric disorders, HLGT: Depressed mood disorders and disturbances, HLT: Depressive disorders, PT: Depression, LLT: Depression - version MedDRA\\23.0.	Coder Import (b) (4)	06 Oct 2020 20:35:26
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	06 Oct 2020 20:35:26
Data point term sent to Coder	System	06 Oct 2020 20:34:16
User entered 'depression'	Karol Moore (b) (4)	06 Oct 2020 20:33:27
	(b) (4)	

**US3312605**

**Folder: Screening**

**Form: Medical History (1)**

**Generated On: 26 Nov 2020 10:55:55**

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

Audit	User	Time (GMT)
User entered 'un UNK 2016'	Karol Moore (b) (4) (b) (4)	06 Oct 2020 20:33:27



**US3312605**

**Folder: Screening**

**Form: Medical History (1)**

**Generated On: 26 Nov 2020 10:55:55**

[Start date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	Karol Moore (b) (4) (b) (4)	06 Oct 2020 20:33:27

**US3312605**

**Folder: Screening**

**Form: Medical History (1)**

**Generated On: 26 Nov 2020 10:55:55**

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Karol Moore (b) (4) (b) (4)	06 Oct 2020 20:33:27

**US3312605**

**Folder: Screening**

**Form: Medical History (1)**

**Generated On: 26 Nov 2020 10:55:55**

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

Audit	User	Time (GMT)
User entered empty.	Karol Moore (b) (4) (b) (4)	06 Oct 2020 20:33:27

**US3312605**

**Folder: Screening**

**Form: Medical History (1)**

**Generated On: 26 Nov 2020 10:55:55**

[Stop date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	Karol Moore (b) (4) (b) (4)	06 Oct 2020 20:33:27

**US3312605**

**Folder: Screening**

**Form: Medical History (1)**

**Generated On: 26 Nov 2020 10:55:55**

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

Audit	User	Time (GMT)
User entered 'Jan 2016'	System	06 Oct 2020 20:33:27

**US3312605**

**Folder: Screening**

**Form: Medical History (1)**

**Generated On: 26 Nov 2020 10:55:55**

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

Audit	User	Time (GMT)
User entered '2016'	System	06 Oct 2020 20:33:27

**US3312605**

**Folder: Screening**

**Form: Medical History (1)**

**Generated On: 26 Nov 2020 10:55:55**

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

Audit	User	Time (GMT)
User entered empty.	System	06 Oct 2020 20:33:27

**US3312605**

**Folder: Screening**

**Form: Medical History (1)**

**Generated On: 26 Nov 2020 10:55:55**

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

Audit	User	Time (GMT)
User entered empty.	System	06 Oct 2020 20:33:27



US3312605

Folder: Screening

Form: Medical History (2)

Generated On: 26 Nov 2020 10:55:55

[Condition](#)

Audit	User	Time (GMT)
User coded data point as SOC: Psychiatric disorders, HLGT: Anxiety disorders and symptoms, HLT: Anxiety symptoms, PT: Anxiety, LLT: Anxiety - version MedDRA\\23.0.	Coder Import (b) (4)	06 Oct 2020 20:35:25
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	06 Oct 2020 20:35:25
Data point term sent to Coder	System	06 Oct 2020 20:34:17
User entered 'anxiety'	Karol Moore (b) (4)	06 Oct 2020 20:33:43
	(b) (4)	

US3312605

Folder: Screening

Form: Medical History (2)

Generated On: 26 Nov 2020 10:55:55

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

Audit	User	Time (GMT)
User entered 'un UNK 2016'	Karol Moore (b) (4) (b) (4)	06 Oct 2020 20:33:43

**US3312605**

**Folder: Screening**

**Form: Medical History (2)**

**Generated On: 26 Nov 2020 10:55:55**

[Start date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	Karol Moore (b) (4) (b) (4)	06 Oct 2020 20:33:43

US3312605

Folder: Screening

Form: Medical History (2)

Generated On: 26 Nov 2020 10:55:55

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Karol Moore (b) (4) (b) (4)	06 Oct 2020 20:33:43

US3312605

Folder: Screening

Form: Medical History (2)

Generated On: 26 Nov 2020 10:55:55

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

Audit	User	Time (GMT)
User entered empty.	Karol Moore (b) (4) (b) (4)	06 Oct 2020 20:33:43

**US3312605**

**Folder: Screening**

**Form: Medical History (2)**

**Generated On: 26 Nov 2020 10:55:55**

[Stop date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	Karol Moore (b) (4) (b) (4)	06 Oct 2020 20:33:43

**US3312605**

**Folder: Screening**

**Form: Medical History (2)**

**Generated On: 26 Nov 2020 10:55:55**

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

Audit	User	Time (GMT)
User entered 'Jan 2016'	System	06 Oct 2020 20:33:43

**US3312605**

**Folder: Screening**

**Form: Medical History (2)**

**Generated On: 26 Nov 2020 10:55:55**

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

Audit	User	Time (GMT)
User entered '2016'	System	06 Oct 2020 20:33:43



**US3312605**

**Folder: Screening**

**Form: Medical History (2)**

**Generated On: 26 Nov 2020 10:55:55**

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

Audit	User	Time (GMT)
User entered empty.	System	06 Oct 2020 20:33:43

**US3312605**

**Folder: Screening**

**Form: Medical History (2)**

**Generated On: 26 Nov 2020 10:55:55**

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

Audit	User	Time (GMT)
User entered empty.	System	06 Oct 2020 20:33:43

US3312605

Folder: Screening

Form: Medical History (3)

Generated On: 26 Nov 2020 10:55:55

[Condition](#)

Audit	User	Time (GMT)
User coded data point as SOC: Psychiatric disorders, HLGT: Cognitive and attention disorders and disturbances, HLT: Attention deficit and disruptive behaviour disorders, PT: Attention deficit hyperactivity disorder, LLT: Attention deficit/hyperactivity disorder - version MedDRA\\23.0.	Coder Import (b) (4)	06 Oct 2020 20:35:25
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	06 Oct 2020 20:35:25
Data point term sent to Coder	System	06 Oct 2020 20:34:17
User entered 'Attention deficit hyperactivity disorder'	Karol Moore (b) (4)	06 Oct 2020 20:33:58
	(b) (4)	

**US3312605**

**Folder: Screening**

**Form: Medical History (3)**

**Generated On: 26 Nov 2020 10:55:55**

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

Audit	User	Time (GMT)
User entered 'un UNK 2011'	Karol Moore (b) (4) (b) (4)	06 Oct 2020 20:33:58

**US3312605**

**Folder: Screening**

**Form: Medical History (3)**

**Generated On: 26 Nov 2020 10:55:55**

[Start date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	Karol Moore (b) (4) (b) (4)	06 Oct 2020 20:33:58

**US3312605**

**Folder: Screening**

**Form: Medical History (3)**

**Generated On: 26 Nov 2020 10:55:55**

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Karol Moore (b) (4) (b) (4)	06 Oct 2020 20:33:58

**US3312605**

**Folder: Screening**

**Form: Medical History (3)**

**Generated On: 26 Nov 2020 10:55:55**

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

Audit	User	Time (GMT)
User entered empty.	Karol Moore (b) (4) (b) (4)	06 Oct 2020 20:33:58

**US3312605**

**Folder: Screening**

**Form: Medical History (3)**

**Generated On: 26 Nov 2020 10:55:55**

[Stop date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	Karol Moore (b) (4) (b) (4)	06 Oct 2020 20:33:58



**US3312605**

**Folder: Screening**

**Form: Medical History (3)**

**Generated On: 26 Nov 2020 10:55:55**

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

Audit	User	Time (GMT)
User entered 'Jan 2011'	System	06 Oct 2020 20:33:58

**US3312605**

**Folder: Screening**

**Form: Medical History (3)**

**Generated On: 26 Nov 2020 10:55:55**

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

Audit	User	Time (GMT)
User entered '2011'	System	06 Oct 2020 20:33:58

**US3312605**

**Folder: Screening**

**Form: Medical History (3)**

**Generated On: 26 Nov 2020 10:55:55**

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

Audit	User	Time (GMT)
User entered empty.	System	06 Oct 2020 20:33:58

**US3312605**

**Folder: Screening**

**Form: Medical History (3)**

**Generated On: 26 Nov 2020 10:55:55**

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

Audit	User	Time (GMT)
User entered empty.	System	06 Oct 2020 20:33:58

US3312605

Folder: Screening

Form: Medical History (4)

Generated On: 26 Nov 2020 10:55:55

Condition

Audit	User	Time (GMT)
User coded data point as SOC: Skin and subcutaneous tissue disorders, HLGT: Skin appendage conditions, HLT: Alopecias, PT: Alopecia, LLT: Hair loss - version MedDRA\\23.0.	Coder Import (b) (4)	06 Oct 2020 20:47:18
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4)	06 Oct 2020 20:47:18
Data point term sent to Coder	System	06 Oct 2020 20:34:19
User entered 'excessive hair loss'	Karol Moore (b) (4)	06 Oct 2020 20:34:10
	(b) (4)	

US3312605

Folder: Screening

Form: Medical History (4)

Generated On: 26 Nov 2020 10:55:55

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

Audit	User	Time (GMT)
User entered 'un UNK 2019'	Karol Moore (b) (4) (b) (4)	06 Oct 2020 20:34:10

US3312605

Folder: Screening

Form: Medical History (4)

Generated On: 26 Nov 2020 10:55:55

[Start date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	Karol Moore (b) (4) (b) (4)	06 Oct 2020 20:34:10

US3312605

Folder: Screening

Form: Medical History (4)

Generated On: 26 Nov 2020 10:55:55

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Karol Moore (b) (4) (b) (4)	06 Oct 2020 20:34:10



**US3312605**

**Folder: Screening**

**Form: Medical History (4)**

**Generated On: 26 Nov 2020 10:55:55**

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

Audit	User	Time (GMT)
User entered empty.	Karol Moore (b) (4) (b) (4)	06 Oct 2020 20:34:10

US3312605

Folder: Screening

Form: Medical History (4)

Generated On: 26 Nov 2020 10:55:55

[Stop date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	Karol Moore (b) (4) (b) (4)	06 Oct 2020 20:34:10

**US3312605**

**Folder: Screening**

**Form: Medical History (4)**

**Generated On: 26 Nov 2020 10:55:55**

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

Audit	User	Time (GMT)
User entered 'Jan 2019'	System	06 Oct 2020 20:34:10

**US3312605**

**Folder: Screening**

**Form: Medical History (4)**

**Generated On: 26 Nov 2020 10:55:55**

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

Audit	User	Time (GMT)
User entered '2019'	System	06 Oct 2020 20:34:10

**US3312605**

**Folder: Screening**

**Form: Medical History (4)**

**Generated On: 26 Nov 2020 10:55:55**

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

Audit	User	Time (GMT)
User entered empty.	System	06 Oct 2020 20:34:10

**US3312605**

**Folder: Screening**

**Form: Medical History (4)**

**Generated On: 26 Nov 2020 10:55:55**

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

Audit	User	Time (GMT)
User entered empty.	System	06 Oct 2020 20:34:10

US3312605

Folder: Screening

Form: Medical History (5)

Generated On: 26 Nov 2020 10:55:55

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)	06 Oct 2020 20:36:29
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	(b) (4)	06 Oct 2020 20:36:29
Data point term sent to Coder	System	06 Oct 2020 20:35:19
User entered 'seasonal allergies'	Karol Moore (b) (4)	06 Oct 2020 20:34:20
	(b) (4)	

**US3312605**

**Folder: Screening**

**Form: Medical History (5)**

**Generated On: 26 Nov 2020 10:55:55**

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

Audit	User	Time (GMT)
User entered 'un UNK 2010'	Karol Moore (b) (4) (b) (4)	06 Oct 2020 20:34:20



US3312605

Folder: Screening

Form: Medical History (5)

Generated On: 26 Nov 2020 10:55:55

[Start date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	Karol Moore (b) (4) (b) (4)	06 Oct 2020 20:34:20

US3312605

Folder: Screening

Form: Medical History (5)

Generated On: 26 Nov 2020 10:55:55

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Karol Moore (b) (4) (b) (4)	06 Oct 2020 20:34:20

US3312605

Folder: Screening

Form: Medical History (5)

Generated On: 26 Nov 2020 10:55:55

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

Audit	User	Time (GMT)
User entered empty.	Karol Moore (b) (4) (b) (4)	06 Oct 2020 20:34:20

**US3312605**

**Folder: Screening**

**Form: Medical History (5)**

**Generated On: 26 Nov 2020 10:55:55**

[Stop date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	Karol Moore (b) (4) (b) (4)	06 Oct 2020 20:34:20

**US3312605**

**Folder: Screening**

**Form: Medical History (5)**

**Generated On: 26 Nov 2020 10:55:55**

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

Audit	User	Time (GMT)
User entered 'Jan 2010'	System	06 Oct 2020 20:34:20

**US3312605**

**Folder: Screening**

**Form: Medical History (5)**

**Generated On: 26 Nov 2020 10:55:55**

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

Audit	User	Time (GMT)
User entered '2010'	System	06 Oct 2020 20:34:20

**US3312605**

**Folder: Screening**

**Form: Medical History (5)**

**Generated On: 26 Nov 2020 10:55:55**

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

Audit	User	Time (GMT)
User entered empty.	System	06 Oct 2020 20:34:20

**US3312605**

**Folder: Screening**

**Form: Medical History (5)**

**Generated On: 26 Nov 2020 10:55:55**

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

Audit	User	Time (GMT)
User entered empty.	System	06 Oct 2020 20:34:20



US3312605

Folder: Screening

Form: Medical History (6)

Generated On: 26 Nov 2020 10:55:55

Condition

Audit	User	Time (GMT)
User coded data point as SOC: Nervous system disorders, HLGT: Headaches, HLT: Headaches NEC, PT: Headache, LLT: Headache - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	24 Nov 2020 09:08:20
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	24 Nov 2020 09:08:20
User coded data point as SOC: Nervous system disorders, HLGT: Headaches, HLT: Headaches NEC, PT: Headache, LLT: Headache - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	06 Oct 2020 20:36:33
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	06 Oct 2020 20:36:33
Data point term sent to Coder	System	06 Oct 2020 20:35:20
User entered 'mild occasional headaches'	Karol Moore (b) (4) (b) (4)	06 Oct 2020 20:34:42

US3312605

Folder: Screening

Form: Medical History (6)

Generated On: 26 Nov 2020 10:55:55

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

Audit	User	Time (GMT)
User entered 'un UNK 2010'	Karol Moore (b) (4) (b) (4)	06 Oct 2020 20:34:42

**US3312605**

**Folder: Screening**

**Form: Medical History (6)**

**Generated On: 26 Nov 2020 10:55:55**

[Start date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	Karol Moore (b) (4) (b) (4)	06 Oct 2020 20:34:42

**US3312605**

**Folder: Screening**

**Form: Medical History (6)**

**Generated On: 26 Nov 2020 10:55:55**

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Karol Moore (b) (4) (b) (4)	06 Oct 2020 20:34:42

**US3312605**

**Folder: Screening**

**Form: Medical History (6)**

**Generated On: 26 Nov 2020 10:55:55**

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

Audit	User	Time (GMT)
User entered empty.	Karol Moore (b) (4) (b) (4)	06 Oct 2020 20:34:42

US3312605

Folder: Screening

Form: Medical History (6)

Generated On: 26 Nov 2020 10:55:55

[Stop date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	Karol Moore (b) (4) (b) (4)	06 Oct 2020 20:34:42

**US3312605**

**Folder: Screening**

**Form: Medical History (6)**

**Generated On: 26 Nov 2020 10:55:55**

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

Audit	User	Time (GMT)
User entered 'Jan 2010'	System	06 Oct 2020 20:34:42

**US3312605**

**Folder: Screening**

**Form: Medical History (6)**

**Generated On: 26 Nov 2020 10:55:55**

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

Audit	User	Time (GMT)
User entered '2010'	System	06 Oct 2020 20:34:42



**US3312605**

**Folder: Screening**

**Form: Medical History (6)**

**Generated On: 26 Nov 2020 10:55:55**

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

Audit	User	Time (GMT)
User entered empty.	System	06 Oct 2020 20:34:42

**US3312605**

**Folder: Screening**

**Form: Medical History (6)**

**Generated On: 26 Nov 2020 10:55:55**

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

Audit	User	Time (GMT)
User entered empty.	System	06 Oct 2020 20:34:42

US3312605

Folder: Screening

Form: Medical History (7)

Generated On: 26 Nov 2020 10:55:55

[Condition](#)

Audit	User	Time (GMT)
User coded data point as SOC: Infections and infestations, HLGT: Infections - pathogen unspecified, HLT: Upper respiratory tract infections, PT: Tonsillitis, LLT: Tonsillitis recurrent - version MedDRA\\23.0.	Coder Import (b) (4)	06 Oct 2020 20:36:27
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	06 Oct 2020 20:36:27
Data point term sent to Coder	System	06 Oct 2020 20:35:20
User entered 'recurrent tonsillitis'	Karol Moore (b) (4)	06 Oct 2020 20:35:08
	(b) (4)	

US3312605

Folder: Screening

Form: Medical History (7)

Generated On: 26 Nov 2020 10:55:55

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

Audit	User	Time (GMT)
User entered 'un UNK 2000'	Karol Moore (b) (4) (b) (4)	06 Oct 2020 20:35:08

**US3312605**

**Folder: Screening**

**Form: Medical History (7)**

**Generated On: 26 Nov 2020 10:55:55**

[Start date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	Karol Moore (b) (4) (b) (4)	06 Oct 2020 20:35:08

US3312605

Folder: Screening

Form: Medical History (7)

Generated On: 26 Nov 2020 10:55:55

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Karol Moore (b) (4) (b) (4)	06 Oct 2020 20:35:08

**US3312605**

**Folder: Screening**

**Form: Medical History (7)**

**Generated On: 26 Nov 2020 10:55:55**

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

Audit	User	Time (GMT)
User entered 'un UNK 2001'	Karol Moore (b) (4) (b) (4)	06 Oct 2020 20:35:08

**US3312605**

**Folder: Screening**

**Form: Medical History (7)**

**Generated On: 26 Nov 2020 10:55:55**

[Stop date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	Karol Moore (b) (4) (b) (4)	06 Oct 2020 20:35:08



**US3312605**

**Folder: Screening**

**Form: Medical History (7)**

**Generated On: 26 Nov 2020 10:55:55**

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

Audit	User	Time (GMT)
User entered 'Jan 2000'	System	06 Oct 2020 20:35:08

**US3312605**

**Folder: Screening**

**Form: Medical History (7)**

**Generated On: 26 Nov 2020 10:55:55**

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

Audit	User	Time (GMT)
User entered '2000'	System	06 Oct 2020 20:35:08

**US3312605**

**Folder: Screening**

**Form: Medical History (7)**

**Generated On: 26 Nov 2020 10:55:55**

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

Audit	User	Time (GMT)
User entered 'Jan 2001'	System	06 Oct 2020 20:35:08

**US3312605**

**Folder: Screening**

**Form: Medical History (7)**

**Generated On: 26 Nov 2020 10:55:55**

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

Audit	User	Time (GMT)
User entered '2001'	System	06 Oct 2020 20:35:08

US3312605

Folder: Screening

Form: Medical History (8)

Generated On: 26 Nov 2020 10:55:55

[Condition](#)

Audit	User	Time (GMT)
User coded data point as SOC: Surgical and medical procedures, HLG: Head and neck therapeutic procedures, HLT: Tonsillar therapeutic procedures, PT: Tonsillectomy, LLT: Tonsillectomy - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	06 Oct 2020 20:37:21
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	06 Oct 2020 20:37:21
Data point term sent to Coder	System	06 Oct 2020 20:36:22
User entered 'tonsillectomy'	Karol Moore (b) (4) (b) (4)	06 Oct 2020 20:35:37

US3312605

Folder: Screening

Form: Medical History (8)

Generated On: 26 Nov 2020 10:55:55

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

Audit	User	Time (GMT)
User entered 'un UNK 2001'	Karol Moore (b) (4) (b) (4)	06 Oct 2020 20:35:37

**US3312605**

**Folder: Screening**

**Form: Medical History (8)**

**Generated On: 26 Nov 2020 10:55:55**

[Start date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	Karol Moore (b) (4) (b) (4)	06 Oct 2020 20:35:37

US3312605

Folder: Screening

Form: Medical History (8)

Generated On: 26 Nov 2020 10:55:55

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Karol Moore (b) (4) (b) (4)	06 Oct 2020 20:35:37



**US3312605**

**Folder: Screening**

**Form: Medical History (8)**

**Generated On: 26 Nov 2020 10:55:55**

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

Audit	User	Time (GMT)
User entered 'un UNK 2001'	Karol Moore (b) (4) (b) (4)	06 Oct 2020 20:35:37

**US3312605**

**Folder: Screening**

**Form: Medical History (8)**

**Generated On: 26 Nov 2020 10:55:55**

[Stop date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	Karol Moore (b) (4) (b) (4)	06 Oct 2020 20:35:37

**US3312605**

**Folder: Screening**

**Form: Medical History (8)**

**Generated On: 26 Nov 2020 10:55:55**

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

Audit	User	Time (GMT)
User entered 'Jan 2001'	System	06 Oct 2020 20:35:37

**US3312605**

**Folder: Screening**

**Form: Medical History (8)**

**Generated On: 26 Nov 2020 10:55:55**

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

Audit	User	Time (GMT)
User entered '2001'	System	06 Oct 2020 20:35:37

**US3312605**

**Folder: Screening**

**Form: Medical History (8)**

**Generated On: 26 Nov 2020 10:55:55**

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

Audit	User	Time (GMT)
User entered 'Jan 2001'	System	06 Oct 2020 20:35:37

**US3312605**

**Folder: Screening**

**Form: Medical History (8)**

**Generated On: 26 Nov 2020 10:55:55**

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

Audit	User	Time (GMT)
User entered '2001'	System	06 Oct 2020 20:35:37

US3312605

Folder: Screening

Form: Medical History (9)

Generated On: 26 Nov 2020 10:55:55

[Condition](#)

Audit	User	Time (GMT)
User coded data point as SOC: Renal and urinary disorders, HLGT: Urolithiasis, HLT: Renal lithiasis, PT: Nephrolithiasis, LLT: Nephrolithiasis recurrent - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	09 Oct 2020 15:06:23
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	09 Oct 2020 15:06:23
Data point term sent to Coder	System	06 Oct 2020 20:46:49
User entered 'recurrent nephrolithiasis'	Karol Moore (b) (4) (b) (4)	06 Oct 2020 20:46:13

**US3312605**

**Folder: Screening**

**Form: Medical History (9)**

**Generated On: 26 Nov 2020 10:55:55**

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

Audit	User	Time (GMT)
User entered 'UN UNK 2016' reason for change:	Monica Atwood (b) (4)	09 Oct 2020 17:34:43
Data Entry Error	(b) (4)	
User entered 'un Aug 2016'	Karol Moore (b) (4)	06 Oct 2020 20:46:13
	(b) (4)	



**US3312605**

**Folder: Screening**

**Form: Medical History (9)**

**Generated On: 26 Nov 2020 10:55:55**

[Start date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	Karol Moore (b) (4) (b) (4)	06 Oct 2020 20:46:13

US3312605

Folder: Screening

Form: Medical History (9)

Generated On: 26 Nov 2020 10:55:55

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Karol Moore (b) (4) (b) (4)	06 Oct 2020 20:46:13

US3312605

Folder: Screening

Form: Medical History (9)

Generated On: 26 Nov 2020 10:55:55

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

Audit	User	Time (GMT)
User entered empty.	Karol Moore (b) (4) (b) (4)	06 Oct 2020 20:46:13

US3312605

Folder: Screening

Form: Medical History (9)

Generated On: 26 Nov 2020 10:55:55

[Stop date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	Karol Moore (b) (4) (b) (4)	06 Oct 2020 20:46:13

**US3312605**

**Folder: Screening**

**Form: Medical History (9)**

**Generated On: 26 Nov 2020 10:55:55**

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

Audit	User	Time (GMT)
User entered 'Jan 2016'	System	09 Oct 2020 17:34:43
User entered 'Aug 2016'	System	06 Oct 2020 20:46:13

**US3312605**

**Folder: Screening**

**Form: Medical History (9)**

**Generated On: 26 Nov 2020 10:55:55**

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

Audit	User	Time (GMT)
User entered '2016'	System	06 Oct 2020 20:46:13

**US3312605**

**Folder: Screening**

**Form: Medical History (9)**

**Generated On: 26 Nov 2020 10:55:55**

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

Audit	User	Time (GMT)
User entered empty.	System	06 Oct 2020 20:46:13

**US3312605**

**Folder: Screening**

**Form: Medical History (9)**

**Generated On: 26 Nov 2020 10:55:55**

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

Audit	User	Time (GMT)
User entered empty.	System	06 Oct 2020 20:46:13



US3312605

Folder: Screening

Form: Medical History (10)

Generated On: 26 Nov 2020 10:55:55

[Condition](#)

Audit	User	Time (GMT)
User coded data point as SOC: Injury, poisoning and procedural complications, HLGT: Bone and joint injuries, HLT: Skull fractures, facial bone fractures and dislocations, PT: Facial bones fracture, LLT: Fractured nose - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	06 Oct 2020 20:48:22
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	06 Oct 2020 20:48:22
Data point term sent to Coder	System	06 Oct 2020 20:46:52
User entered 'nose fracture'	Karol Moore (b) (4) (b) (4)	06 Oct 2020 20:46:39

US3312605

Folder: Screening

Form: Medical History (10)

Generated On: 26 Nov 2020 10:55:55

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

Audit	User	Time (GMT)
User entered 'un UNK 2010'	Karol Moore (b) (4) (b) (4)	06 Oct 2020 20:46:39

**US3312605**

**Folder: Screening**

**Form: Medical History (10)**

**Generated On: 26 Nov 2020 10:55:55**

[Start date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	Karol Moore (b) (4) (b) (4)	06 Oct 2020 20:46:39

US3312605

Folder: Screening

Form: Medical History (10)

Generated On: 26 Nov 2020 10:55:55

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Karol Moore (b) (4) (b) (4)	06 Oct 2020 20:46:39

**US3312605**

**Folder: Screening**

**Form: Medical History (10)**

**Generated On: 26 Nov 2020 10:55:55**

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

Audit	User	Time (GMT)
User entered 'un UNK 2010'	Karol Moore (b) (4) (b) (4)	06 Oct 2020 20:46:39

**US3312605**

**Folder: Screening**

**Form: Medical History (10)**

**Generated On: 26 Nov 2020 10:55:55**

[Stop date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	Karol Moore (b) (4) (b) (4)	06 Oct 2020 20:46:39

**US3312605**

**Folder: Screening**

**Form: Medical History (10)**

**Generated On: 26 Nov 2020 10:55:55**

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

Audit	User	Time (GMT)
User entered 'Jan 2010'	System	06 Oct 2020 20:46:39

**US3312605**

**Folder: Screening**

**Form: Medical History (10)**

**Generated On: 26 Nov 2020 10:55:55**

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

Audit	User	Time (GMT)
User entered '2010'	System	06 Oct 2020 20:46:39



**US3312605**

**Folder: Screening**

**Form: Medical History (10)**

**Generated On: 26 Nov 2020 10:55:55**

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

Audit	User	Time (GMT)
User entered 'Jan 2010'	System	06 Oct 2020 20:46:39

**US3312605**

**Folder: Screening**

**Form: Medical History (10)**

**Generated On: 26 Nov 2020 10:55:55**

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

Audit	User	Time (GMT)
User entered '2010'	System	06 Oct 2020 20:46:39

US3312605

Folder: Screening

Form: Medical History (11)

Generated On: 26 Nov 2020 10:55:55

[Condition](#)

Audit	User	Time (GMT)
User coded data point as SOC: Surgical and medical procedures, HLGT: Head and neck therapeutic procedures, HLT: Nasal therapeutic procedures, PT: Nasal operation, LLT: Nasal operation - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	08 Nov 2020 19:28:36
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	08 Nov 2020 19:28:36
Data point term sent to Coder	System	06 Oct 2020 21:07:30
User entered 'RECONSTRUCTIVE NASAL SURGERy' reason for change: Data Entry Error	Karol Moore (b) (4) (b) (4)	06 Oct 2020 21:06:34
Data point term sent to Coder	System	06 Oct 2020 21:06:27
User entered 'reconstructive nasal surgert'	Karol Moore (b) (4) (b) (4)	06 Oct 2020 21:06:25

**US3312605**

**Folder: Screening**

**Form: Medical History (11)**

**Generated On: 26 Nov 2020 10:55:55**

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

Audit	User	Time (GMT)
User entered 'un UNK 2010'	Karol Moore (b) (4) (b) (4)	06 Oct 2020 21:06:25

**US3312605**

**Folder: Screening**

**Form: Medical History (11)**

**Generated On: 26 Nov 2020 10:55:55**

[Start date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	Karol Moore (b) (4) (b) (4)	06 Oct 2020 21:06:25

US3312605

Folder: Screening

Form: Medical History (11)

Generated On: 26 Nov 2020 10:55:55

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Karol Moore (b) (4) (b) (4)	06 Oct 2020 21:06:25

US3312605

Folder: Screening

Form: Medical History (11)

Generated On: 26 Nov 2020 10:55:55

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

Audit	User	Time (GMT)
User entered 'un UNK 2010'	Karol Moore (b) (4) (b) (4)	06 Oct 2020 21:06:25

**US3312605**

**Folder: Screening**

**Form: Medical History (11)**

**Generated On: 26 Nov 2020 10:55:55**

[Stop date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	Karol Moore (b) (4) (b) (4)	06 Oct 2020 21:06:25



**US3312605**

**Folder: Screening**

**Form: Medical History (11)**

**Generated On: 26 Nov 2020 10:55:55**

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

Audit	User	Time (GMT)
User entered 'Jan 2010'	System	06 Oct 2020 21:06:25

**US3312605**

**Folder: Screening**

**Form: Medical History (11)**

**Generated On: 26 Nov 2020 10:55:55**

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

Audit	User	Time (GMT)
User entered '2010'	System	06 Oct 2020 21:06:25

**US3312605**

**Folder: Screening**

**Form: Medical History (11)**

**Generated On: 26 Nov 2020 10:55:55**

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

Audit	User	Time (GMT)
User entered 'Jan 2010'	System	06 Oct 2020 21:06:25

**US3312605**

**Folder: Screening**

**Form: Medical History (11)**

**Generated On: 26 Nov 2020 10:55:55**

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

Audit	User	Time (GMT)
User entered '2010'	System	06 Oct 2020 21:06:25

US3312605

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 10:55:55

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Karol Moore (b) (4) (b) (4)	06 Oct 2020 22:05:30

US3312605

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 10:55:55

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered '10 Sep 2020'	Karol Moore (b) (4) (b) (4)	06 Oct 2020 22:05:30

US3312605

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 10:55:55

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

Audit	User	Time (GMT)
User entered '13:54'	Karol Moore (b) (4) (b) (4)	06 Oct 2020 22:05:30

**US3312605**

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 26 Nov 2020 10:55:55**

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

Audit	User	Time (GMT)
User entered '10 Sep 2020 13:54'	System	06 Oct 2020 22:05:30



US3312605

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 10:55:55

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

Audit	User	Time (GMT)
User entered '72.0' in	Karol Moore (b) (4)	06 Oct 2020 22:05:30
DataPoint set to visible.	(b) (4) System	10 Sep 2020 19:58:47

US3312605

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 10:55:55

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

Audit	User	Time (GMT)
User entered '209.6' lb	Karol Moore (b) (4)	06 Oct 2020 22:05:30
DataPoint set to visible.	(b) (4) System	10 Sep 2020 19:58:47

**US3312605**

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 26 Nov 2020 10:55:55**

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

Audit	User	Time (GMT)
User entered '28.48631'	System	06 Oct 2020 22:05:30
DataPoint set to visible.	System	10 Sep 2020 19:58:47

**US3312605**

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 26 Nov 2020 10:55:55**

[BMI units](#)

Audit	User	Time (GMT)
User entered 'kg/m2'	System	06 Oct 2020 22:05:30
DataPoint set to visible.	System	10 Sep 2020 19:58:47

US3312605

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 10:55:55

Temperature (xxx.x)

Audit	User	Time (GMT)
User entered missing code ND - Not Done.	Karol Moore (b) (4) (b) (4)	06 Oct 2020 22:05:30

US3312605

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 10:55:55

[Route of measurement](#)

Audit	User	Time (GMT)
User entered 'Oral (Oral)'	Karol Moore (b) (4) (b) (4)	06 Oct 2020 22:05:30

US3312605

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 10:55:55

[If Other, specify](#)

Audit	User	Time (GMT)
User entered empty.	Karol Moore (b) (4) (b) (4)	06 Oct 2020 22:05:30

US3312605

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 10:55:55

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
User entered missing code ND - Not Done.	Karol Moore (b) (4) (b) (4)	06 Oct 2020 22:05:30



**US3312605**

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 26 Nov 2020 10:55:55**

[Pulse units](#)

Audit	User	Time (GMT)
User entered 'bpm'	System	06 Oct 2020 22:05:30

US3312605

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 10:55:55

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

Audit	User	Time (GMT)
User entered missing code ND - Not Done.	Karol Moore (b) (4) (b) (4)	06 Oct 2020 22:05:30

US3312605

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 10:55:55

[Respiratory Rate units](#)

Audit	User	Time (GMT)
User entered 'breaths/min'	System	06 Oct 2020 22:05:30

US3312605

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 10:55:55

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

Audit	User	Time (GMT)
User entered missing code ND - Not Done.	Karol Moore (b) (4) (b) (4)	06 Oct 2020 22:05:30

US3312605

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 10:55:55

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	06 Oct 2020 22:05:30

US3312605

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 10:55:55

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
User entered missing code ND - Not Done.	Karol Moore (b) (4) (b) (4)	06 Oct 2020 22:05:30

US3312605

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 10:55:55

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	06 Oct 2020 22:05:30

US3312605

Folder: Screening

Form: Physical Examination

Generated On: 26 Nov 2020 10:55:55

Was the physical examination performed?

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Karol Moore (b) (4) (b) (4)	06 Oct 2020 22:05:51



US3312605

Folder: Screening

Form: Physical Examination

Generated On: 26 Nov 2020 10:55:55

Date of examination (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered '10 Sep 2020'	Karol Moore (b) (4) (b) (4)	06 Oct 2020 22:05:51

US3312605

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 10:55:55

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

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Karol Moore (b) (4) (b) (4)	06 Oct 2020 22:06:52

US3312605

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 10:55:55

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

Audit	User	Time (GMT)
User entered 'No (N)'	Karol Moore (b) (4) (b) (4)	06 Oct 2020 22:06:52

US3312605

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 10:55:55

**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)'	Karol Moore (b) (4) (b) (4)	06 Oct 2020 22:06:52

US3312605

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 10:55:55

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

Audit	User	Time (GMT)
User entered 'No (N)'	Karol Moore (b) (4) (b) (4)	06 Oct 2020 22:06:52

US3312605

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 10:55:55

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

Audit	User	Time (GMT)
User entered 'No (N)'	Karol Moore (b) (4) (b) (4)	06 Oct 2020 22:06:52

US3312605

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 10:55:55

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

Audit	User	Time (GMT)
User entered 'No (N)'	Karol Moore (b) (4) (b) (4)	06 Oct 2020 22:06:52

US3312605

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 10:55:55

**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)'	Karol Moore (b) (4) (b) (4)	06 Oct 2020 22:06:52



US3312605

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 10:55:55

**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)'	Karol Moore (b) (4) (b) (4)	06 Oct 2020 22:06:52

US3312605

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 10:55:55

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

Audit	User	Time (GMT)
User entered 'No (N)'	Karol Moore (b) (4) (b) (4)	06 Oct 2020 22:06:52

US3312605

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 10:55:55

**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)'	Karol Moore (b) (4) (b) (4)	06 Oct 2020 22:06:52

US3312605

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 10:55:55

**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)'	Karol Moore (b) (4) (b) (4)	06 Oct 2020 22:06:52

US3312605

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 10:55:55

[Other](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Karol Moore (b) (4) (b) (4)	06 Oct 2020 22:06:52

US3312605

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 10:55:55

[Specify](#)

Audit	User	Time (GMT)
User entered empty.	Karol Moore (b) (4) (b) (4)	06 Oct 2020 22:06:52

US3312605

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 10:55:55

**No Risk Identified**

Audit	User	Time (GMT)
User entered '0'	Karol Moore (b) (4) (b) (4)	06 Oct 2020 22:06:52

US3312605

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 10:55:55

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

Audit	User	Time (GMT)
User entered '0'	Karol Moore (b) (4) (b) (4)	06 Oct 2020 22:06:52



US3312605

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 10:55:55

**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'	Karol Moore (b) (4) (b) (4)	06 Oct 2020 22:06:52

US3312605

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 10:55:55

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

Audit	User	Time (GMT)
User entered '0'	Karol Moore (b) (4) (b) (4)	06 Oct 2020 22:06:52

US3312605

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 10:55:55

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'	Karol Moore (b) (4) (b) (4)	06 Oct 2020 22:06:52

US3312605

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 10:55:55

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

Audit	User	Time (GMT)
User entered '0'	Karol Moore (b) (4) (b) (4)	06 Oct 2020 22:06:52

US3312605

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 10:55:55

[Other](#)

Audit	User	Time (GMT)
User entered 'I'	Karol Moore (b) (4) (b) (4)	06 Oct 2020 22:06:52

US3312605

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 10:55:55

[Specify](#)

Audit	User	Time (GMT)
User entered 'resides in community with ongoing person to person transmission'	Karol Moore (b) (4) (b) (4)	06 Oct 2020 22:06:52

**US3312605**

**Folder: Visit 1 Day 1**

**Form: Visit Date**

**Generated On: 26 Nov 2020 10:55:55**

[Was this visit performed?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Christa Estrada (b) (4) (b) (4)	10 Sep 2020 19:58:56

US3312605

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 26 Nov 2020 10:55:55

Visit date (dd MMM yyyy)

Audit	User	Time (GMT)
User entered '10 Sep 2020'	Christa Estrada (b) (4) (b) (4)	10 Sep 2020 19:58:56



US3312605

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 26 Nov 2020 10:55:55

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

Audit	User	Time (GMT)
User entered 'Clinic (Clinic)'	Christa Estrada (b) (4) (b) (4)	10 Sep 2020 19:58:56

**US3312605**

**Folder: Visit 1 Day 1**

**Form: Visit Date**

**Generated On: 26 Nov 2020 10:55:55**

[Folder OID](#)

Audit	User	Time (GMT)
User entered 'VISIT1'	System	10 Sep 2020 19:58:56

US3312605

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 26 Nov 2020 10:55:55

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

Audit	User	Time (GMT)
User entered '10 SEP 2020'	RWS_ENDPOINT ENDPOINT (b) (4) <div></div>	10 Sep 2020 19:39:31

US3312605

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 26 Nov 2020 10:55:55

What was the participant's randomization number?

Audit	User	Time (GMT)
User entered '113213'	RWS_ENDPOINT ENDPOINT (b) (4) <div></div>	10 Sep 2020 19:39:31

US3312605

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 26 Nov 2020 10:55:55

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

Audit	User	Time (GMT)
User entered '>=18 and <65 years and not at risk (1)'	RWS_ENDPOINT ENDPOINT (b) (4) <div></div>	10 Sep 2020 19:39:31

US3312605

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 26 Nov 2020 10:55:55

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

Audit	User	Time (GMT)
User entered 'No (N)'	Christa Estrada (b) (4) (b) (4)	10 Sep 2020 19:59:06

**US3312605**

**Folder: Visit 1 Day 1**

**Form: Randomization**

**Generated On: 26 Nov 2020 10:55:55**

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

Audit	User	Time (GMT)
User entered 'No (N)'	Christa Estrada (b) (4) (b) (4)	10 Sep 2020 19:59:06

US3312605

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 26 Nov 2020 10:55:55

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

Audit	User	Time (GMT)
User entered 'No (N)'	Christa Estrada (b) (4) (b) (4)	10 Sep 2020 19:59:06



US3312605

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 26 Nov 2020 10:55:55

Diabetes (Type I, Type 2, or gestational)

Audit	User	Time (GMT)
User entered 'No (N)'	Christa Estrada (b) (4) (b) (4)	10 Sep 2020 19:59:06

US3312605

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 26 Nov 2020 10:55:55

[Liver Disease](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Christa Estrada (b) (4) (b) (4)	10 Sep 2020 19:59:06

US3312605

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 26 Nov 2020 10:55:55

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

Audit	User	Time (GMT)
User entered 'No (N)'	Karol Moore (b) (4)	06 Oct 2020 22:07:07
	(b) (4)	
Amendment Manager: DataPoint set to visible.	System	19 Sep 2020 06:02:36
Amendment Manager inserted this DataPoint.	System	19 Sep 2020 06:02:35

US3312605

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 26 Nov 2020 10:55:55

Height

Audit	User	Time (GMT)
User entered missing code ND - Not Done.	Karol Moore (b) (4) (b) (4)	06 Oct 2020 22:08:51

US3312605

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 26 Nov 2020 10:55:55

Weight

Audit	User	Time (GMT)
User entered missing code ND - Not Done.	Karol Moore (b) (4) (b) (4)	06 Oct 2020 22:08:51

US3312605

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 26 Nov 2020 10:55:55

Height

Audit	User	Time (GMT)
User entered missing code ND - Not Done.	Karol Moore (b) (4) (b) (4)	06 Oct 2020 22:08:51

US3312605

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 26 Nov 2020 10:55:55

Weight

Audit	User	Time (GMT)
User entered missing code ND - Not Done.	Karol Moore (b) (4) (b) (4)	06 Oct 2020 22:08:51

US3312605

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 10:55:55

[Timepoint](#)

Audit	User	Time (GMT)
User accepted default value 'Pre-Dose (PREDOSE)'	Karol Moore (b) (4) (b) (4)	06 Oct 2020 22:08:51



US3312605

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 10:55:55

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Karol Moore (b) (4) (b) (4)	06 Oct 2020 22:08:51

US3312605

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 10:55:55

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered '10 Sep 2020'	Karol Moore (b) (4) (b) (4)	06 Oct 2020 22:08:51

**US3312605**

**Folder: Visit 1 Day 1**

**Form: Vital Signs - Dosing (1)**

**Generated On: 26 Nov 2020 10:55:55**

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

Audit	User	Time (GMT)
User entered '13:54'	Karol Moore (b) (4) (b) (4)	06 Oct 2020 22:08:51

**US3312605**

**Folder: Visit 1 Day 1**

**Form: Vital Signs - Dosing (1)**

**Generated On: 26 Nov 2020 10:55:55**

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

Audit	User	Time (GMT)
User entered '10 Sep 2020 13:54'	System	06 Oct 2020 22:08:51

US3312605

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 10:55:55

Temperature (xxx.x)

Audit	User	Time (GMT)
User entered '97.9' F	Karol Moore (b) (4) (b) (4)	06 Oct 2020 22:08:51

US3312605

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 10:55:55

[Route of measurement](#)

Audit	User	Time (GMT)
User entered 'Oral (Oral)'	Karol Moore (b) (4) (b) (4)	06 Oct 2020 22:08:51

US3312605

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 10:55:55

[If Other, specify](#)

Audit	User	Time (GMT)
User entered empty.	Karol Moore (b) (4) (b) (4)	06 Oct 2020 22:08:51

**US3312605**

**Folder: Visit 1 Day 1**

**Form: Vital Signs - Dosing (1)**

**Generated On: 26 Nov 2020 10:55:55**

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
User entered '67'	Karol Moore (b) (4) (b) (4)	06 Oct 2020 22:08:51



**US3312605**

**Folder: Visit 1 Day 1**

**Form: Vital Signs - Dosing (1)**

**Generated On: 26 Nov 2020 10:55:55**

[Pulse units](#)

Audit	User	Time (GMT)
User entered 'bpm'	System	06 Oct 2020 22:08:51

US3312605

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 10:55:55

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

Audit	User	Time (GMT)
User entered '16'	Karol Moore (b) (4) (b) (4)	06 Oct 2020 22:08:51

US3312605

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 10:55:55

[Respiratory Rate units](#)

Audit	User	Time (GMT)
User entered 'breaths/min'	System	06 Oct 2020 22:08:51

US3312605

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 10:55:55

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
User entered '137'	Karol Moore (b) (4) (b) (4)	06 Oct 2020 22:08:51

US3312605

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 10:55:55

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	06 Oct 2020 22:08:51

US3312605

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 10:55:55

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
User entered '82'	Karol Moore (b) (4) (b) (4)	06 Oct 2020 22:08:51

US3312605

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 10:55:55

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	06 Oct 2020 22:08:51

US3312605

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 26 Nov 2020 10:55:55

Height

Audit	User	Time (GMT)
User entered missing code ND - Not Done.	Karol Moore (b) (4) (b) (4)	06 Oct 2020 22:08:51



US3312605

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 26 Nov 2020 10:55:55

Weight

Audit	User	Time (GMT)
User entered missing code ND - Not Done.	Karol Moore (b) (4) (b) (4)	06 Oct 2020 22:08:51

US3312605

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 10:55:55

[Timepoint](#)

Audit	User	Time (GMT)
User accepted default value 'Post-Dose (POSTDOSE)'	Karol Moore (b) (4) (b) (4)	06 Oct 2020 22:08:51

US3312605

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 10:55:55

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Karol Moore (b) (4) (b) (4)	06 Oct 2020 22:08:51

US3312605

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 10:55:55

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered '10 Sep 2020'	Karol Moore (b) (4) (b) (4)	06 Oct 2020 22:08:51

US3312605

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 10:55:55

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

Audit	User	Time (GMT)
User entered '15:25'	Karol Moore (b) (4) (b) (4)	06 Oct 2020 22:08:51

**US3312605**

**Folder: Visit 1 Day 1**

**Form: Vital Signs - Dosing (2)**

**Generated On: 26 Nov 2020 10:55:55**

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

Audit	User	Time (GMT)
User entered '10 Sep 2020 15:25'	System	06 Oct 2020 22:08:51

US3312605

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 10:55:55

Temperature (xxx.x)

Audit	User	Time (GMT)
User entered '98.6' F	Karol Moore (b) (4) (b) (4)	06 Oct 2020 22:08:51

US3312605

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 10:55:55

[Route of measurement](#)

Audit	User	Time (GMT)
User entered 'Oral (Oral)'	Karol Moore (b) (4) (b) (4)	06 Oct 2020 22:08:51



US3312605

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 10:55:55

[If Other, specify](#)

Audit	User	Time (GMT)
User entered empty.	Karol Moore (b) (4) (b) (4)	06 Oct 2020 22:08:51

US3312605

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 10:55:55

Pulse (xxx)

Audit	User	Time (GMT)
User entered '67'	Karol Moore (b) (4) (b) (4)	06 Oct 2020 22:08:51

**US3312605**

**Folder: Visit 1 Day 1**

**Form: Vital Signs - Dosing (2)**

**Generated On: 26 Nov 2020 10:55:55**

[Pulse units](#)

Audit	User	Time (GMT)
User entered 'bpm'	System	06 Oct 2020 22:08:51

US3312605

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 10:55:55

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

Audit	User	Time (GMT)
User entered '16'	Karol Moore (b) (4) (b) (4)	06 Oct 2020 22:08:51

US3312605

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 10:55:55

[Respiratory Rate units](#)

Audit	User	Time (GMT)
User entered 'breaths/min'	System	06 Oct 2020 22:08:51

US3312605

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 10:55:55

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
User entered '137'	Karol Moore (b) (4) (b) (4)	06 Oct 2020 22:08:51

**US3312605**

**Folder: Visit 1 Day 1**

**Form: Vital Signs - Dosing (2)**

**Generated On: 26 Nov 2020 10:55:55**

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	06 Oct 2020 22:08:51

US3312605

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 10:55:55

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
User entered '74'	Karol Moore (b) (4) (b) (4)	06 Oct 2020 22:08:51



**US3312605**

**Folder: Visit 1 Day 1**

**Form: Vital Signs - Dosing (2)**

**Generated On: 26 Nov 2020 10:55:55**

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	06 Oct 2020 22:08:51

US3312605

Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 26 Nov 2020 10:55:55

Was the physical examination performed?

Audit	User	Time (GMT)
User entered 'No (N)'	Karol Moore (b) (4) (b) (4)	06 Oct 2020 22:09:13

US3312605

Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 26 Nov 2020 10:55:55

Date of examination (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered empty.	Karol Moore (b) (4) (b) (4)	06 Oct 2020 22:09:13

US3312605

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 26 Nov 2020 10:55:55

[Was study treatment given?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Christa Estrada (b) (4) (b) (4)	10 Sep 2020 19:59:28

US3312605

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 26 Nov 2020 10:55:55

If No, reason not given

Audit	User	Time (GMT)
User entered empty.	Christa Estrada (b) (4) (b) (4)	10 Sep 2020 19:59:28

US3312605

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 26 Nov 2020 10:55:55

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

Audit	User	Time (GMT)
User entered empty.	Christa Estrada (b) (4) (b) (4)	10 Sep 2020 19:59:28

**US3312605**

**Folder: Visit 1 Day 1**

**Form: Exposure**

**Generated On: 26 Nov 2020 10:55:55**

[What was the study treatment?](#)

Audit	User	Time (GMT)
User entered 'MRNA-1273 OR PLACEBO'	System	10 Sep 2020 19:59:28

US3312605

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 26 Nov 2020 10:55:55

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
User entered '10 Sep 2020'	Christa Estrada (b) (4) (b) (4)	10 Sep 2020 19:59:28



US3312605

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 26 Nov 2020 10:55:55

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

Audit	User	Time (GMT)
User entered '14:54'	Christa Estrada (b) (4) (b) (4)	10 Sep 2020 19:59:28

**US3312605**

**Folder: Visit 1 Day 1**

**Form: Exposure**

**Generated On: 26 Nov 2020 10:55:55**

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

Audit	User	Time (GMT)
User entered '10 Sep 2020 14:54'	System	10 Sep 2020 19:59:28

US3312605

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 26 Nov 2020 10:55:55

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

Audit	User	Time (GMT)
User entered 'Left Arm (LEFT ARM)'	Christa Estrada (b) (4) (b) (4)	10 Sep 2020 19:59:28

US3312605

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 26 Nov 2020 10:55:55

[What was the frequency of the study treatment dosing?](#)

Audit	User	Time (GMT)
User entered 'ONCE'	System	10 Sep 2020 19:59:28

**US3312605**

**Folder: Visit 1 Day 1**

**Form: Exposure**

**Generated On: 26 Nov 2020 10:55:55**

[What was the route of administration for the study treatment?](#)

Audit	User	Time (GMT)
User entered 'INTRAMUSCULAR'	System	10 Sep 2020 19:59:28

US3312605

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 10:55:55

[Was the sample collected?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Karol Moore (b) (4) (b) (4)	06 Oct 2020 22:09:50

US3312605

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 10:55:55

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered '10 Sep 2020'	Karol Moore (b) (4) (b) (4)	06 Oct 2020 22:09:50

US3312605

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 10:55:55

Collection time (00:00-23:59)

Audit	User	Time (GMT)
User entered '14:23'	Karol Moore (b) (4) (b) (4)	06 Oct 2020 22:09:50



**US3312605**

**Folder: Visit 1 Day 1**

**Form: Immunogenicity Assessment**

**Generated On: 26 Nov 2020 10:55:55**

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

Audit	User	Time (GMT)
User entered '10 Sep 2020 14:23'	System	06 Oct 2020 22:09:50

US3312605

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 26 Nov 2020 10:55:55

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered '10 Sep 2020'	Karol Moore (b) (4) (b) (4)	06 Oct 2020 22:10:10

US3312605

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 26 Nov 2020 10:55:55

[Lab Test](#)

Audit	User	Time (GMT)
User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)'	Karol Moore (b) (4) (b) (4)	06 Oct 2020 22:10:10

US3312605

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 26 Nov 2020 10:55:55

[Was the sample collected?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Karol Moore (b) (4) (b) (4)	06 Oct 2020 22:10:10

US3312605

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 26 Nov 2020 10:55:55

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
User entered '14:15'	Karol Moore (b) (4) (b) (4)	06 Oct 2020 22:10:10

**US3312605**

**Folder: Visit 1 Day 1**

**Form: Central Laboratory - Nasopharyngeal Swab (1)**

**Generated On: 26 Nov 2020 10:55:55**

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

Audit	User	Time (GMT)
User entered '10 Sep 2020 14:15'	System	06 Oct 2020 22:10:10

US3312605

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 26 Nov 2020 10:55:55

[Lab Test](#)

Audit	User	Time (GMT)
User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)'	Karol Moore (b) (4) (b) (4)	06 Oct 2020 22:10:10

US3312605

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 26 Nov 2020 10:55:55

[Was the sample collected?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Karol Moore (b) (4) (b) (4)	06 Oct 2020 22:10:10



US3312605

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 26 Nov 2020 10:55:55

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
User entered empty.	Karol Moore (b) (4) (b) (4)	06 Oct 2020 22:10:10

**US3312605**

**Folder: Visit 1 Day 1**

**Form: Central Laboratory - Nasopharyngeal Swab (2)**

**Generated On: 26 Nov 2020 10:55:55**

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

Audit	User	Time (GMT)
User entered empty.	System	06 Oct 2020 22:10:10

US3312605

Folder: Visit 1 Day 1

Form: Continuing

Generated On: 26 Nov 2020 10:55:55

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

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Karol Moore (b) (4) (b) (4)	06 Oct 2020 22:10:13

**US3312605**

**Folder: Visit 1 Day 1**

**Form: Continuing**

**Generated On: 26 Nov 2020 10:55:55**

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered 'I'	System	06 Oct 2020 22:10:13

**US3312605**

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

**Form: Temperature\_Day(1/1)**

**Generated On: 26 Nov 2020 10:55:55**

**TIMEPOINT**

Audit	User	Time (GMT)
Data entry locked.	System	10 Sep 2020 19:59:28
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	10 Sep 2020 19:59:28

US3312605

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/1)

Generated On: 26 Nov 2020 10:55:55

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (16C1CAA1-C746-4C21-8AE6-4CD30C39C33C)', Time: '2020-09-10T15:25:40', User OID: 'PatientReportedOutcome (US3312605)', ODM File OID: '692558ea-1bf5-4f75-9e32-a5555e47db0f'	System	10 Sep 2020 20:25:56
User entered 'Yes (Y)'	System	10 Sep 2020 20:25:56

US3312605

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/1)

Generated On: 26 Nov 2020 10:55:55

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (16C1CAA1-C746-4C21-8AE6-4CD30C39C33C)', Time: '2020-09-10T15:25:44', User OID: 'PatientReportedOutcome (US3312605)', ODM File OID: '692558ea-1bf5-4f75-9e32-a5555e47db0f'	System	10 Sep 2020 20:25:56
User entered '98.6'	System	10 Sep 2020 20:25:56

US3312605

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/1)

Generated On: 26 Nov 2020 10:55:55

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (16C1CAA1-C746-4C21-8AE6-4CD30C39C33C)', Time: '2020-09-10T15:25:47', User OID: 'PatientReportedOutcome (US3312605)', ODM File OID: '692558ea-1bf5-4f75-9e32-a5555e47db0f'	System	10 Sep 2020 20:25:56
User entered 'No (N)'	System	10 Sep 2020 20:25:56



**US3312605**

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

**Form: Temperature\_Day(1/1)**

**Generated On: 26 Nov 2020 10:55:55**

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (16C1CAA1-C746-4C21-8AE6-4CD30C39C33C)', Time: '2020-09-10T15:25:51', User OID: 'PatientReportedOutcome (US3312605)', ODM File OID: '692558ea-1bf5-4f75-9e32-a5555e47db0f'	System	10 Sep 2020 20:25:56
User entered '10 Sep 2020 15:25'	System	10 Sep 2020 20:25:56

**US3312605**

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

**Form: Temperature\_Day(1/1)**

**Generated On: 26 Nov 2020 10:55:55**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '10 Sep 2020 15:14'	System	10 Sep 2020 19:59:28

**US3312605**

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

**Form: Temperature\_Day(1/1)**

**Generated On: 26 Nov 2020 10:55:55**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '10 Sep 2020 17:44'	System	10 Sep 2020 19:59:28

**US3312605**

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

**Form: Temperature\_Day(1/2)**

**Generated On: 26 Nov 2020 10:55:55**

**TIMEPOINT**

Audit	User	Time (GMT)
Data entry locked.	System	10 Sep 2020 19:59:28
User entered 'Day 1, after vaccination (at home)'	System	10 Sep 2020 19:59:28

US3312605

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/2)

Generated On: 26 Nov 2020 10:55:55

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (16C1CAA1-C746-4C21-8AE6-4CD30C39C33C)', Time: '2020-09-11T09:12:44', User OID: 'PatientReportedOutcome (US3312605)', ODM File OID: 'fa63b3ea-1e65-462e-b231-2f41318c6e0e'	System	11 Sep 2020 14:13:11
User entered 'Yes (Y)'	System	11 Sep 2020 14:13:11

US3312605

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/2)

Generated On: 26 Nov 2020 10:55:55

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (16C1CAA1-C746-4C21-8AE6-4CD30C39C33C)', Time: '2020-09-11T09:12:49', User OID: 'PatientReportedOutcome (US3312605)', ODM File OID: 'fa63b3ea-1e65-462e-b231-2f41318c6e0e'	System	11 Sep 2020 14:13:11
User entered '98.5'	System	11 Sep 2020 14:13:11

US3312605

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/2)

Generated On: 26 Nov 2020 10:55:55

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (16C1CAA1-C746-4C21-8AE6-4CD30C39C33C)', Time: '2020-09-11T09:12:52', User OID: 'PatientReportedOutcome (US3312605)', ODM File OID: 'fa63b3ea-1e65-462e-b231-2f41318c6e0e'	System	11 Sep 2020 14:13:11
User entered 'No (N)'	System	11 Sep 2020 14:13:11

**US3312605**

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

**Form: Temperature\_Day(1/2)**

**Generated On: 26 Nov 2020 10:55:55**

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (16C1CAA1-C746-4C21-8AE6-4CD30C39C33C)', Time: '2020-09-11T09:12:55', User OID: 'PatientReportedOutcome (US3312605)', ODM File OID: 'fa63b3ea-1e65-462e-b231-2f41318c6e0e'	System	11 Sep 2020 14:13:11
User entered '11 Sep 2020 09:12'	System	11 Sep 2020 14:13:11



**US3312605**

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

**Form: Temperature\_Day(1/2)**

**Generated On: 26 Nov 2020 10:55:55**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '10 Sep 2020 18:39'	System	10 Sep 2020 19:59:28

US3312605

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/2)

Generated On: 26 Nov 2020 10:55:55

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '11 Sep 2020 11:59'	System	10 Sep 2020 19:59:28

**US3312605**

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

**Form: Temperature\_Day(2)**

**Generated On: 26 Nov 2020 10:55:55**

**TIMEPOINT**

Audit	User	Time (GMT)
Data entry locked.	System	10 Sep 2020 19:59:28
User entered 'Day 2'	System	10 Sep 2020 19:59:28

US3312605

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(2)

Generated On: 26 Nov 2020 10:55:55

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (16C1CAA1-C746-4C21-8AE6-4CD30C39C33C)', Time: '2020-09-12T11:06:25', User OID: 'PatientReportedOutcome (US3312605)', ODM File OID: '9dae1adf-df89-4908-b260-52a72088d881'	System	12 Sep 2020 16:14:11
User entered 'Yes (Y)'	System	12 Sep 2020 16:14:11

US3312605

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(2)

Generated On: 26 Nov 2020 10:55:55

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (16C1CAA1-C746-4C21-8AE6-4CD30C39C33C)', Time: '2020-09-12T11:06:33', User OID: 'PatientReportedOutcome (US3312605)', ODM File OID: '9dae1adf-df89-4908-b260-52a72088d881'	System	12 Sep 2020 16:14:11
User entered '98.6'	System	12 Sep 2020 16:14:11

US3312605

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(2)

Generated On: 26 Nov 2020 10:55:55

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (16C1CAA1-C746-4C21-8AE6-4CD30C39C33C)', Time: '2020-09-12T11:06:36', User OID: 'PatientReportedOutcome (US3312605)', ODM File OID: '9dae1adf-df89-4908-b260-52a72088d881'	System	12 Sep 2020 16:14:11
User entered 'No (N)'	System	12 Sep 2020 16:14:11

**US3312605**

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

**Form: Temperature\_Day(2)**

**Generated On: 26 Nov 2020 10:55:55**

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (16C1CAA1-C746-4C21-8AE6-4CD30C39C33C)', Time: '2020-09-12T11:06:41', User OID: 'PatientReportedOutcome (US3312605)', ODM File OID: '9dae1adf-df89-4908-b260-52a72088d881'	System	12 Sep 2020 16:14:11
User entered '12 Sep 2020 11:06'	System	12 Sep 2020 16:14:11

**US3312605**

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

**Form: Temperature\_Day(2)**

**Generated On: 26 Nov 2020 10:55:55**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '11 Sep 2020 12:00'	System	10 Sep 2020 19:59:28



**US3312605**

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

**Form: Temperature\_Day(2)**

**Generated On: 26 Nov 2020 10:55:55**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '12 Sep 2020 11:59'	System	10 Sep 2020 19:59:28

**US3312605**

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

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

**Generated On: 26 Nov 2020 10:55:55**

**TIMEPOINT**

Audit	User	Time (GMT)
Data entry locked.	System	10 Sep 2020 19:59:28
User entered 'Day 3'	System	10 Sep 2020 19:59:28

**US3312605**

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

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

**Generated On: 26 Nov 2020 10:55:55**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '12 Sep 2020 12:00'	System	10 Sep 2020 19:59:28

**US3312605**

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

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

**Generated On: 26 Nov 2020 10:55:55**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '13 Sep 2020 11:59'	System	10 Sep 2020 19:59:28

**US3312605**

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

**Form: Temperature\_Day(4)**

**Generated On: 26 Nov 2020 10:55:55**

**TIMEPOINT**

Audit	User	Time (GMT)
Data entry locked.	System	10 Sep 2020 19:59:28
User entered 'Day 4'	System	10 Sep 2020 19:59:28

US3312605

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(4)

Generated On: 26 Nov 2020 10:55:55

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (16C1CAA1-C746-4C21-8AE6-4CD30C39C33C)', Time: '2020-09-13T21:01:35', User OID: 'PatientReportedOutcome (US3312605)', ODM File OID: '848a9730-62ab-4f52-8777-8b7a2f6cb78d'	System	14 Sep 2020 02:01:45
User entered 'Yes (Y)'	System	14 Sep 2020 02:01:45

US3312605

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(4)

Generated On: 26 Nov 2020 10:55:55

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (16C1CAA1-C746-4C21-8AE6-4CD30C39C33C)', Time: '2020-09-13T21:01:38', User OID: 'PatientReportedOutcome (US3312605)', ODM File OID: '848a9730-62ab-4f52-8777-8b7a2f6cb78d' User entered '98.6'	System	14 Sep 2020 02:01:45
	System	14 Sep 2020 02:01:45

US3312605

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(4)

Generated On: 26 Nov 2020 10:55:55

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (16C1CAA1-C746-4C21-8AE6-4CD30C39C33C)', Time: '2020-09-13T21:01:41', User OID: 'PatientReportedOutcome (US3312605)', ODM File OID: '848a9730-62ab-4f52-8777-8b7a2f6cb78d'	System	14 Sep 2020 02:01:45
User entered 'No (N)'	System	14 Sep 2020 02:01:45



**US3312605**

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

**Form: Temperature\_Day(4)**

**Generated On: 26 Nov 2020 10:55:55**

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (16C1CAA1-C746-4C21-8AE6-4CD30C39C33C)', Time: '2020-09-13T21:01:43', User OID: 'PatientReportedOutcome (US3312605)', ODM File OID: '848a9730-62ab-4f52-8777-8b7a2f6cb78d'	System	14 Sep 2020 02:01:45
User entered '13 Sep 2020 21:01'	System	14 Sep 2020 02:01:45

**US3312605**

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

**Form: Temperature\_Day(4)**

**Generated On: 26 Nov 2020 10:55:55**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '13 Sep 2020 12:00'	System	10 Sep 2020 19:59:28

**US3312605**

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

**Form: Temperature\_Day(4)**

**Generated On: 26 Nov 2020 10:55:55**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '14 Sep 2020 11:59'	System	10 Sep 2020 19:59:28

**US3312605**

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

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

**Generated On: 26 Nov 2020 10:55:55**

**TIMEPOINT**

Audit	User	Time (GMT)
Data entry locked.	System	10 Sep 2020 19:59:28
User entered 'Day 5'	System	10 Sep 2020 19:59:28

US3312605

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(5)

Generated On: 26 Nov 2020 10:55:55

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (16C1CAA1-C746-4C21-8AE6-4CD30C39C33C)', Time: '2020-09-15T09:35:27', User OID: 'PatientReportedOutcome (US3312605)', ODM File OID: '78a0f150-d548-4ecb-8354-3023be66faef'	System	15 Sep 2020 14:35:39
User entered 'Yes (Y)'	System	15 Sep 2020 14:35:39

US3312605

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(5)

Generated On: 26 Nov 2020 10:55:55

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (16C1CAA1-C746-4C21-8AE6-4CD30C39C33C)', Time: '2020-09-15T09:35:30', User OID: 'PatientReportedOutcome (US3312605)', ODM File OID: '78a0f150-d548-4ecb-8354-3023be66faef'	System	15 Sep 2020 14:35:39
User entered '98.6'	System	15 Sep 2020 14:35:39

US3312605

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(5)

Generated On: 26 Nov 2020 10:55:55

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (16C1CAA1-C746-4C21-8AE6-4CD30C39C33C)', Time: '2020-09-15T09:35:32', User OID: 'PatientReportedOutcome (US3312605)', ODM File OID: '78a0f150-d548-4ecb-8354-3023be66faef'	System	15 Sep 2020 14:35:39
User entered 'No (N)'	System	15 Sep 2020 14:35:39

**US3312605**

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

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

**Generated On: 26 Nov 2020 10:55:55**

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (16C1CAA1-C746-4C21-8AE6-4CD30C39C33C)', Time: '2020-09-15T09:35:34', User OID: 'PatientReportedOutcome (US3312605)', ODM File OID: '78a0f150-d548-4ecb-8354-3023be66faef' User entered '15 Sep 2020 09:35'	System	15 Sep 2020 14:35:39
	System	15 Sep 2020 14:35:39



**US3312605**

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

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

**Generated On: 26 Nov 2020 10:55:55**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '14 Sep 2020 12:00'	System	10 Sep 2020 19:59:28

**US3312605**

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

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

**Generated On: 26 Nov 2020 10:55:55**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '15 Sep 2020 11:59'	System	10 Sep 2020 19:59:28

**US3312605**

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

**Form: Temperature\_Day(6)**

**Generated On: 26 Nov 2020 10:55:55**

**TIMEPOINT**

Audit	User	Time (GMT)
Data entry locked.	System	10 Sep 2020 19:59:28
User entered 'Day 6'	System	10 Sep 2020 19:59:28

US3312605

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(6)

Generated On: 26 Nov 2020 10:55:55

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (16C1CAA1-C746-4C21-8AE6-4CD30C39C33C)', Time: '2020-09-16T09:16:33', User OID: 'PatientReportedOutcome (US3312605)', ODM File OID: '9a6b27c3-c6b9-4717-a1bc-7ba84ec8115a'	System	16 Sep 2020 14:16:44
User entered 'Yes (Y)'	System	16 Sep 2020 14:16:44

US3312605

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(6)

Generated On: 26 Nov 2020 10:55:55

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (16C1CAA1-C746-4C21-8AE6-4CD30C39C33C)', Time: '2020-09-16T09:16:36', User OID: 'PatientReportedOutcome (US3312605)', ODM File OID: '9a6b27c3-c6b9-4717-a1bc-7ba84ec8115a'	System	16 Sep 2020 14:16:44
User entered '98.6'	System	16 Sep 2020 14:16:44

US3312605

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(6)

Generated On: 26 Nov 2020 10:55:55

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (16C1CAA1-C746-4C21-8AE6-4CD30C39C33C)', Time: '2020-09-16T09:16:39', User OID: 'PatientReportedOutcome (US3312605)', ODM File OID: '9a6b27c3-c6b9-4717-a1bc-7ba84ec8115a'	System	16 Sep 2020 14:16:44
User entered 'No (N)'	System	16 Sep 2020 14:16:44

**US3312605**

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

**Form: Temperature\_Day(6)**

**Generated On: 26 Nov 2020 10:55:55**

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (16C1CAA1-C746-4C21-8AE6-4CD30C39C33C)', Time: '2020-09-16T09:16:42', User OID: 'PatientReportedOutcome (US3312605)', ODM File OID: '9a6b27c3-c6b9-4717-a1bc-7ba84ec8115a' User entered '16 Sep 2020 09:16'	System	16 Sep 2020 14:16:44
	System	16 Sep 2020 14:16:44

**US3312605**

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

**Form: Temperature\_Day(6)**

**Generated On: 26 Nov 2020 10:55:55**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '15 Sep 2020 12:00'	System	10 Sep 2020 19:59:28



**US3312605**

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

**Form: Temperature\_Day(6)**

**Generated On: 26 Nov 2020 10:55:55**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '16 Sep 2020 11:59'	System	10 Sep 2020 19:59:28

**US3312605**

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

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

**Generated On: 26 Nov 2020 10:55:55**

**TIMEPOINT**

Audit	User	Time (GMT)
Data entry locked.	System	10 Sep 2020 19:59:28
User entered 'Day 7'	System	10 Sep 2020 19:59:28

US3312605

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(7)

Generated On: 26 Nov 2020 10:55:55

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (16C1CAA1-C746-4C21-8AE6-4CD30C39C33C)', Time: '2020-09-17T09:39:02', User OID: 'PatientReportedOutcome (US3312605)', ODM File OID: 'a61b9b0d-8d43-4899-b3dc-4aac5228195f'	System	17 Sep 2020 14:39:36
User entered 'Yes (Y)'	System	17 Sep 2020 14:39:36

**US3312605**

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

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

**Generated On: 26 Nov 2020 10:55:55**

Please record your **TEMPERATURE in °F**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (16C1CAA1-C746-4C21-8AE6-4CD30C39C33C)', Time: '2020-09-17T09:39:07', User OID: 'PatientReportedOutcome (US3312605)', ODM File OID: 'a61b9b0d-8d43-4899-b3dc-4aac5228195f'	System	17 Sep 2020 14:39:36
User entered '98.6'	System	17 Sep 2020 14:39:36

US3312605

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(7)

Generated On: 26 Nov 2020 10:55:55

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (16C1CAA1-C746-4C21-8AE6-4CD30C39C33C)', Time: '2020-09-17T09:39:09', User OID: 'PatientReportedOutcome (US3312605)', ODM File OID: 'a61b9b0d-8d43-4899-b3dc-4aac5228195f'	System	17 Sep 2020 14:39:36
User entered 'No (N)'	System	17 Sep 2020 14:39:36

**US3312605**

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

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

**Generated On: 26 Nov 2020 10:55:55**

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (16C1CAA1-C746-4C21-8AE6-4CD30C39C33C)', Time: '2020-09-17T09:39:11', User OID: 'PatientReportedOutcome (US3312605)', ODM File OID: 'a61b9b0d-8d43-4899-b3dc-4aac5228195f'	System	17 Sep 2020 14:39:36
User entered '17 Sep 2020 09:39'	System	17 Sep 2020 14:39:36

US3312605

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(7)

Generated On: 26 Nov 2020 10:55:55

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '16 Sep 2020 12:00'	System	10 Sep 2020 19:59:28

**US3312605**

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

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

**Generated On: 26 Nov 2020 10:55:55**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '17 Sep 2020 11:59'	System	10 Sep 2020 19:59:28



**US3312605**

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

**Form: Injection Site\_Day(1/1)**

**Generated On: 26 Nov 2020 10:55:55**

**TIMEPOINT**

Audit	User	Time (GMT)
Data entry locked.	System	10 Sep 2020 19:59:28
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	10 Sep 2020 19:59:28

US3312605

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 26 Nov 2020 10:55:55

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 (16C1CAA1-C746-4C21-8AE6-4CD30C39C33C)', Time: '2020-09-10T15:25:58', User OID: 'PatientReportedOutcome (US3312605)', ODM File OID: '2d23f80a-09de-4d98-9ca9-74d9b3e24d1f'	System	10 Sep 2020 20:26:13
User entered 'None (1)'	System	10 Sep 2020 20:26:13

US3312605

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 26 Nov 2020 10:55:55

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (16C1CAA1-C746-4C21-8AE6-4CD30C39C33C)', Time: '2020-09-10T15:26:01', User OID: 'PatientReportedOutcome (US3312605)', ODM File OID: '2d23f80a-09de-4d98-9ca9-74d9b3e24d1f'	System	10 Sep 2020 20:26:13
User entered 'No (N)'	System	10 Sep 2020 20:26:13

US3312605

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 26 Nov 2020 10:55:55

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (16C1CAA1-C746-4C21-8AE6-4CD30C39C33C)', Time: '2020-09-10T15:26:03', User OID: 'PatientReportedOutcome (US3312605)', ODM File OID: '2d23f80a-09de-4d98-9ca9-74d9b3e24d1f'	System	10 Sep 2020 20:26:13
User entered 'No (N)'	System	10 Sep 2020 20:26:13

US3312605

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 26 Nov 2020 10:55:55

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 (16C1CAA1-C746-4C21-8AE6-4CD30C39C33C)', Time: '2020-09-10T15:26:05', User OID: 'PatientReportedOutcome (US3312605)', ODM File OID: '2d23f80a-09de-4d98-9ca9-74d9b3e24d1f' User entered 'None (1)'	System	10 Sep 2020 20:26:13
	System	10 Sep 2020 20:26:13

**US3312605**

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

**Form: Injection Site\_Day(1/1)**

**Generated On: 26 Nov 2020 10:55:55**

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (16C1CAA1-C746-4C21-8AE6-4CD30C39C33C)', Time: '2020-09-10T15:26:08', User OID: 'PatientReportedOutcome (US3312605)', ODM File OID: '2d23f80a-09de-4d98-9ca9-74d9b3e24d1f' User entered '10 Sep 2020 15:26'	System	10 Sep 2020 20:26:13
	System	10 Sep 2020 20:26:13

**US3312605**

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

**Form: Injection Site\_Day(1/1)**

**Generated On: 26 Nov 2020 10:55:55**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '10 Sep 2020 15:14'	System	10 Sep 2020 19:59:28

**US3312605**

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

**Form: Injection Site\_Day(1/1)**

**Generated On: 26 Nov 2020 10:55:55**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '10 Sep 2020 17:44'	System	10 Sep 2020 19:59:28



**US3312605**

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

**Form: Injection Site\_Day(1/2)**

**Generated On: 26 Nov 2020 10:55:55**

**TIMEPOINT**

Audit	User	Time (GMT)
Data entry locked.	System	10 Sep 2020 19:59:28
User entered 'Day 1, after vaccination (at home)'	System	10 Sep 2020 19:59:28

US3312605

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 26 Nov 2020 10:55:55

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 (16C1CAA1-C746-4C21-8AE6-4CD30C39C33C)', Time: '2020-09-11T09:12:59', User OID: 'PatientReportedOutcome (US3312605)', ODM File OID: '26dfb8bc-5806-49e9-8698-a091dc28505d'	System	11 Sep 2020 14:13:11
User entered 'None (1)'	System	11 Sep 2020 14:13:11

US3312605

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 26 Nov 2020 10:55:55

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (16C1CAA1-C746-4C21-8AE6-4CD30C39C33C)', Time: '2020-09-11T09:13:01', User OID: 'PatientReportedOutcome (US3312605)', ODM File OID: '26dfb8bc-5806-49e9-8698-a091dc28505d'	System	11 Sep 2020 14:13:11
User entered 'No (N)'	System	11 Sep 2020 14:13:11

US3312605

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 26 Nov 2020 10:55:55

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (16C1CAA1-C746-4C21-8AE6-4CD30C39C33C)', Time: '2020-09-11T09:13:04', User OID: 'PatientReportedOutcome (US3312605)', ODM File OID: '26dfb8bc-5806-49e9-8698-a091dc28505d'	System	11 Sep 2020 14:13:11
User entered 'No (N)'	System	11 Sep 2020 14:13:11

US3312605

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 26 Nov 2020 10:55:55

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 (16C1CAA1-C746-4C21-8AE6-4CD30C39C33C)', Time: '2020-09-11T09:13:07', User OID: 'PatientReportedOutcome (US3312605)', ODM File OID: '26dfb8bc-5806-49e9-8698-a091dc28505d'	System	11 Sep 2020 14:13:11
User entered 'None (1)'	System	11 Sep 2020 14:13:11

**US3312605**

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

**Form: Injection Site\_Day(1/2)**

**Generated On: 26 Nov 2020 10:55:55**

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (16C1CAA1-C746-4C21-8AE6-4CD30C39C33C)', Time: '2020-09-11T09:13:10', User OID: 'PatientReportedOutcome (US3312605)', ODM File OID: '26dfb8bc-5806-49e9-8698-a091dc28505d' User entered '11 Sep 2020 09:13'	System	11 Sep 2020 14:13:11
	System	11 Sep 2020 14:13:11

**US3312605**

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

**Form: Injection Site\_Day(1/2)**

**Generated On: 26 Nov 2020 10:55:55**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '10 Sep 2020 18:39'	System	10 Sep 2020 19:59:28

**US3312605**

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

**Form: Injection Site\_Day(1/2)**

**Generated On: 26 Nov 2020 10:55:55**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '11 Sep 2020 11:59'	System	10 Sep 2020 19:59:28



**US3312605**

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

**Form: Injection Site\_Day(2)**

**Generated On: 26 Nov 2020 10:55:55**

**TIMEPOINT**

Audit	User	Time (GMT)
Data entry locked.	System	10 Sep 2020 19:59:28
User entered 'Day 2'	System	10 Sep 2020 19:59:28

US3312605

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 26 Nov 2020 10:55:55

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 (16C1CAA1-C746-4C21-8AE6-4CD30C39C33C)', Time: '2020-09-12T11:06:44', User OID: 'PatientReportedOutcome (US3312605)', ODM File OID: '2ad45a49-75c7-4b77-8f6e-6ddc5342819e'	System	12 Sep 2020 16:14:18
User entered 'None (1)'	System	12 Sep 2020 16:14:18

US3312605

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 26 Nov 2020 10:55:55

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (16C1CAA1-C746-4C21-8AE6-4CD30C39C33C)', Time: '2020-09-12T11:06:48', User OID: 'PatientReportedOutcome (US3312605)', ODM File OID: '2ad45a49-75c7-4b77-8f6e-6ddc5342819e'	System	12 Sep 2020 16:14:18
User entered 'No (N)'	System	12 Sep 2020 16:14:18

US3312605

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 26 Nov 2020 10:55:55

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (16C1CAA1-C746-4C21-8AE6-4CD30C39C33C)', Time: '2020-09-12T11:06:51', User OID: 'PatientReportedOutcome (US3312605)', ODM File OID: '2ad45a49-75c7-4b77-8f6e-6ddc5342819e'	System	12 Sep 2020 16:14:18
User entered 'No (N)'	System	12 Sep 2020 16:14:18

US3312605

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 26 Nov 2020 10:55:55

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 (16C1CAA1-C746-4C21-8AE6-4CD30C39C33C)', Time: '2020-09-12T11:06:54', User OID: 'PatientReportedOutcome (US3312605)', ODM File OID: '2ad45a49-75c7-4b77-8f6e-6ddc5342819e'	System	12 Sep 2020 16:14:18
User entered 'None (1)'	System	12 Sep 2020 16:14:18

**US3312605**

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

**Form: Injection Site\_Day(2)**

**Generated On: 26 Nov 2020 10:55:55**

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (16C1CAA1-C746-4C21-8AE6-4CD30C39C33C)', Time: '2020-09-12T11:06:56', User OID: 'PatientReportedOutcome (US3312605)', ODM File OID: '2ad45a49-75c7-4b77-8f6e-6ddc5342819e'	System	12 Sep 2020 16:14:18
User entered '12 Sep 2020 11:06'	System	12 Sep 2020 16:14:18

**US3312605**

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

**Form: Injection Site\_Day(2)**

**Generated On: 26 Nov 2020 10:55:55**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '11 Sep 2020 12:00'	System	10 Sep 2020 19:59:28

**US3312605**

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

**Form: Injection Site\_Day(2)**

**Generated On: 26 Nov 2020 10:55:55**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '12 Sep 2020 11:59'	System	10 Sep 2020 19:59:28



**US3312605**

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

**Form: Injection Site\_Day(3)**

**Generated On: 26 Nov 2020 10:55:55**

**TIMEPOINT**

Audit	User	Time (GMT)
Data entry locked.	System	10 Sep 2020 19:59:28
User entered 'Day 3'	System	10 Sep 2020 19:59:28

**US3312605**

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

**Form: Injection Site\_Day(3)**

**Generated On: 26 Nov 2020 10:55:55**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '12 Sep 2020 12:00'	System	10 Sep 2020 19:59:28

**US3312605**

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

**Form: Injection Site\_Day(3)**

**Generated On: 26 Nov 2020 10:55:55**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '13 Sep 2020 11:59'	System	10 Sep 2020 19:59:28

**US3312605**

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

**Form: Injection Site\_Day(4)**

**Generated On: 26 Nov 2020 10:55:55**

**TIMEPOINT**

Audit	User	Time (GMT)
Data entry locked.	System	10 Sep 2020 19:59:28
User entered 'Day 4'	System	10 Sep 2020 19:59:28

**US3312605**

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

**Form: Injection Site\_Day(4)**

**Generated On: 26 Nov 2020 10:55:55**

[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 (16C1CAA1-C746-4C21-8AE6-4CD30C39C33C)', Time: '2020-09-13T21:01:45', User OID: 'PatientReportedOutcome (US3312605)', ODM File OID: 'e9cb9687-0703-48b2-85ed-1863a2d298ab' User entered 'None (1)'	System	14 Sep 2020 02:01:55
	System	14 Sep 2020 02:01:55

US3312605

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 26 Nov 2020 10:55:55

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (16C1CAA1-C746-4C21-8AE6-4CD30C39C33C)', Time: '2020-09-13T21:01:47', User OID: 'PatientReportedOutcome (US3312605)', ODM File OID: 'e9cb9687-0703-48b2-85ed-1863a2d298ab'	System	14 Sep 2020 02:01:55
User entered 'No (N)'	System	14 Sep 2020 02:01:55

US3312605

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 26 Nov 2020 10:55:55

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (16C1CAA1-C746-4C21-8AE6-4CD30C39C33C)', Time: '2020-09-13T21:01:48', User OID: 'PatientReportedOutcome (US3312605)', ODM File OID: 'e9cb9687-0703-48b2-85ed-1863a2d298ab'	System	14 Sep 2020 02:01:55
User entered 'No (N)'	System	14 Sep 2020 02:01:55

US3312605

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 26 Nov 2020 10:55:55

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 (16C1CAA1-C746-4C21-8AE6-4CD30C39C33C)', Time: '2020-09-13T21:01:50', User OID: 'PatientReportedOutcome (US3312605)', ODM File OID: 'e9cb9687-0703-48b2-85ed-1863a2d298ab'	System	14 Sep 2020 02:01:55
User entered 'None (1)'	System	14 Sep 2020 02:01:55



**US3312605**

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

**Form: Injection Site\_Day(4)**

**Generated On: 26 Nov 2020 10:55:55**

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (16C1CAA1-C746-4C21-8AE6-4CD30C39C33C)', Time: '2020-09-13T21:01:52', User OID: 'PatientReportedOutcome (US3312605)', ODM File OID: 'e9cb9687-0703-48b2-85ed-1863a2d298ab'	System	14 Sep 2020 02:01:55
User entered '13 Sep 2020 21:01'	System	14 Sep 2020 02:01:55

**US3312605**

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

**Form: Injection Site\_Day(4)**

**Generated On: 26 Nov 2020 10:55:55**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '13 Sep 2020 12:00'	System	10 Sep 2020 19:59:28

**US3312605**

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

**Form: Injection Site\_Day(4)**

**Generated On: 26 Nov 2020 10:55:55**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '14 Sep 2020 11:59'	System	10 Sep 2020 19:59:28

**US3312605**

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

**Form: Injection Site\_Day(5)**

**Generated On: 26 Nov 2020 10:55:55**

**TIMEPOINT**

Audit	User	Time (GMT)
Data entry locked.	System	10 Sep 2020 19:59:28
User entered 'Day 5'	System	10 Sep 2020 19:59:28

US3312605

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 26 Nov 2020 10:55:55

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 (16C1CAA1-C746-4C21-8AE6-4CD30C39C33C)', Time: '2020-09-15T09:35:51', User OID: 'PatientReportedOutcome (US3312605)', ODM File OID: '858ccf1e-5d05-46f4-aa23-4f63b0772585'	System	15 Sep 2020 14:36:04
User entered 'None (1)'	System	15 Sep 2020 14:36:04

US3312605

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 26 Nov 2020 10:55:55

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (16C1CAA1-C746-4C21-8AE6-4CD30C39C33C)', Time: '2020-09-15T09:35:53', User OID: 'PatientReportedOutcome (US3312605)', ODM File OID: '858ccf1e-5d05-46f4-aa23-4f63b0772585'	System	15 Sep 2020 14:36:04
User entered 'No (N)'	System	15 Sep 2020 14:36:04

US3312605

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 26 Nov 2020 10:55:55

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (16C1CAA1-C746-4C21-8AE6-4CD30C39C33C)', Time: '2020-09-15T09:35:55', User OID: 'PatientReportedOutcome (US3312605)', ODM File OID: '858ccf1e-5d05-46f4-aa23-4f63b0772585'	System	15 Sep 2020 14:36:04
User entered 'No (N)'	System	15 Sep 2020 14:36:04

US3312605

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 26 Nov 2020 10:55:55

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 (16C1CAA1-C746-4C21-8AE6-4CD30C39C33C)', Time: '2020-09-15T09:35:56', User OID: 'PatientReportedOutcome (US3312605)', ODM File OID: '858ccf1e-5d05-46f4-aa23-4f63b0772585'	System	15 Sep 2020 14:36:04
User entered 'None (1)'	System	15 Sep 2020 14:36:04



**US3312605**

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

**Form: Injection Site\_Day(5)**

**Generated On: 26 Nov 2020 10:55:55**

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (16C1CAA1-C746-4C21-8AE6-4CD30C39C33C)', Time: '2020-09-15T09:35:58', User OID: 'PatientReportedOutcome (US3312605)', ODM File OID: '858ccf1e-5d05-46f4-aa23-4f63b0772585'	System	15 Sep 2020 14:36:04
User entered '15 Sep 2020 09:35'	System	15 Sep 2020 14:36:04

**US3312605**

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

**Form: Injection Site\_Day(5)**

**Generated On: 26 Nov 2020 10:55:55**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '14 Sep 2020 12:00'	System	10 Sep 2020 19:59:28

**US3312605**

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

**Form: Injection Site\_Day(5)**

**Generated On: 26 Nov 2020 10:55:55**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '15 Sep 2020 11:59'	System	10 Sep 2020 19:59:28

**US3312605**

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

**Form: Injection Site\_Day(6)**

**Generated On: 26 Nov 2020 10:55:55**

**TIMEPOINT**

Audit	User	Time (GMT)
Data entry locked.	System	10 Sep 2020 19:59:28
User entered 'Day 6'	System	10 Sep 2020 19:59:28

US3312605

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(6)

Generated On: 26 Nov 2020 10:55:55

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 (16C1CAA1-C746-4C21-8AE6-4CD30C39C33C)', Time: '2020-09-16T09:16:45', User OID: 'PatientReportedOutcome (US3312605)', ODM File OID: 'b97f0135-4a10-46f9-952c-81562d7942b5'	System	16 Sep 2020 14:16:55
User entered 'None (1)'	System	16 Sep 2020 14:16:55

US3312605

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(6)

Generated On: 26 Nov 2020 10:55:55

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (16C1CAA1-C746-4C21-8AE6-4CD30C39C33C)', Time: '2020-09-16T09:16:47', User OID: 'PatientReportedOutcome (US3312605)', ODM File OID: 'b97f0135-4a10-46f9-952c-81562d7942b5'	System	16 Sep 2020 14:16:55
User entered 'No (N)'	System	16 Sep 2020 14:16:55

US3312605

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(6)

Generated On: 26 Nov 2020 10:55:55

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (16C1CAA1-C746-4C21-8AE6-4CD30C39C33C)', Time: '2020-09-16T09:16:48', User OID: 'PatientReportedOutcome (US3312605)', ODM File OID: 'b97f0135-4a10-46f9-952c-81562d7942b5'	System	16 Sep 2020 14:16:55
User entered 'No (N)'	System	16 Sep 2020 14:16:55

US3312605

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(6)

Generated On: 26 Nov 2020 10:55:55

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 (16C1CAA1-C746-4C21-8AE6-4CD30C39C33C)', Time: '2020-09-16T09:16:49', User OID: 'PatientReportedOutcome (US3312605)', ODM File OID: 'b97f0135-4a10-46f9-952c-81562d7942b5'	System	16 Sep 2020 14:16:55
User entered 'None (1)'	System	16 Sep 2020 14:16:55



**US3312605**

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

**Form: Injection Site\_Day(6)**

**Generated On: 26 Nov 2020 10:55:55**

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (16C1CAA1-C746-4C21-8AE6-4CD30C39C33C)', Time: '2020-09-16T09:16:51', User OID: 'PatientReportedOutcome (US3312605)', ODM File OID: 'b97f0135-4a10-46f9-952c-81562d7942b5'	System	16 Sep 2020 14:16:55
User entered '16 Sep 2020 09:16'	System	16 Sep 2020 14:16:55

**US3312605**

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

**Form: Injection Site\_Day(6)**

**Generated On: 26 Nov 2020 10:55:55**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '15 Sep 2020 12:00'	System	10 Sep 2020 19:59:28

**US3312605**

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

**Form: Injection Site\_Day(6)**

**Generated On: 26 Nov 2020 10:55:55**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '16 Sep 2020 11:59'	System	10 Sep 2020 19:59:28

**US3312605**

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

**Form: Injection Site\_Day(7)**

**Generated On: 26 Nov 2020 10:55:55**

**TIMEPOINT**

Audit	User	Time (GMT)
Data entry locked.	System	10 Sep 2020 19:59:28
User entered 'Day 7'	System	10 Sep 2020 19:59:28

US3312605

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 26 Nov 2020 10:55:55

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 (16C1CAA1-C746-4C21-8AE6-4CD30C39C33C)', Time: '2020-09-17T09:39:14', User OID: 'PatientReportedOutcome (US3312605)', ODM File OID: 'e73db90f-775f-4c4b-a847-287634d2372d'	System	17 Sep 2020 14:39:38
User entered 'None (1)'	System	17 Sep 2020 14:39:38

US3312605

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 26 Nov 2020 10:55:55

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (16C1CAA1-C746-4C21-8AE6-4CD30C39C33C)', Time: '2020-09-17T09:39:16', User OID: 'PatientReportedOutcome (US3312605)', ODM File OID: 'e73db90f-775f-4c4b-a847-287634d2372d'	System	17 Sep 2020 14:39:38
User entered 'No (N)'	System	17 Sep 2020 14:39:38

US3312605

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 26 Nov 2020 10:55:55

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (16C1CAA1-C746-4C21-8AE6-4CD30C39C33C)', Time: '2020-09-17T09:39:18', User OID: 'PatientReportedOutcome (US3312605)', ODM File OID: 'e73db90f-775f-4c4b-a847-287634d2372d'	System	17 Sep 2020 14:39:38
User entered 'No (N)'	System	17 Sep 2020 14:39:38

US3312605

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 26 Nov 2020 10:55:55

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 (16C1CAA1-C746-4C21-8AE6-4CD30C39C33C)', Time: '2020-09-17T09:39:19', User OID: 'PatientReportedOutcome (US3312605)', ODM File OID: 'e73db90f-775f-4c4b-a847-287634d2372d' User entered 'None (1)'	System	17 Sep 2020 14:39:38
	System	17 Sep 2020 14:39:38



**US3312605**

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

**Form: Injection Site\_Day(7)**

**Generated On: 26 Nov 2020 10:55:55**

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (16C1CAA1-C746-4C21-8AE6-4CD30C39C33C)', Time: '2020-09-17T09:39:22', User OID: 'PatientReportedOutcome (US3312605)', ODM File OID: 'e73db90f-775f-4c4b-a847-287634d2372d' User entered '17 Sep 2020 09:39'	System	17 Sep 2020 14:39:38
	System	17 Sep 2020 14:39:38

**US3312605**

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

**Form: Injection Site\_Day(7)**

**Generated On: 26 Nov 2020 10:55:55**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '16 Sep 2020 12:00'	System	10 Sep 2020 19:59:28

**US3312605**

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

**Form: Injection Site\_Day(7)**

**Generated On: 26 Nov 2020 10:55:55**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '17 Sep 2020 11:59'	System	10 Sep 2020 19:59:28

**US3312605**

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

**Form: General\_Day(1/1)**

**Generated On: 26 Nov 2020 10:55:55**

**TIMEPOINT**

Audit	User	Time (GMT)
Data entry locked.	System	10 Sep 2020 19:59:28
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	10 Sep 2020 19:59:28

**US3312605**

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

**Form: General\_Day(1/1)**

**Generated On: 26 Nov 2020 10:55:55**

**HEADACHE**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (16C1CAA1-C746-4C21-8AE6-4CD30C39C33C)', Time: '2020-09-10T15:26:11', User OID: 'PatientReportedOutcome (US3312605)', ODM File OID: '53742de6-ab29-41bf-a155-a388b602e9c9'	System	10 Sep 2020 20:26:38
User entered 'None (0)'	System	10 Sep 2020 20:26:38

**US3312605**

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

**Form: General\_Day(1/1)**

**Generated On: 26 Nov 2020 10:55:55**

**FATIGUE**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (16C1CAA1-C746-4C21-8AE6-4CD30C39C33C)', Time: '2020-09-10T15:26:13', User OID: 'PatientReportedOutcome (US3312605)', ODM File OID: '53742de6-ab29-41bf-a155-a388b602e9c9'	System	10 Sep 2020 20:26:38
User entered 'None (0)'	System	10 Sep 2020 20:26:38

US3312605

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 26 Nov 2020 10:55:55

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (16C1CAA1-C746-4C21-8AE6-4CD30C39C33C)', Time: '2020-09-10T15:26:15', User OID: 'PatientReportedOutcome (US3312605)', ODM File OID: '53742de6-ab29-41bf-a155-a388b602e9c9'	System	10 Sep 2020 20:26:38
User entered 'None (0)'	System	10 Sep 2020 20:26:38

**US3312605**

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

**Form: General\_Day(1/1)**

**Generated On: 26 Nov 2020 10:55:55**

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (16C1CAA1-C746-4C21-8AE6-4CD30C39C33C)', Time: '2020-09-10T15:26:17', User OID: 'PatientReportedOutcome (US3312605)', ODM File OID: '53742de6-ab29-41bf-a155-a388b602e9c9'	System	10 Sep 2020 20:26:38
User entered 'None (0)'	System	10 Sep 2020 20:26:38



**US3312605**

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

**Form: General\_Day(1/1)**

**Generated On: 26 Nov 2020 10:55:55**

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (16C1CAA1-C746-4C21-8AE6-4CD30C39C33C)', Time: '2020-09-10T15:26:18', User OID: 'PatientReportedOutcome (US3312605)', ODM File OID: '53742de6-ab29-41bf-a155-a388b602e9c9'	System	10 Sep 2020 20:26:38
User entered 'None (0)'	System	10 Sep 2020 20:26:38

**US3312605**

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

**Form: General\_Day(1/1)**

**Generated On: 26 Nov 2020 10:55:55**

**CHILLS**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (16C1CAA1-C746-4C21-8AE6-4CD30C39C33C)', Time: '2020-09-10T15:26:20', User OID: 'PatientReportedOutcome (US3312605)', ODM File OID: '53742de6-ab29-41bf-a155-a388b602e9c9' User entered 'None (0)'	System	10 Sep 2020 20:26:38
	System	10 Sep 2020 20:26:38

US3312605

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 26 Nov 2020 10:55:55

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 (16C1CAA1-C746-4C21-8AE6-4CD30C39C33C)', Time: '2020-09-10T15:26:29', User OID: 'PatientReportedOutcome (US3312605)', ODM File OID: '53742de6-ab29-41bf-a155-a388b602e9c9'	System	10 Sep 2020 20:26:38
User entered 'No (N)'	System	10 Sep 2020 20:26:38

**US3312605**

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

**Form: General\_Day(1/1)**

**Generated On: 26 Nov 2020 10:55:55**

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (16C1CAA1-C746-4C21-8AE6-4CD30C39C33C)', Time: '2020-09-10T15:26:35', User OID: 'PatientReportedOutcome (US3312605)', ODM File OID: '53742de6-ab29-41bf-a155-a388b602e9c9' User entered '10 Sep 2020 15:26'	System	10 Sep 2020 20:26:38
	System	10 Sep 2020 20:26:38

**US3312605**

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

**Form: General\_Day(1/1)**

**Generated On: 26 Nov 2020 10:55:55**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '10 Sep 2020 15:14'	System	10 Sep 2020 19:59:28

**US3312605**

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

**Form: General\_Day(1/1)**

**Generated On: 26 Nov 2020 10:55:55**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '10 Sep 2020 17:44'	System	10 Sep 2020 19:59:28

**US3312605**

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

**Form: General\_Day(1/2)**

**Generated On: 26 Nov 2020 10:55:55**

**TIMEPOINT**

Audit	User	Time (GMT)
Data entry locked.	System	10 Sep 2020 19:59:28
User entered 'Day 1, after vaccination (at home)'	System	10 Sep 2020 19:59:28

**US3312605**

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

**Form: General\_Day(1/2)**

**Generated On: 26 Nov 2020 10:55:55**

**HEADACHE**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (16C1CAA1-C746-4C21-8AE6-4CD30C39C33C)', Time: '2020-09-11T09:13:13', User OID: 'PatientReportedOutcome (US3312605)', ODM File OID: 'ab4bdf01-cea0-42d9-94ca-5a2757a7c005'	System	11 Sep 2020 14:17:09
User entered 'None (0)'	System	11 Sep 2020 14:17:09



**US3312605**

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

**Form: General\_Day(1/2)**

**Generated On: 26 Nov 2020 10:55:55**

**FATIGUE**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (16C1CAA1-C746-4C21-8AE6-4CD30C39C33C)', Time: '2020-09-11T09:16:55', User OID: 'PatientReportedOutcome (US3312605)', ODM File OID: 'ab4bdf01-cea0-42d9-94ca-5a2757a7c005'	System	11 Sep 2020 14:17:09
User entered 'None (0)'	System	11 Sep 2020 14:17:09

**US3312605**

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

**Form: General\_Day(1/2)**

**Generated On: 26 Nov 2020 10:55:55**

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (16C1CAA1-C746-4C21-8AE6-4CD30C39C33C)', Time: '2020-09-11T09:16:56', User OID: 'PatientReportedOutcome (US3312605)', ODM File OID: 'ab4bdf01-cea0-42d9-94ca-5a2757a7c005'	System	11 Sep 2020 14:17:09
User entered 'None (0)'	System	11 Sep 2020 14:17:09

**US3312605**

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

**Form: General\_Day(1/2)**

**Generated On: 26 Nov 2020 10:55:55**

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (16C1CAA1-C746-4C21-8AE6-4CD30C39C33C)', Time: '2020-09-11T09:16:57', User OID: 'PatientReportedOutcome (US3312605)', ODM File OID: 'ab4bdf01-cea0-42d9-94ca-5a2757a7c005'	System	11 Sep 2020 14:17:09
User entered 'None (0)'	System	11 Sep 2020 14:17:09

**US3312605**

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

**Form: General\_Day(1/2)**

**Generated On: 26 Nov 2020 10:55:55**

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (16C1CAA1-C746-4C21-8AE6-4CD30C39C33C)', Time: '2020-09-11T09:16:59', User OID: 'PatientReportedOutcome (US3312605)', ODM File OID: 'ab4bdf01-cea0-42d9-94ca-5a2757a7c005'	System	11 Sep 2020 14:17:09
User entered 'None (0)'	System	11 Sep 2020 14:17:09

**US3312605**

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

**Form: General\_Day(1/2)**

**Generated On: 26 Nov 2020 10:55:55**

**CHILLS**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (16C1CAA1-C746-4C21-8AE6-4CD30C39C33C)', Time: '2020-09-11T09:17:00', User OID: 'PatientReportedOutcome (US3312605)', ODM File OID: 'ab4bdf01-cea0-42d9-94ca-5a2757a7c005'	System	11 Sep 2020 14:17:09
User entered 'None (0)'	System	11 Sep 2020 14:17:09

US3312605

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 26 Nov 2020 10:55:55

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 (16C1CAA1-C746-4C21-8AE6-4CD30C39C33C)', Time: '2020-09-11T09:17:05', User OID: 'PatientReportedOutcome (US3312605)', ODM File OID: 'ab4bdf01-cea0-42d9-94ca-5a2757a7c005'	System	11 Sep 2020 14:17:09
User entered 'No (N)'	System	11 Sep 2020 14:17:09

**US3312605**

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

**Form: General\_Day(1/2)**

**Generated On: 26 Nov 2020 10:55:55**

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (16C1CAA1-C746-4C21-8AE6-4CD30C39C33C)', Time: '2020-09-11T09:17:07', User OID: 'PatientReportedOutcome (US3312605)', ODM File OID: 'ab4bdf01-cea0-42d9-94ca-5a2757a7c005'	System	11 Sep 2020 14:17:09
User entered '11 Sep 2020 09:17'	System	11 Sep 2020 14:17:09

**US3312605**

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

**Form: General\_Day(1/2)**

**Generated On: 26 Nov 2020 10:55:55**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '10 Sep 2020 18:39'	System	10 Sep 2020 19:59:28



**US3312605**

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

**Form: General\_Day(1/2)**

**Generated On: 26 Nov 2020 10:55:55**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '11 Sep 2020 11:59'	System	10 Sep 2020 19:59:28

**US3312605**

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

**Form: General\_Day(2)**

**Generated On: 26 Nov 2020 10:55:55**

**TIMEPOINT**

Audit	User	Time (GMT)
Data entry locked.	System	10 Sep 2020 19:59:28
User entered 'Day 2'	System	10 Sep 2020 19:59:28

**US3312605**

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

**Form: General\_Day(2)**

**Generated On: 26 Nov 2020 10:55:55**

**HEADACHE**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (16C1CAA1-C746-4C21-8AE6-4CD30C39C33C)', Time: '2020-09-12T11:06:59', User OID: 'PatientReportedOutcome (US3312605)', ODM File OID: '23c90ea2-fcec-44f5-a036-a86a3267fa8c'	System	12 Sep 2020 16:14:46
User entered 'None (0)'	System	12 Sep 2020 16:14:46

**US3312605**

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

**Form: General\_Day(2)**

**Generated On: 26 Nov 2020 10:55:55**

**FATIGUE**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (16C1CAA1-C746-4C21-8AE6-4CD30C39C33C)', Time: '2020-09-12T11:07:02', User OID: 'PatientReportedOutcome (US3312605)', ODM File OID: '23c90ea2-fcec-44f5-a036-a86a3267fa8c'	System	12 Sep 2020 16:14:46
User entered 'None (0)'	System	12 Sep 2020 16:14:46

US3312605

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 26 Nov 2020 10:55:55

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (16C1CAA1-C746-4C21-8AE6-4CD30C39C33C)', Time: '2020-09-12T11:07:05', User OID: 'PatientReportedOutcome (US3312605)', ODM File OID: '23c90ea2-fcec-44f5-a036-a86a3267fa8c'	System	12 Sep 2020 16:14:46
User entered 'None (0)'	System	12 Sep 2020 16:14:46

**US3312605**

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

**Form: General\_Day(2)**

**Generated On: 26 Nov 2020 10:55:55**

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (16C1CAA1-C746-4C21-8AE6-4CD30C39C33C)', Time: '2020-09-12T11:07:07', User OID: 'PatientReportedOutcome (US3312605)', ODM File OID: '23c90ea2-fcec-44f5-a036-a86a3267fa8c'	System	12 Sep 2020 16:14:46
User entered 'None (0)'	System	12 Sep 2020 16:14:46

**US3312605**

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

**Form: General\_Day(2)**

**Generated On: 26 Nov 2020 10:55:55**

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (16C1CAA1-C746-4C21-8AE6-4CD30C39C33C)', Time: '2020-09-12T11:07:10', User OID: 'PatientReportedOutcome (US3312605)', ODM File OID: '23c90ea2-fcec-44f5-a036-a86a3267fa8c'	System	12 Sep 2020 16:14:46
User entered 'None (0)'	System	12 Sep 2020 16:14:46

**US3312605**

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

**Form: General\_Day(2)**

**Generated On: 26 Nov 2020 10:55:55**

**CHILLS**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (16C1CAA1-C746-4C21-8AE6-4CD30C39C33C)', Time: '2020-09-12T11:07:12', User OID: 'PatientReportedOutcome (US3312605)', ODM File OID: '23c90ea2-fcec-44f5-a036-a86a3267fa8c'	System	12 Sep 2020 16:14:46
User entered 'None (0)'	System	12 Sep 2020 16:14:46



US3312605

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 26 Nov 2020 10:55:55

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 (16C1CAA1-C746-4C21-8AE6-4CD30C39C33C)', Time: '2020-09-12T11:07:16', User OID: 'PatientReportedOutcome (US3312605)', ODM File OID: '23c90ea2-fcec-44f5-a036-a86a3267fa8c'	System	12 Sep 2020 16:14:46
User entered 'No (N)'	System	12 Sep 2020 16:14:46

**US3312605**

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

**Form: General\_Day(2)**

**Generated On: 26 Nov 2020 10:55:55**

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (16C1CAA1-C746-4C21-8AE6-4CD30C39C33C)', Time: '2020-09-12T11:07:20', User OID: 'PatientReportedOutcome (US3312605)', ODM File OID: '23c90ea2-fcec-44f5-a036-a86a3267fa8c'	System	12 Sep 2020 16:14:46
User entered '12 Sep 2020 11:07'	System	12 Sep 2020 16:14:46

**US3312605**

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

**Form: General\_Day(2)**

**Generated On: 26 Nov 2020 10:55:55**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '11 Sep 2020 12:00'	System	10 Sep 2020 19:59:28

**US3312605**

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

**Form: General\_Day(2)**

**Generated On: 26 Nov 2020 10:55:55**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '12 Sep 2020 11:59'	System	10 Sep 2020 19:59:28

**US3312605**

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

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

**Generated On: 26 Nov 2020 10:55:55**

**TIMEPOINT**

Audit	User	Time (GMT)
Data entry locked.	System	10 Sep 2020 19:59:28
User entered 'Day 3'	System	10 Sep 2020 19:59:28

**US3312605**

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

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

**Generated On: 26 Nov 2020 10:55:55**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '12 Sep 2020 12:00'	System	10 Sep 2020 19:59:28

**US3312605**

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

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

**Generated On: 26 Nov 2020 10:55:55**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '13 Sep 2020 11:59'	System	10 Sep 2020 19:59:28

**US3312605**

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

**Form: General\_Day(4)**

**Generated On: 26 Nov 2020 10:55:55**

**TIMEPOINT**

Audit	User	Time (GMT)
Data entry locked.	System	10 Sep 2020 19:59:28
User entered 'Day 4'	System	10 Sep 2020 19:59:28



**US3312605**

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

**Form: General\_Day(4)**

**Generated On: 26 Nov 2020 10:55:55**

**HEADACHE**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (16C1CAA1-C746-4C21-8AE6-4CD30C39C33C)', Time: '2020-09-14T09:47:19', User OID: 'PatientReportedOutcome (US3312605)', ODM File OID: 'd650d580-3d3c-42d2-897e-969ee3e8e8e5'	System	14 Sep 2020 14:47:33
User entered 'None (0)'	System	14 Sep 2020 14:47:33

**US3312605**

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

**Form: General\_Day(4)**

**Generated On: 26 Nov 2020 10:55:55**

**FATIGUE**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (16C1CAA1-C746-4C21-8AE6-4CD30C39C33C)', Time: '2020-09-14T09:47:21', User OID: 'PatientReportedOutcome (US3312605)', ODM File OID: 'd650d580-3d3c-42d2-897e-969ee3e8e8e5'	System	14 Sep 2020 14:47:33
User entered 'None (0)'	System	14 Sep 2020 14:47:33

US3312605

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 26 Nov 2020 10:55:55

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (16C1CAA1-C746-4C21-8AE6-4CD30C39C33C)', Time: '2020-09-14T09:47:22', User OID: 'PatientReportedOutcome (US3312605)', ODM File OID: 'd650d580-3d3c-42d2-897e-969ee3e8e8e5'	System	14 Sep 2020 14:47:33
User entered 'None (0)'	System	14 Sep 2020 14:47:33

**US3312605**

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

**Form: General\_Day(4)**

**Generated On: 26 Nov 2020 10:55:55**

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (16C1CAA1-C746-4C21-8AE6-4CD30C39C33C)', Time: '2020-09-14T09:47:23', User OID: 'PatientReportedOutcome (US3312605)', ODM File OID: 'd650d580-3d3c-42d2-897e-969ee3e8e8e5'	System	14 Sep 2020 14:47:33
User entered 'None (0)'	System	14 Sep 2020 14:47:33

**US3312605**

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

**Form: General\_Day(4)**

**Generated On: 26 Nov 2020 10:55:55**

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (16C1CAA1-C746-4C21-8AE6-4CD30C39C33C)', Time: '2020-09-14T09:47:24', User OID: 'PatientReportedOutcome (US3312605)', ODM File OID: 'd650d580-3d3c-42d2-897e-969ee3e8e8e5'	System	14 Sep 2020 14:47:33
User entered 'None (0)'	System	14 Sep 2020 14:47:33

**US3312605**

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

**Form: General\_Day(4)**

**Generated On: 26 Nov 2020 10:55:55**

**CHILLS**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (16C1CAA1-C746-4C21-8AE6-4CD30C39C33C)', Time: '2020-09-14T09:47:25', User OID: 'PatientReportedOutcome (US3312605)', ODM File OID: 'd650d580-3d3c-42d2-897e-969ee3e8e8e5'	System	14 Sep 2020 14:47:33
User entered 'None (0)'	System	14 Sep 2020 14:47:33

US3312605

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 26 Nov 2020 10:55:55

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 (16C1CAA1-C746-4C21-8AE6-4CD30C39C33C)', Time: '2020-09-14T09:47:28', User OID: 'PatientReportedOutcome (US3312605)', ODM File OID: 'd650d580-3d3c-42d2-897e-969ee3e8e8e5'	System	14 Sep 2020 14:47:33
User entered 'No (N)'	System	14 Sep 2020 14:47:33

**US3312605**

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

**Form: General\_Day(4)**

**Generated On: 26 Nov 2020 10:55:55**

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (16C1CAA1-C746-4C21-8AE6-4CD30C39C33C)', Time: '2020-09-14T09:47:30', User OID: 'PatientReportedOutcome (US3312605)', ODM File OID: 'd650d580-3d3c-42d2-897e-969ee3e8e8e5'	System	14 Sep 2020 14:47:33
User entered '14 Sep 2020 09:47'	System	14 Sep 2020 14:47:33



**US3312605**

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

**Form: General\_Day(4)**

**Generated On: 26 Nov 2020 10:55:55**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '13 Sep 2020 12:00'	System	10 Sep 2020 19:59:28

**US3312605**

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

**Form: General\_Day(4)**

**Generated On: 26 Nov 2020 10:55:55**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '14 Sep 2020 11:59'	System	10 Sep 2020 19:59:28

**US3312605**

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

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

**Generated On: 26 Nov 2020 10:55:55**

**TIMEPOINT**

Audit	User	Time (GMT)
Data entry locked.	System	10 Sep 2020 19:59:28
User entered 'Day 5'	System	10 Sep 2020 19:59:28

**US3312605**

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

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

**Generated On: 26 Nov 2020 10:55:55**

**HEADACHE**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (16C1CAA1-C746-4C21-8AE6-4CD30C39C33C)', Time: '2020-09-15T09:35:36', User OID: 'PatientReportedOutcome (US3312605)', ODM File OID: '6300fd8f-d19c-488c-87b0-962a4120dcb1'	System	15 Sep 2020 14:35:51
User entered 'None (0)'	System	15 Sep 2020 14:35:51

**US3312605**

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

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

**Generated On: 26 Nov 2020 10:55:55**

**FATIGUE**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (16C1CAA1-C746-4C21-8AE6-4CD30C39C33C)', Time: '2020-09-15T09:35:38', User OID: 'PatientReportedOutcome (US3312605)', ODM File OID: '6300fd8f-d19c-488c-87b0-962a4120dcb1' User entered 'None (0)'	System	15 Sep 2020 14:35:51
	System	15 Sep 2020 14:35:51

**US3312605**

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

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

**Generated On: 26 Nov 2020 10:55:55**

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (16C1CAA1-C746-4C21-8AE6-4CD30C39C33C)', Time: '2020-09-15T09:35:39', User OID: 'PatientReportedOutcome (US3312605)', ODM File OID: '6300fd8f-d19c-488c-87b0-962a4120dcb1'	System	15 Sep 2020 14:35:51
User entered 'None (0)'	System	15 Sep 2020 14:35:51

**US3312605**

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

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

**Generated On: 26 Nov 2020 10:55:55**

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (16C1CAA1-C746-4C21-8AE6-4CD30C39C33C)', Time: '2020-09-15T09:35:41', User OID: 'PatientReportedOutcome (US3312605)', ODM File OID: '6300fd8f-d19c-488c-87b0-962a4120dcb1'	System	15 Sep 2020 14:35:51
User entered 'None (0)'	System	15 Sep 2020 14:35:51

**US3312605**

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

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

**Generated On: 26 Nov 2020 10:55:55**

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (16C1CAA1-C746-4C21-8AE6-4CD30C39C33C)', Time: '2020-09-15T09:35:42', User OID: 'PatientReportedOutcome (US3312605)', ODM File OID: '6300fd8f-d19c-488c-87b0-962a4120dcb1'	System	15 Sep 2020 14:35:51
User entered 'None (0)'	System	15 Sep 2020 14:35:51



**US3312605**

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

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

**Generated On: 26 Nov 2020 10:55:55**

**CHILLS**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (16C1CAA1-C746-4C21-8AE6-4CD30C39C33C)', Time: '2020-09-15T09:35:43', User OID: 'PatientReportedOutcome (US3312605)', ODM File OID: '6300fd8f-d19c-488c-87b0-962a4120dcb1' User entered 'None (0)'	System	15 Sep 2020 14:35:51
	System	15 Sep 2020 14:35:51

US3312605

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 26 Nov 2020 10:55:55

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 (16C1CAA1-C746-4C21-8AE6-4CD30C39C33C)', Time: '2020-09-15T09:35:46', User OID: 'PatientReportedOutcome (US3312605)', ODM File OID: '6300fd8f-d19c-488c-87b0-962a4120dcb1'	System	15 Sep 2020 14:35:51
User entered 'No (N)'	System	15 Sep 2020 14:35:51

**US3312605**

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

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

**Generated On: 26 Nov 2020 10:55:55**

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (16C1CAA1-C746-4C21-8AE6-4CD30C39C33C)', Time: '2020-09-15T09:35:48', User OID: 'PatientReportedOutcome (US3312605)', ODM File OID: '6300fd8f-d19c-488c-87b0-962a4120dcb1' User entered '15 Sep 2020 09:35'	System	15 Sep 2020 14:35:51
	System	15 Sep 2020 14:35:51

**US3312605**

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

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

**Generated On: 26 Nov 2020 10:55:55**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '14 Sep 2020 12:00'	System	10 Sep 2020 19:59:28

**US3312605**

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

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

**Generated On: 26 Nov 2020 10:55:55**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '15 Sep 2020 11:59'	System	10 Sep 2020 19:59:28

**US3312605**

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

**Form: General\_Day(6)**

**Generated On: 26 Nov 2020 10:55:55**

**TIMEPOINT**

Audit	User	Time (GMT)
Data entry locked.	System	10 Sep 2020 19:59:28
User entered 'Day 6'	System	10 Sep 2020 19:59:28

**US3312605**

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

**Form: General\_Day(6)**

**Generated On: 26 Nov 2020 10:55:55**

**HEADACHE**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (16C1CAA1-C746-4C21-8AE6-4CD30C39C33C)', Time: '2020-09-16T09:16:53', User OID: 'PatientReportedOutcome (US3312605)', ODM File OID: '7ebc0369-3180-44db-b351-acd6be54e85d'	System	16 Sep 2020 14:17:09
User entered 'None (0)'	System	16 Sep 2020 14:17:09

**US3312605**

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

**Form: General\_Day(6)**

**Generated On: 26 Nov 2020 10:55:55**

**FATIGUE**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (16C1CAA1-C746-4C21-8AE6-4CD30C39C33C)', Time: '2020-09-16T09:16:55', User OID: 'PatientReportedOutcome (US3312605)', ODM File OID: '7ebc0369-3180-44db-b351-acd6be54e85d'	System	16 Sep 2020 14:17:09
User entered 'None (0)'	System	16 Sep 2020 14:17:09



**US3312605**

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

**Form: General\_Day(6)**

**Generated On: 26 Nov 2020 10:55:55**

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (16C1CAA1-C746-4C21-8AE6-4CD30C39C33C)', Time: '2020-09-16T09:16:56', User OID: 'PatientReportedOutcome (US3312605)', ODM File OID: '7ebc0369-3180-44db-b351-acd6be54e85d'	System	16 Sep 2020 14:17:09
User entered 'None (0)'	System	16 Sep 2020 14:17:09

**US3312605**

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

**Form: General\_Day(6)**

**Generated On: 26 Nov 2020 10:55:55**

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (16C1CAA1-C746-4C21-8AE6-4CD30C39C33C)', Time: '2020-09-16T09:16:57', User OID: 'PatientReportedOutcome (US3312605)', ODM File OID: '7ebc0369-3180-44db-b351-acd6be54e85d'	System	16 Sep 2020 14:17:09
User entered 'None (0)'	System	16 Sep 2020 14:17:09

**US3312605**

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

**Form: General\_Day(6)**

**Generated On: 26 Nov 2020 10:55:55**

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (16C1CAA1-C746-4C21-8AE6-4CD30C39C33C)', Time: '2020-09-16T09:16:58', User OID: 'PatientReportedOutcome (US3312605)', ODM File OID: '7ebc0369-3180-44db-b351-acd6be54e85d'	System	16 Sep 2020 14:17:09
User entered 'None (0)'	System	16 Sep 2020 14:17:09

**US3312605**

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

**Form: General\_Day(6)**

**Generated On: 26 Nov 2020 10:55:55**

**CHILLS**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (16C1CAA1-C746-4C21-8AE6-4CD30C39C33C)', Time: '2020-09-16T09:16:59', User OID: 'PatientReportedOutcome (US3312605)', ODM File OID: '7ebc0369-3180-44db-b351-acd6be54e85d'	System	16 Sep 2020 14:17:09
User entered 'None (0)'	System	16 Sep 2020 14:17:09

US3312605

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 26 Nov 2020 10:55:55

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 (16C1CAA1-C746-4C21-8AE6-4CD30C39C33C)', Time: '2020-09-16T09:17:06', User OID: 'PatientReportedOutcome (US3312605)', ODM File OID: '7ebc0369-3180-44db-b351-acd6be54e85d'	System	16 Sep 2020 14:17:09
User entered 'No (N)'	System	16 Sep 2020 14:17:09

**US3312605**

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

**Form: General\_Day(6)**

**Generated On: 26 Nov 2020 10:55:55**

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (16C1CAA1-C746-4C21-8AE6-4CD30C39C33C)', Time: '2020-09-16T09:17:08', User OID: 'PatientReportedOutcome (US3312605)', ODM File OID: '7ebc0369-3180-44db-b351-acd6be54e85d' User entered '16 Sep 2020 09:17'	System	16 Sep 2020 14:17:09
	System	16 Sep 2020 14:17:09

**US3312605**

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

**Form: General\_Day(6)**

**Generated On: 26 Nov 2020 10:55:55**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '15 Sep 2020 12:00'	System	10 Sep 2020 19:59:28

**US3312605**

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

**Form: General\_Day(6)**

**Generated On: 26 Nov 2020 10:55:55**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '16 Sep 2020 11:59'	System	10 Sep 2020 19:59:28



**US3312605**

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

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

**Generated On: 26 Nov 2020 10:55:55**

**TIMEPOINT**

Audit	User	Time (GMT)
Data entry locked.	System	10 Sep 2020 19:59:28
User entered 'Day 7'	System	10 Sep 2020 19:59:28

**US3312605**

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

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

**Generated On: 26 Nov 2020 10:55:55**

**HEADACHE**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (16C1CAA1-C746-4C21-8AE6-4CD30C39C33C)', Time: '2020-09-17T09:39:26', User OID: 'PatientReportedOutcome (US3312605)', ODM File OID: 'f692c121-4f1d-42ec-8311-5386fe3248c4'	System	17 Sep 2020 14:39:41
User entered 'None (0)'	System	17 Sep 2020 14:39:41

**US3312605**

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

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

**Generated On: 26 Nov 2020 10:55:55**

**FATIGUE**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (16C1CAA1-C746-4C21-8AE6-4CD30C39C33C)', Time: '2020-09-17T09:39:27', User OID: 'PatientReportedOutcome (US3312605)', ODM File OID: 'f692c121-4f1d-42ec-8311-5386fe3248c4'	System	17 Sep 2020 14:39:41
User entered 'None (0)'	System	17 Sep 2020 14:39:41

**US3312605**

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

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

**Generated On: 26 Nov 2020 10:55:55**

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (16C1CAA1-C746-4C21-8AE6-4CD30C39C33C)', Time: '2020-09-17T09:39:30', User OID: 'PatientReportedOutcome (US3312605)', ODM File OID: 'f692c121-4f1d-42ec-8311-5386fe3248c4'	System	17 Sep 2020 14:39:41
User entered 'None (0)'	System	17 Sep 2020 14:39:41

US3312605

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 26 Nov 2020 10:55:55

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (16C1CAA1-C746-4C21-8AE6-4CD30C39C33C)', Time: '2020-09-17T09:39:31', User OID: 'PatientReportedOutcome (US3312605)', ODM File OID: 'f692c121-4f1d-42ec-8311-5386fe3248c4'	System	17 Sep 2020 14:39:41
User entered 'None (0)'	System	17 Sep 2020 14:39:41

**US3312605**

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

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

**Generated On: 26 Nov 2020 10:55:55**

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (16C1CAA1-C746-4C21-8AE6-4CD30C39C33C)', Time: '2020-09-17T09:39:32', User OID: 'PatientReportedOutcome (US3312605)', ODM File OID: 'f692c121-4f1d-42ec-8311-5386fe3248c4'	System	17 Sep 2020 14:39:41
User entered 'None (0)'	System	17 Sep 2020 14:39:41

**US3312605**

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

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

**Generated On: 26 Nov 2020 10:55:55**

**CHILLS**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (16C1CAA1-C746-4C21-8AE6-4CD30C39C33C)', Time: '2020-09-17T09:39:33', User OID: 'PatientReportedOutcome (US3312605)', ODM File OID: 'f692c121-4f1d-42ec-8311-5386fe3248c4'	System	17 Sep 2020 14:39:41
User entered 'None (0)'	System	17 Sep 2020 14:39:41

US3312605

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 26 Nov 2020 10:55:55

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 (16C1CAA1-C746-4C21-8AE6-4CD30C39C33C)', Time: '2020-09-17T09:39:36', User OID: 'PatientReportedOutcome (US3312605)', ODM File OID: 'f692c121-4f1d-42ec-8311-5386fe3248c4'	System	17 Sep 2020 14:39:41
User entered 'No (N)'	System	17 Sep 2020 14:39:41



**US3312605**

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

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

**Generated On: 26 Nov 2020 10:55:55**

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (16C1CAA1-C746-4C21-8AE6-4CD30C39C33C)', Time: '2020-09-17T09:39:38', User OID: 'PatientReportedOutcome (US3312605)', ODM File OID: 'f692c121-4f1d-42ec-8311-5386fe3248c4'	System	17 Sep 2020 14:39:41
User entered '17 Sep 2020 09:39'	System	17 Sep 2020 14:39:41

**US3312605**

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

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

**Generated On: 26 Nov 2020 10:55:55**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '16 Sep 2020 12:00'	System	10 Sep 2020 19:59:28

**US3312605**

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

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

**Generated On: 26 Nov 2020 10:55:55**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '17 Sep 2020 11:59'	System	10 Sep 2020 19:59:28

US3312605

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 26 Nov 2020 10:55:55

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Karol Moore (b) (4) (b) (4)	06 Oct 2020 22:10:52

US3312605

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 26 Nov 2020 10:55:55

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

Audit	User	Time (GMT)
User entered '18 Sep 2020'	Karol Moore (b) (4) (b) (4)	06 Oct 2020 22:10:52

US3312605

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 26 Nov 2020 10:55:55

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
User entered 'Contact Made (CONTACT MADE)'	Karol Moore (b) (4) (b) (4)	06 Oct 2020 22:10:52

**US3312605**

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

**Form: Safety Call**

**Generated On: 26 Nov 2020 10:55:55**

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
User entered empty.	Karol Moore (b) (4) (b) (4)	06 Oct 2020 22:10:52

US3312605

Folder: Safety Call Day 8 (1)

Form: Continuing

Generated On: 26 Nov 2020 10:55:55

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

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Karol Moore (b) (4) (b) (4)	06 Oct 2020 22:10:54



**US3312605**

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

**Form: Continuing**

**Generated On: 26 Nov 2020 10:55:55**

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered 'I'	System	06 Oct 2020 22:10:54

US3312605

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 26 Nov 2020 10:55:55

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Karol Moore (b) (4) (b) (4)	06 Oct 2020 22:11:17

US3312605

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 26 Nov 2020 10:55:55

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

Audit	User	Time (GMT)
User entered '24 Sep 2020'	Karol Moore (b) (4) (b) (4)	06 Oct 2020 22:11:17

US3312605

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 26 Nov 2020 10:55:55

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
User entered 'Contact Made (CONTACT MADE)'	Karol Moore (b) (4) (b) (4)	06 Oct 2020 22:11:17

**US3312605**

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

**Form: Safety Call**

**Generated On: 26 Nov 2020 10:55:55**

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
User entered empty.	Karol Moore (b) (4) (b) (4)	06 Oct 2020 22:11:17

US3312605

Folder: Safety Call Day 15 (1)

Form: Continuing

Generated On: 26 Nov 2020 10:55:55

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

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Karol Moore (b) (4) (b) (4)	06 Oct 2020 22:11:28

**US3312605**

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

**Form: Continuing**

**Generated On: 26 Nov 2020 10:55:55**

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered 'I'	System	06 Oct 2020 22:11:28

US3312605

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 26 Nov 2020 10:55:55

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Karol Moore (b) (4) (b) (4)	06 Oct 2020 22:13:44



US3312605

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 26 Nov 2020 10:55:55

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

Audit	User	Time (GMT)
User entered '01 Oct 2020'	Karol Moore (b) (4) (b) (4)	06 Oct 2020 22:13:44

US3312605

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 26 Nov 2020 10:55:55

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
User entered 'Contact Made (CONTACT MADE)'	Karol Moore (b) (4) (b) (4)	06 Oct 2020 22:13:44

**US3312605**

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

**Form: Safety Call**

**Generated On: 26 Nov 2020 10:55:55**

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
User entered empty.	Karol Moore (b) (4) (b) (4)	06 Oct 2020 22:13:44

US3312605

Folder: Safety Call Day 22 (1)

Form: Continuing

Generated On: 26 Nov 2020 10:55:55

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

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Karol Moore (b) (4) (b) (4)	06 Oct 2020 22:14:42

**US3312605**

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

**Form: Continuing**

**Generated On: 26 Nov 2020 10:55:55**

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered 'I'	System	06 Oct 2020 22:14:42

**US3312605**

**Folder: Visit 2 Day 29 (1)**

**Form: Visit Date**

**Generated On: 26 Nov 2020 10:55:55**

[Was this visit performed?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	08 Oct 2020 19:32:05

US3312605

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 26 Nov 2020 10:55:55

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

Audit	User	Time (GMT)
User entered '8 Oct 2020'	(b) (4), (b) (6)	08 Oct 2020 19:32:05

US3312605

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 26 Nov 2020 10:55:55

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

Audit	User	Time (GMT)
User entered 'Clinic (Clinic)'	(b) (4), (b) (6)	08 Oct 2020 19:32:05



**US3312605**

**Folder: Visit 2 Day 29 (1)**

**Form: Visit Date**

**Generated On: 26 Nov 2020 10:55:55**

[Folder OID](#)

Audit	User	Time (GMT)
User entered 'VISIT2'	System	08 Oct 2020 19:32:05

US3312605

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 10:55:55

[Timepoint](#)

Audit	User	Time (GMT)
User accepted default value 'Pre-Dose (PREDOSE)'	(b) (4), (b) (6)	12 Oct 2020 14:45:51

US3312605

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 10:55:55

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	12 Oct 2020 14:45:51

US3312605

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 10:55:55

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered '8 Oct 2020'	(b) (4), (b) (6)	12 Oct 2020 14:45:51

US3312605

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 10:55:55

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

Audit	User	Time (GMT)
User entered '13:41'	(b) (4), (b) (6)	12 Oct 2020 14:45:51

**US3312605**

**Folder: Visit 2 Day 29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 26 Nov 2020 10:55:55**

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

Audit	User	Time (GMT)
User entered '8 Oct 2020 13:41'	System	12 Oct 2020 14:45:51

US3312605

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 10:55:55

Temperature (xxx.x)

Audit	User	Time (GMT)
User entered '98.2' F	(b) (4), (b) (6)	12 Oct 2020 14:45:51

US3312605

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 10:55:55

[Route of measurement](#)

Audit	User	Time (GMT)
User entered 'Oral (Oral)'	(b) (4), (b) (6)	12 Oct 2020 14:45:51



US3312605

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 10:55:55

[If Other, specify](#)

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	12 Oct 2020 14:45:51

US3312605

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 10:55:55

Pulse (xxx)

Audit	User	Time (GMT)
User entered '67'	(b) (4), (b) (6)	12 Oct 2020 14:45:51

**US3312605**

**Folder: Visit 2 Day 29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 26 Nov 2020 10:55:55**

[Pulse units](#)

Audit	User	Time (GMT)
User entered 'bpm'	System	12 Oct 2020 14:45:51

US3312605

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 10:55:55

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

Audit	User	Time (GMT)
User entered '12'	(b) (4), (b) (6)	12 Oct 2020 14:45:51

US3312605

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 10:55:55

[Respiratory Rate units](#)

Audit	User	Time (GMT)
User entered 'breaths/min'	System	12 Oct 2020 14:45:51

US3312605

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 10:55:55

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
User entered '129'	(b) (4), (b) (6)	12 Oct 2020 14:45:51

**US3312605**

**Folder: Visit 2 Day 29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 26 Nov 2020 10:55:55**

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	12 Oct 2020 14:45:51

US3312605

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 10:55:55

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
User entered '69'	(b) (4), (b) (6)	12 Oct 2020 14:45:51



**US3312605**

**Folder: Visit 2 Day 29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 26 Nov 2020 10:55:55**

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	12 Oct 2020 14:45:51

US3312605

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 10:55:55

[Timepoint](#)

Audit	User	Time (GMT)
User accepted default value 'Post-Dose (POSTDOSE)'	(b) (4), (b) (6)	12 Oct 2020 14:45:51

US3312605

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 10:55:55

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	12 Oct 2020 14:45:51

US3312605

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 10:55:55

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered '8 Oct 2020'	(b) (4), (b) (6)	12 Oct 2020 14:45:51

US3312605

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 10:55:55

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

Audit	User	Time (GMT)
User entered '15:00'	(b) (4), (b) (6)	12 Oct 2020 14:45:51

**US3312605**

**Folder: Visit 2 Day 29 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 26 Nov 2020 10:55:55**

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

Audit	User	Time (GMT)
User entered '8 Oct 2020 15:00'	System	12 Oct 2020 14:45:51

US3312605

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 10:55:55

Temperature (xxx.x)

Audit	User	Time (GMT)
User entered '97.9' F	(b) (4), (b) (6)	12 Oct 2020 14:45:51

US3312605

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 10:55:55

[Route of measurement](#)

Audit	User	Time (GMT)
User entered 'Oral (Oral)'	(b) (4), (b) (6)	12 Oct 2020 14:45:51



US3312605

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 10:55:55

[If Other, specify](#)

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	12 Oct 2020 14:45:51

US3312605

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 10:55:55

Pulse (xxx)

Audit	User	Time (GMT)
User entered '83'	(b) (4), (b) (6)	12 Oct 2020 14:45:51

**US3312605**

**Folder: Visit 2 Day 29 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 26 Nov 2020 10:55:55**

[Pulse units](#)

Audit	User	Time (GMT)
User entered 'bpm'	System	12 Oct 2020 14:45:51

US3312605

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 10:55:55

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

Audit	User	Time (GMT)
User entered '16'	(b) (4), (b) (6)	12 Oct 2020 14:45:51

US3312605

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 10:55:55

[Respiratory Rate units](#)

Audit	User	Time (GMT)
User entered 'breaths/min'	System	12 Oct 2020 14:45:51

US3312605

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 10:55:55

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
User entered '131'	(b) (4), (b) (6)	12 Oct 2020 14:45:51

**US3312605**

**Folder: Visit 2 Day 29 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 26 Nov 2020 10:55:55**

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	12 Oct 2020 14:45:51

US3312605

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 10:55:55

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
User entered '69'	(b) (4), (b) (6)	12 Oct 2020 14:45:51



US3312605

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 10:55:55

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	12 Oct 2020 14:45:51

US3312605

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Generated On: 26 Nov 2020 10:55:55

Was the physical examination performed?

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	12 Oct 2020 14:46:41

US3312605

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Generated On: 26 Nov 2020 10:55:55

Date of examination (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered '8 Oct 2020'	(b) (4), (b) (6)	12 Oct 2020 14:46:41

US3312605

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 26 Nov 2020 10:55:55

[Was study treatment given?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	08 Oct 2020 19:33:08

US3312605

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 26 Nov 2020 10:55:55

If No, reason not given

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	08 Oct 2020 19:33:08

US3312605

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 26 Nov 2020 10:55:55

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

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	08 Oct 2020 19:33:08

**US3312605**

**Folder: Visit 2 Day 29 (1)**

**Form: Exposure**

**Generated On: 26 Nov 2020 10:55:55**

[What was the study treatment?](#)

Audit	User	Time (GMT)
User entered 'MRNA-1273 OR PLACEBO'	System	08 Oct 2020 19:33:08

US3312605

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 26 Nov 2020 10:55:55

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
User closed query 'Per CDM: Please consider updating the date format to DD-MM-YYYY, including 2 digits for day (for example 01-JAN-2020). ' (Site from DM).	(b) (4), (b) (6)	22 Oct 2020 18:06:32
Query 'Per CDM: Please consider updating the date format to DD-MM-YYYY, including 2 digits for day (for example 01-JAN-2020). ' answered with 'updated' (Site from DM).	Heather Barker (b) (4)	21 Oct 2020 19:14:48
User entered '08 Oct 2020' reason for change: Data Entry Error	(b) (4)	21 Oct 2020 19:14:39
User opened query 'Per CDM: Please consider updating the date format to DD-MM-YYYY, including 2 digits for day (for example 01-JAN-2020). ' (Site from DM).	(b) (4), (b) (6)	14 Oct 2020 17:59:48
User entered '8 Oct 2020'	(b) (4), (b) (6)	08 Oct 2020 19:33:08



US3312605

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 26 Nov 2020 10:55:55

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

Audit	User	Time (GMT)
User entered '14:29'	(b) (4), (b) (6)	08 Oct 2020 19:33:08

**US3312605**

**Folder: Visit 2 Day 29 (1)**

**Form: Exposure**

**Generated On: 26 Nov 2020 10:55:55**

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

Audit	User	Time (GMT)
User entered '08 Oct 2020 14:29'	System	21 Oct 2020 19:14:39
User entered '8 Oct 2020 14:29'	System	08 Oct 2020 19:33:08

US3312605

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 26 Nov 2020 10:55:55

Which arm was used to give treatment?

Audit	User	Time (GMT)
User entered 'Left Arm (LEFT ARM)'	(b) (4), (b) (6)	08 Oct 2020 19:33:08

US3312605

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 26 Nov 2020 10:55:55

[What was the frequency of the study treatment dosing?](#)

Audit	User	Time (GMT)
User entered 'ONCE'	System	08 Oct 2020 19:33:08

US3312605

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 26 Nov 2020 10:55:55

What was the route of administration for the study treatment?

Audit	User	Time (GMT)
User entered 'INTRAMUSCULAR'	System	08 Oct 2020 19:33:08

US3312605

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 10:55:55

[Was the sample collected?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	12 Oct 2020 14:47:06

US3312605

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 10:55:55

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered '8 Oct 2020'	(b) (4), (b) (6)	12 Oct 2020 14:47:06

US3312605

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 10:55:55

Collection time (00:00-23:59)

Audit	User	Time (GMT)
User entered '13:53'	(b) (4), (b) (6)	12 Oct 2020 14:47:06



**US3312605**

**Folder: Visit 2 Day 29 (1)**

**Form: Immunogenicity Assessment**

**Generated On: 26 Nov 2020 10:55:55**

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

Audit	User	Time (GMT)
User entered '8 Oct 2020 13:53'	System	12 Oct 2020 14:47:06

US3312605

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 26 Nov 2020 10:55:55

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered '8 Oct 2020'	(b) (4), (b) (6)	12 Oct 2020 14:47:22

**US3312605**

**Folder: Visit 2 Day 29 (1)**

**Form: Central Laboratory - Nasopharyngeal Swab (1)**

**Generated On: 26 Nov 2020 10:55:55**

[Lab Test](#)

Audit	User	Time (GMT)
User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)'	(b) (4), (b) (6)	12 Oct 2020 14:47:22

US3312605

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 26 Nov 2020 10:55:55

[Was the sample collected?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	12 Oct 2020 14:47:22

**US3312605**

**Folder: Visit 2 Day 29 (1)**

**Form: Central Laboratory - Nasopharyngeal Swab (1)**

**Generated On: 26 Nov 2020 10:55:55**

[Collection time \(00:00 - 23:59\)](#)

Audit	User	Time (GMT)
User entered '13:50'	(b) (4), (b) (6)	12 Oct 2020 14:47:22

**US3312605**

**Folder: Visit 2 Day 29 (1)**

**Form: Central Laboratory - Nasopharyngeal Swab (1)**

**Generated On: 26 Nov 2020 10:55:55**

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

Audit	User	Time (GMT)
User entered '8 Oct 2020 13:50'	System	12 Oct 2020 14:47:22

**US3312605**

**Folder: Visit 2 Day 29 (1)**

**Form: Central Laboratory - Nasopharyngeal Swab (2)**

**Generated On: 26 Nov 2020 10:55:55**

[Lab Test](#)

Audit	User	Time (GMT)
User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)'	(b) (4), (b) (6)	12 Oct 2020 14:47:22

US3312605

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 26 Nov 2020 10:55:55

[Was the sample collected?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	(b) (4), (b) (6)	12 Oct 2020 14:47:22



US3312605

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 26 Nov 2020 10:55:55

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	12 Oct 2020 14:47:22

**US3312605**

**Folder: Visit 2 Day 29 (1)**

**Form: Central Laboratory - Nasopharyngeal Swab (2)**

**Generated On: 26 Nov 2020 10:55:55**

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

Audit	User	Time (GMT)
User entered empty.	System	12 Oct 2020 14:47:22

US3312605

Folder: Visit 2 Day 29 (1)

Form: Continuing

Generated On: 26 Nov 2020 10:55:55

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

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	08 Oct 2020 19:33:19

**US3312605**

**Folder: Visit 2 Day 29 (1)**

**Form: Continuing**

**Generated On: 26 Nov 2020 10:55:55**

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered 'I'	System	08 Oct 2020 19:33:19

**US3312605**

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

**Form: Temperature\_Day(1/1)**

**Generated On: 26 Nov 2020 10:55:55**

**TIMEPOINT**

Audit	User	Time (GMT)
Data entry locked.	System	08 Oct 2020 19:33:08
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	08 Oct 2020 19:33:08

US3312605

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/1)

Generated On: 26 Nov 2020 10:55:55

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (16C1CAA1-C746-4C21-8AE6-4CD30C39C33C)', Time: '2020-10-08T15:01:44', User OID: 'PatientReportedOutcome (US3312605)', ODM File OID: '11dba23a-2179-4464-8477-d68c46a58ded' User entered 'Yes (Y)'	System	08 Oct 2020 20:01:56
	System	08 Oct 2020 20:01:56

US3312605

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/1)

Generated On: 26 Nov 2020 10:55:55

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (16C1CAA1-C746-4C21-8AE6-4CD30C39C33C)', Time: '2020-10-08T15:01:49', User OID: 'PatientReportedOutcome (US3312605)', ODM File OID: '11dba23a-2179-4464-8477-d68c46a58ded' User entered '97.9'	System	08 Oct 2020 20:01:56
	System	08 Oct 2020 20:01:56

US3312605

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/1)

Generated On: 26 Nov 2020 10:55:55

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (16C1CAA1-C746-4C21-8AE6-4CD30C39C33C)', Time: '2020-10-08T15:01:51', User OID: 'PatientReportedOutcome (US3312605)', ODM File OID: '11dba23a-2179-4464-8477-d68c46a58ded'	System	08 Oct 2020 20:01:56
User entered 'No (N)'	System	08 Oct 2020 20:01:56



**US3312605**

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

**Form: Temperature\_Day(1/1)**

**Generated On: 26 Nov 2020 10:55:55**

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (16C1CAA1-C746-4C21-8AE6-4CD30C39C33C)', Time: '2020-10-08T15:01:54', User OID: 'PatientReportedOutcome (US3312605)', ODM File OID: '11dba23a-2179-4464-8477-d68c46a58ded' User entered '08 Oct 2020 15:01'	System	08 Oct 2020 20:01:56
	System	08 Oct 2020 20:01:56

US3312605

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/1)

Generated On: 26 Nov 2020 10:55:55

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '08 Oct 2020 14:49'	System	08 Oct 2020 19:33:08

**US3312605**

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

**Form: Temperature\_Day(1/1)**

**Generated On: 26 Nov 2020 10:55:55**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '08 Oct 2020 17:19'	System	08 Oct 2020 19:33:08

**US3312605**

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

**Form: Temperature\_Day(1/2)**

**Generated On: 26 Nov 2020 10:55:55**

**TIMEPOINT**

Audit	User	Time (GMT)
Data entry locked.	System	08 Oct 2020 19:33:08
User entered 'Day 1, after vaccination (at home)'	System	08 Oct 2020 19:33:08

US3312605

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/2)

Generated On: 26 Nov 2020 10:55:55

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (16C1CAA1-C746-4C21-8AE6-4CD30C39C33C)', Time: '2020-10-09T09:37:31', User OID: 'PatientReportedOutcome (US3312605)', ODM File OID: 'c53ee078-0c68-45fc-a6a3-2e95e3fc48a0' User entered 'Yes (Y)'	System	09 Oct 2020 14:37:43

US3312605

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/2)

Generated On: 26 Nov 2020 10:55:55

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (16C1CAA1-C746-4C21-8AE6-4CD30C39C33C)', Time: '2020-10-09T09:37:35', User OID: 'PatientReportedOutcome (US3312605)', ODM File OID: 'c53ee078-0c68-45fc-a6a3-2e95e3fc48a0'	System	09 Oct 2020 14:37:43
User entered '96.8'	System	09 Oct 2020 14:37:43

US3312605

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/2)

Generated On: 26 Nov 2020 10:55:55

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (16C1CAA1-C746-4C21-8AE6-4CD30C39C33C)', Time: '2020-10-09T09:37:38', User OID: 'PatientReportedOutcome (US3312605)', ODM File OID: 'c53ee078-0c68-45fc-a6a3-2e95e3fc48a0'	System	09 Oct 2020 14:37:43
User entered 'No (N)'	System	09 Oct 2020 14:37:43

**US3312605**

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

**Form: Temperature\_Day(1/2)**

**Generated On: 26 Nov 2020 10:55:55**

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (16C1CAA1-C746-4C21-8AE6-4CD30C39C33C)', Time: '2020-10-09T09:37:41', User OID: 'PatientReportedOutcome (US3312605)', ODM File OID: 'c53ee078-0c68-45fc-a6a3-2e95e3fc48a0' User entered '09 Oct 2020 09:37'	System	09 Oct 2020 14:37:43
	System	09 Oct 2020 14:37:43



**US3312605**

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

**Form: Temperature\_Day(1/2)**

**Generated On: 26 Nov 2020 10:55:55**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '08 Oct 2020 18:14'	System	08 Oct 2020 19:33:08

**US3312605**

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

**Form: Temperature\_Day(1/2)**

**Generated On: 26 Nov 2020 10:55:55**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '09 Oct 2020 11:59'	System	08 Oct 2020 19:33:08

**US3312605**

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

**Form: Temperature\_Day(2)**

**Generated On: 26 Nov 2020 10:55:55**

**TIMEPOINT**

Audit	User	Time (GMT)
Data entry locked.	System	08 Oct 2020 19:33:08
User entered 'Day 2'	System	08 Oct 2020 19:33:08

US3312605

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(2)

Generated On: 26 Nov 2020 10:55:55

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (16C1CAA1-C746-4C21-8AE6-4CD30C39C33C)', Time: '2020-10-10T00:11:17', User OID: 'PatientReportedOutcome (US3312605)', ODM File OID: '3ba96431-f157-4c61-878d-2cd0165dbf2c' User entered 'Yes (Y)'	System	10 Oct 2020 05:11:29
	System	10 Oct 2020 05:11:29

US3312605

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(2)

Generated On: 26 Nov 2020 10:55:55

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (16C1CAA1-C746-4C21-8AE6-4CD30C39C33C)', Time: '2020-10-10T00:11:21', User OID: 'PatientReportedOutcome (US3312605)', ODM File OID: '3ba96431-f157-4c61-878d-2cd0165dbf2c' User entered '97.8'	System	10 Oct 2020 05:11:29
	System	10 Oct 2020 05:11:29

US3312605

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(2)

Generated On: 26 Nov 2020 10:55:55

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (16C1CAA1-C746-4C21-8AE6-4CD30C39C33C)', Time: '2020-10-10T00:11:24', User OID: 'PatientReportedOutcome (US3312605)', ODM File OID: '3ba96431-f157-4c61-878d-2cd0165dbf2c'	System	10 Oct 2020 05:11:29
User entered 'No (N)'	System	10 Oct 2020 05:11:29

**US3312605**

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

**Form: Temperature\_Day(2)**

**Generated On: 26 Nov 2020 10:55:55**

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (16C1CAA1-C746-4C21-8AE6-4CD30C39C33C)', Time: '2020-10-10T00:11:27', User OID: 'PatientReportedOutcome (US3312605)', ODM File OID: '3ba96431-f157-4c61-878d-2cd0165dbf2c' User entered '10 Oct 2020 00:11'	System	10 Oct 2020 05:11:29
	System	10 Oct 2020 05:11:29

**US3312605**

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

**Form: Temperature\_Day(2)**

**Generated On: 26 Nov 2020 10:55:55**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '09 Oct 2020 12:00'	System	08 Oct 2020 19:33:08



**US3312605**

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

**Form: Temperature\_Day(2)**

**Generated On: 26 Nov 2020 10:55:55**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '10 Oct 2020 11:59'	System	08 Oct 2020 19:33:08

**US3312605**

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

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

**Generated On: 26 Nov 2020 10:55:55**

**TIMEPOINT**

Audit	User	Time (GMT)
Data entry locked.	System	08 Oct 2020 19:33:08
User entered 'Day 3'	System	08 Oct 2020 19:33:08

**US3312605**

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

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

**Generated On: 26 Nov 2020 10:55:55**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '10 Oct 2020 12:00'	System	08 Oct 2020 19:33:08

**US3312605**

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

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

**Generated On: 26 Nov 2020 10:55:55**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '11 Oct 2020 11:59'	System	08 Oct 2020 19:33:08

**US3312605**

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

**Form: Temperature\_Day(4)**

**Generated On: 26 Nov 2020 10:55:55**

**TIMEPOINT**

Audit	User	Time (GMT)
Data entry locked.	System	08 Oct 2020 19:33:08
User entered 'Day 4'	System	08 Oct 2020 19:33:08

US3312605

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(4)

Generated On: 26 Nov 2020 10:55:55

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (16C1CAA1-C746-4C21-8AE6-4CD30C39C33C)', Time: '2020-10-12T08:40:32', User OID: 'PatientReportedOutcome (US3312605)', ODM File OID: 'e5216060-8ac8-4b21-8c47-8bc79073fd31'	System	12 Oct 2020 13:40:46
User entered 'Yes (Y)'	System	12 Oct 2020 13:40:46

US3312605

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(4)

Generated On: 26 Nov 2020 10:55:55

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (16C1CAA1-C746-4C21-8AE6-4CD30C39C33C)', Time: '2020-10-12T08:40:37', User OID: 'PatientReportedOutcome (US3312605)', ODM File OID: 'e5216060-8ac8-4b21-8c47-8bc79073fd31'	System	12 Oct 2020 13:40:46
User entered '98.6'	System	12 Oct 2020 13:40:46

US3312605

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(4)

Generated On: 26 Nov 2020 10:55:55

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (16C1CAA1-C746-4C21-8AE6-4CD30C39C33C)', Time: '2020-10-12T08:40:40', User OID: 'PatientReportedOutcome (US3312605)', ODM File OID: 'e5216060-8ac8-4b21-8c47-8bc79073fd31'	System	12 Oct 2020 13:40:46
User entered 'No (N)'	System	12 Oct 2020 13:40:46



**US3312605**

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

**Form: Temperature\_Day(4)**

**Generated On: 26 Nov 2020 10:55:55**

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (16C1CAA1-C746-4C21-8AE6-4CD30C39C33C)', Time: '2020-10-12T08:40:43', User OID: 'PatientReportedOutcome (US3312605)', ODM File OID: 'e5216060-8ac8-4b21-8c47-8bc79073fd31'	System	12 Oct 2020 13:40:46
User entered '12 Oct 2020 08:40'	System	12 Oct 2020 13:40:46

**US3312605**

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

**Form: Temperature\_Day(4)**

**Generated On: 26 Nov 2020 10:55:55**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '11 Oct 2020 12:00'	System	08 Oct 2020 19:33:08

**US3312605**

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

**Form: Temperature\_Day(4)**

**Generated On: 26 Nov 2020 10:55:55**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '12 Oct 2020 11:59'	System	08 Oct 2020 19:33:08

**US3312605**

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

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

**Generated On: 26 Nov 2020 10:55:55**

**TIMEPOINT**

Audit	User	Time (GMT)
Data entry locked.	System	08 Oct 2020 19:33:08
User entered 'Day 5'	System	08 Oct 2020 19:33:08

US3312605

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(5)

Generated On: 26 Nov 2020 10:55:55

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (16C1CAA1-C746-4C21-8AE6-4CD30C39C33C)', Time: '2020-10-12T12:34:10', User OID: 'PatientReportedOutcome (US3312605)', ODM File OID: 'b8517fe9-96b3-4aaa-bfc8-231416098b15'	System	12 Oct 2020 17:34:24
User entered 'Yes (Y)'	System	12 Oct 2020 17:34:24

US3312605

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(5)

Generated On: 26 Nov 2020 10:55:55

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (16C1CAA1-C746-4C21-8AE6-4CD30C39C33C)', Time: '2020-10-12T12:34:15', User OID: 'PatientReportedOutcome (US3312605)', ODM File OID: 'b8517fe9-96b3-4aaa-bfc8-231416098b15'	System	12 Oct 2020 17:34:24
User entered '99.0'	System	12 Oct 2020 17:34:24

US3312605

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(5)

Generated On: 26 Nov 2020 10:55:55

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (16C1CAA1-C746-4C21-8AE6-4CD30C39C33C)', Time: '2020-10-12T12:34:19', User OID: 'PatientReportedOutcome (US3312605)', ODM File OID: 'b8517fe9-96b3-4aaa-bfc8-231416098b15'	System	12 Oct 2020 17:34:24
User entered 'No (N)'	System	12 Oct 2020 17:34:24

**US3312605**

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

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

**Generated On: 26 Nov 2020 10:55:55**

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (16C1CAA1-C746-4C21-8AE6-4CD30C39C33C)', Time: '2020-10-12T12:34:21', User OID: 'PatientReportedOutcome (US3312605)', ODM File OID: 'b8517fe9-96b3-4aaa-bfc8-231416098b15'	System	12 Oct 2020 17:34:24
User entered '12 Oct 2020 12:34'	System	12 Oct 2020 17:34:24



**US3312605**

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

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

**Generated On: 26 Nov 2020 10:55:55**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '12 Oct 2020 12:00'	System	08 Oct 2020 19:33:08

**US3312605**

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

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

**Generated On: 26 Nov 2020 10:55:55**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '13 Oct 2020 11:59'	System	08 Oct 2020 19:33:08

**US3312605**

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

**Form: Temperature\_Day(6)**

**Generated On: 26 Nov 2020 10:55:55**

**TIMEPOINT**

Audit	User	Time (GMT)
Data entry locked.	System	08 Oct 2020 19:33:08
User entered 'Day 6'	System	08 Oct 2020 19:33:08

**US3312605**

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

**Form: Temperature\_Day(6)**

**Generated On: 26 Nov 2020 10:55:55**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '13 Oct 2020 12:00'	System	08 Oct 2020 19:33:08

**US3312605**

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

**Form: Temperature\_Day(6)**

**Generated On: 26 Nov 2020 10:55:55**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '14 Oct 2020 11:59'	System	08 Oct 2020 19:33:08

**US3312605**

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

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

**Generated On: 26 Nov 2020 10:55:55**

**TIMEPOINT**

Audit	User	Time (GMT)
Data entry locked.	System	08 Oct 2020 19:33:08
User entered 'Day 7'	System	08 Oct 2020 19:33:08

US3312605

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(7)

Generated On: 26 Nov 2020 10:55:55

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (16C1CAA1-C746-4C21-8AE6-4CD30C39C33C)', Time: '2020-10-14T12:00:26', User OID: 'PatientReportedOutcome (US3312605)', ODM File OID: '8040ac39-c908-4860-8a0e-8acff32a6efc'	System	14 Oct 2020 17:00:54
User entered 'Yes (Y)'	System	14 Oct 2020 17:00:54

US3312605

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(7)

Generated On: 26 Nov 2020 10:55:55

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (16C1CAA1-C746-4C21-8AE6-4CD30C39C33C)', Time: '2020-10-14T12:00:30', User OID: 'PatientReportedOutcome (US3312605)', ODM File OID: '8040ac39-c908-4860-8a0e-8acff32a6efc' User entered '97.0'	System	14 Oct 2020 17:00:54
	System	14 Oct 2020 17:00:54



US3312605

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(7)

Generated On: 26 Nov 2020 10:55:55

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (16C1CAA1-C746-4C21-8AE6-4CD30C39C33C)', Time: '2020-10-14T12:00:32', User OID: 'PatientReportedOutcome (US3312605)', ODM File OID: '8040ac39-c908-4860-8a0e-8acff32a6efc'	System	14 Oct 2020 17:00:54
User entered 'No (N)'	System	14 Oct 2020 17:00:54

**US3312605**

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

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

**Generated On: 26 Nov 2020 10:55:55**

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (16C1CAA1-C746-4C21-8AE6-4CD30C39C33C)', Time: '2020-10-14T12:00:33', User OID: 'PatientReportedOutcome (US3312605)', ODM File OID: '8040ac39-c908-4860-8a0e-8acff32a6efc' User entered '14 Oct 2020 12:00'	System	14 Oct 2020 17:00:54
	System	14 Oct 2020 17:00:54

**US3312605**

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

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

**Generated On: 26 Nov 2020 10:55:55**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '14 Oct 2020 12:00'	System	08 Oct 2020 19:33:08

**US3312605**

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

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

**Generated On: 26 Nov 2020 10:55:55**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '15 Oct 2020 11:59'	System	08 Oct 2020 19:33:08

**US3312605**

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

**Form: Injection Site\_Day(1/1)**

**Generated On: 26 Nov 2020 10:55:55**

**TIMEPOINT**

Audit	User	Time (GMT)
Data entry locked.	System	08 Oct 2020 19:33:08
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	08 Oct 2020 19:33:08

US3312605

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/1)

Generated On: 26 Nov 2020 10:55:55

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 (16C1CAA1-C746-4C21-8AE6-4CD30C39C33C)', Time: '2020-10-08T15:01:57', User OID: 'PatientReportedOutcome (US3312605)', ODM File OID: '62511d9b-9018-4491-bd69-677a5ddb08f3'	System	08 Oct 2020 20:02:09
User entered 'None (1)'	System	08 Oct 2020 20:02:09

US3312605

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/1)

Generated On: 26 Nov 2020 10:55:55

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (16C1CAA1-C746-4C21-8AE6-4CD30C39C33C)', Time: '2020-10-08T15:01:59', User OID: 'PatientReportedOutcome (US3312605)', ODM File OID: '62511d9b-9018-4491-bd69-677a5ddb08f3'	System	08 Oct 2020 20:02:09
User entered 'No (N)'	System	08 Oct 2020 20:02:09

US3312605

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/1)

Generated On: 26 Nov 2020 10:55:55

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (16C1CAA1-C746-4C21-8AE6-4CD30C39C33C)', Time: '2020-10-08T15:02:01', User OID: 'PatientReportedOutcome (US3312605)', ODM File OID: '62511d9b-9018-4491-bd69-677a5ddb08f3'	System	08 Oct 2020 20:02:09
User entered 'No (N)'	System	08 Oct 2020 20:02:09



US3312605

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/1)

Generated On: 26 Nov 2020 10:55:55

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 (16C1CAA1-C746-4C21-8AE6-4CD30C39C33C)', Time: '2020-10-08T15:02:03', User OID: 'PatientReportedOutcome (US3312605)', ODM File OID: '62511d9b-9018-4491-bd69-677a5ddb08f3'	System	08 Oct 2020 20:02:09
User entered 'None (1)'	System	08 Oct 2020 20:02:09

**US3312605**

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

**Form: Injection Site\_Day(1/1)**

**Generated On: 26 Nov 2020 10:55:55**

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (16C1CAA1-C746-4C21-8AE6-4CD30C39C33C)', Time: '2020-10-08T15:02:05', User OID: 'PatientReportedOutcome (US3312605)', ODM File OID: '62511d9b-9018-4491-bd69-677a5ddb08f3'	System	08 Oct 2020 20:02:09
User entered '08 Oct 2020 15:02'	System	08 Oct 2020 20:02:09

**US3312605**

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

**Form: Injection Site\_Day(1/1)**

**Generated On: 26 Nov 2020 10:55:55**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '08 Oct 2020 14:49'	System	08 Oct 2020 19:33:08

**US3312605**

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

**Form: Injection Site\_Day(1/1)**

**Generated On: 26 Nov 2020 10:55:55**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '08 Oct 2020 17:19'	System	08 Oct 2020 19:33:08

**US3312605**

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

**Form: Injection Site\_Day(1/2)**

**Generated On: 26 Nov 2020 10:55:55**

**TIMEPOINT**

Audit	User	Time (GMT)
Data entry locked.	System	08 Oct 2020 19:33:08
User entered 'Day 1, after vaccination (at home)'	System	08 Oct 2020 19:33:08

US3312605

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/2)

Generated On: 26 Nov 2020 10:55:55

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 (16C1CAA1-C746-4C21-8AE6-4CD30C39C33C)', Time: '2020-10-09T09:37:44', User OID: 'PatientReportedOutcome (US3312605)', ODM File OID: 'b42b2c0d-1652-4122-9fd0-7b5622750f2e'	System	09 Oct 2020 14:37:56
User entered 'None (1)'	System	09 Oct 2020 14:37:56

US3312605

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/2)

Generated On: 26 Nov 2020 10:55:55

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (16C1CAA1-C746-4C21-8AE6-4CD30C39C33C)', Time: '2020-10-09T09:37:46', User OID: 'PatientReportedOutcome (US3312605)', ODM File OID: 'b42b2c0d-1652-4122-9fd0-7b5622750f2e'	System	09 Oct 2020 14:37:56
User entered 'No (N)'	System	09 Oct 2020 14:37:56

US3312605

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/2)

Generated On: 26 Nov 2020 10:55:55

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (16C1CAA1-C746-4C21-8AE6-4CD30C39C33C)', Time: '2020-10-09T09:37:47', User OID: 'PatientReportedOutcome (US3312605)', ODM File OID: 'b42b2c0d-1652-4122-9fd0-7b5622750f2e'	System	09 Oct 2020 14:37:56
User entered 'No (N)'	System	09 Oct 2020 14:37:56



US3312605

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/2)

Generated On: 26 Nov 2020 10:55:55

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 (16C1CAA1-C746-4C21-8AE6-4CD30C39C33C)', Time: '2020-10-09T09:37:49', User OID: 'PatientReportedOutcome (US3312605)', ODM File OID: 'b42b2c0d-1652-4122-9fd0-7b5622750f2e' User entered 'None (1)'	System	09 Oct 2020 14:37:56
	System	09 Oct 2020 14:37:56

**US3312605**

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

**Form: Injection Site\_Day(1/2)**

**Generated On: 26 Nov 2020 10:55:55**

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (16C1CAA1-C746-4C21-8AE6-4CD30C39C33C)', Time: '2020-10-09T09:37:51', User OID: 'PatientReportedOutcome (US3312605)', ODM File OID: 'b42b2c0d-1652-4122-9fd0-7b5622750f2e' User entered '09 Oct 2020 09:37'	System	09 Oct 2020 14:37:56
	System	09 Oct 2020 14:37:56

**US3312605**

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

**Form: Injection Site\_Day(1/2)**

**Generated On: 26 Nov 2020 10:55:55**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '08 Oct 2020 18:14'	System	08 Oct 2020 19:33:08

**US3312605**

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

**Form: Injection Site\_Day(1/2)**

**Generated On: 26 Nov 2020 10:55:55**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '09 Oct 2020 11:59'	System	08 Oct 2020 19:33:08

**US3312605**

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

**Form: Injection Site\_Day(2)**

**Generated On: 26 Nov 2020 10:55:55**

**TIMEPOINT**

Audit	User	Time (GMT)
Data entry locked.	System	08 Oct 2020 19:33:08
User entered 'Day 2'	System	08 Oct 2020 19:33:08

US3312605

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(2)

Generated On: 26 Nov 2020 10:55:55

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 (16C1CAA1-C746-4C21-8AE6-4CD30C39C33C)', Time: '2020-10-10T00:11:29', User OID: 'PatientReportedOutcome (US3312605)', ODM File OID: 'a024535c-b9be-4937-b2ee-2acb91fde7a1'	System	10 Oct 2020 05:11:42
User entered 'None (1)'	System	10 Oct 2020 05:11:42

US3312605

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(2)

Generated On: 26 Nov 2020 10:55:55

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (16C1CAA1-C746-4C21-8AE6-4CD30C39C33C)', Time: '2020-10-10T00:11:32', User OID: 'PatientReportedOutcome (US3312605)', ODM File OID: 'a024535c-b9be-4937-b2ee-2acb91fde7a1'	System	10 Oct 2020 05:11:42
User entered 'No (N)'	System	10 Oct 2020 05:11:42

**US3312605**

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

**Form: Injection Site\_Day(2)**

**Generated On: 26 Nov 2020 10:55:55**

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (16C1CAA1-C746-4C21-8AE6-4CD30C39C33C)', Time: '2020-10-10T00:11:34', User OID: 'PatientReportedOutcome (US3312605)', ODM File OID: 'a024535c-b9be-4937-b2ee-2acb91fde7a1'	System	10 Oct 2020 05:11:42
User entered 'No (N)'	System	10 Oct 2020 05:11:42



US3312605

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(2)

Generated On: 26 Nov 2020 10:55:55

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 (16C1CAA1-C746-4C21-8AE6-4CD30C39C33C)', Time: '2020-10-10T00:11:35', User OID: 'PatientReportedOutcome (US3312605)', ODM File OID: 'a024535c-b9be-4937-b2ee-2acb91fde7a1'	System	10 Oct 2020 05:11:42
User entered 'None (1)'	System	10 Oct 2020 05:11:42

**US3312605**

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

**Form: Injection Site\_Day(2)**

**Generated On: 26 Nov 2020 10:55:55**

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (16C1CAA1-C746-4C21-8AE6-4CD30C39C33C)', Time: '2020-10-10T00:11:38', User OID: 'PatientReportedOutcome (US3312605)', ODM File OID: 'a024535c-b9be-4937-b2ee-2acb91fde7a1' User entered '10 Oct 2020 00:11'	System	10 Oct 2020 05:11:42
	System	10 Oct 2020 05:11:42

**US3312605**

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

**Form: Injection Site\_Day(2)**

**Generated On: 26 Nov 2020 10:55:55**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '09 Oct 2020 12:00'	System	08 Oct 2020 19:33:08

**US3312605**

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

**Form: Injection Site\_Day(2)**

**Generated On: 26 Nov 2020 10:55:55**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '10 Oct 2020 11:59'	System	08 Oct 2020 19:33:08

**US3312605**

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

**Form: Injection Site\_Day(3)**

**Generated On: 26 Nov 2020 10:55:55**

**TIMEPOINT**

Audit	User	Time (GMT)
Data entry locked.	System	08 Oct 2020 19:33:08
User entered 'Day 3'	System	08 Oct 2020 19:33:08

**US3312605**

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

**Form: Injection Site\_Day(3)**

**Generated On: 26 Nov 2020 10:55:55**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '10 Oct 2020 12:00'	System	08 Oct 2020 19:33:08

**US3312605**

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

**Form: Injection Site\_Day(3)**

**Generated On: 26 Nov 2020 10:55:55**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '11 Oct 2020 11:59'	System	08 Oct 2020 19:33:08

**US3312605**

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

**Form: Injection Site\_Day(4)**

**Generated On: 26 Nov 2020 10:55:55**

**TIMEPOINT**

Audit	User	Time (GMT)
Data entry locked.	System	08 Oct 2020 19:33:08
User entered 'Day 4'	System	08 Oct 2020 19:33:08



US3312605

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(4)

Generated On: 26 Nov 2020 10:55:55

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 (16C1CAA1-C746-4C21-8AE6-4CD30C39C33C)', Time: '2020-10-12T08:40:14', User OID: 'PatientReportedOutcome (US3312605)', ODM File OID: '7b683b3f-86ca-4609-9278-88c1c39fe63d'	System	12 Oct 2020 13:40:30
User entered 'None (1)'	System	12 Oct 2020 13:40:30

US3312605

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(4)

Generated On: 26 Nov 2020 10:55:55

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (16C1CAA1-C746-4C21-8AE6-4CD30C39C33C)', Time: '2020-10-12T08:40:16', User OID: 'PatientReportedOutcome (US3312605)', ODM File OID: '7b683b3f-86ca-4609-9278-88c1c39fe63d'	System	12 Oct 2020 13:40:30
User entered 'No (N)'	System	12 Oct 2020 13:40:30

US3312605

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(4)

Generated On: 26 Nov 2020 10:55:55

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (16C1CAA1-C746-4C21-8AE6-4CD30C39C33C)', Time: '2020-10-12T08:40:19', User OID: 'PatientReportedOutcome (US3312605)', ODM File OID: '7b683b3f-86ca-4609-9278-88c1c39fe63d'	System	12 Oct 2020 13:40:30
User entered 'No (N)'	System	12 Oct 2020 13:40:30

US3312605

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(4)

Generated On: 26 Nov 2020 10:55:55

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 (16C1CAA1-C746-4C21-8AE6-4CD30C39C33C)', Time: '2020-10-12T08:40:26', User OID: 'PatientReportedOutcome (US3312605)', ODM File OID: '7b683b3f-86ca-4609-9278-88c1c39fe63d'	System	12 Oct 2020 13:40:30
User entered 'None (1)'	System	12 Oct 2020 13:40:30

**US3312605**

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

**Form: Injection Site\_Day(4)**

**Generated On: 26 Nov 2020 10:55:55**

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (16C1CAA1-C746-4C21-8AE6-4CD30C39C33C)', Time: '2020-10-12T08:40:28', User OID: 'PatientReportedOutcome (US3312605)', ODM File OID: '7b683b3f-86ca-4609-9278-88c1c39fe63d' User entered '12 Oct 2020 08:40'	System	12 Oct 2020 13:40:30
	System	12 Oct 2020 13:40:30

**US3312605**

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

**Form: Injection Site\_Day(4)**

**Generated On: 26 Nov 2020 10:55:55**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '11 Oct 2020 12:00'	System	08 Oct 2020 19:33:08

**US3312605**

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

**Form: Injection Site\_Day(4)**

**Generated On: 26 Nov 2020 10:55:55**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '12 Oct 2020 11:59'	System	08 Oct 2020 19:33:08

**US3312605**

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

**Form: Injection Site\_Day(5)**

**Generated On: 26 Nov 2020 10:55:55**

**TIMEPOINT**

Audit	User	Time (GMT)
Data entry locked.	System	08 Oct 2020 19:33:08
User entered 'Day 5'	System	08 Oct 2020 19:33:08



US3312605

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(5)

Generated On: 26 Nov 2020 10:55:55

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 (16C1CAA1-C746-4C21-8AE6-4CD30C39C33C)', Time: '2020-10-12T12:34:39', User OID: 'PatientReportedOutcome (US3312605)', ODM File OID: '31430708-8daa-41df-a76c-076d9e44164e'	System	12 Oct 2020 17:34:49
User entered 'None (1)'	System	12 Oct 2020 17:34:49

US3312605

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(5)

Generated On: 26 Nov 2020 10:55:55

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (16C1CAA1-C746-4C21-8AE6-4CD30C39C33C)', Time: '2020-10-12T12:34:41', User OID: 'PatientReportedOutcome (US3312605)', ODM File OID: '31430708-8daa-41df-a76c-076d9e44164e'	System	12 Oct 2020 17:34:49
User entered 'No (N)'	System	12 Oct 2020 17:34:49

US3312605

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(5)

Generated On: 26 Nov 2020 10:55:55

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (16C1CAA1-C746-4C21-8AE6-4CD30C39C33C)', Time: '2020-10-12T12:34:43', User OID: 'PatientReportedOutcome (US3312605)', ODM File OID: '31430708-8daa-41df-a76c-076d9e44164e'	System	12 Oct 2020 17:34:49
User entered 'No (N)'	System	12 Oct 2020 17:34:49

US3312605

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(5)

Generated On: 26 Nov 2020 10:55:55

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 (16C1CAA1-C746-4C21-8AE6-4CD30C39C33C)', Time: '2020-10-12T12:34:44', User OID: 'PatientReportedOutcome (US3312605)', ODM File OID: '31430708-8daa-41df-a76c-076d9e44164e' User entered 'None (1)'	System	12 Oct 2020 17:34:49
	System	12 Oct 2020 17:34:49

**US3312605**

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

**Form: Injection Site\_Day(5)**

**Generated On: 26 Nov 2020 10:55:55**

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (16C1CAA1-C746-4C21-8AE6-4CD30C39C33C)', Time: '2020-10-12T12:34:46', User OID: 'PatientReportedOutcome (US3312605)', ODM File OID: '31430708-8daa-41df-a76c-076d9e44164e' User entered '12 Oct 2020 12:34'	System	12 Oct 2020 17:34:49
	System	12 Oct 2020 17:34:49

**US3312605**

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

**Form: Injection Site\_Day(5)**

**Generated On: 26 Nov 2020 10:55:55**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '12 Oct 2020 12:00'	System	08 Oct 2020 19:33:08

**US3312605**

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

**Form: Injection Site\_Day(5)**

**Generated On: 26 Nov 2020 10:55:55**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '13 Oct 2020 11:59'	System	08 Oct 2020 19:33:08

**US3312605**

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

**Form: Injection Site\_Day(6)**

**Generated On: 26 Nov 2020 10:55:55**

**TIMEPOINT**

Audit	User	Time (GMT)
Data entry locked.	System	08 Oct 2020 19:33:08
User entered 'Day 6'	System	08 Oct 2020 19:33:08



**US3312605**

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

**Form: Injection Site\_Day(6)**

**Generated On: 26 Nov 2020 10:55:55**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '13 Oct 2020 12:00'	System	08 Oct 2020 19:33:08

**US3312605**

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

**Form: Injection Site\_Day(6)**

**Generated On: 26 Nov 2020 10:55:55**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '14 Oct 2020 11:59'	System	08 Oct 2020 19:33:08

**US3312605**

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

**Form: Injection Site\_Day(7)**

**Generated On: 26 Nov 2020 10:55:55**

**TIMEPOINT**

Audit	User	Time (GMT)
Data entry locked.	System	08 Oct 2020 19:33:08
User entered 'Day 7'	System	08 Oct 2020 19:33:08

US3312605

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(7)

Generated On: 26 Nov 2020 10:55:55

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 (16C1CAA1-C746-4C21-8AE6-4CD30C39C33C)', Time: '2020-10-14T12:00:36', User OID: 'PatientReportedOutcome (US3312605)', ODM File OID: 'f3df480f-3e47-421a-9e5a-4f850d80640a'	System	14 Oct 2020 17:01:08
User entered 'None (1)'	System	14 Oct 2020 17:01:08

US3312605

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(7)

Generated On: 26 Nov 2020 10:55:55

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (16C1CAA1-C746-4C21-8AE6-4CD30C39C33C)', Time: '2020-10-14T12:00:38', User OID: 'PatientReportedOutcome (US3312605)', ODM File OID: 'f3df480f-3e47-421a-9e5a-4f850d80640a'	System	14 Oct 2020 17:01:08
User entered 'No (N)'	System	14 Oct 2020 17:01:08

US3312605

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(7)

Generated On: 26 Nov 2020 10:55:55

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (16C1CAA1-C746-4C21-8AE6-4CD30C39C33C)', Time: '2020-10-14T12:00:39', User OID: 'PatientReportedOutcome (US3312605)', ODM File OID: 'f3df480f-3e47-421a-9e5a-4f850d80640a'	System	14 Oct 2020 17:01:08
User entered 'No (N)'	System	14 Oct 2020 17:01:08

US3312605

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(7)

Generated On: 26 Nov 2020 10:55:55

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 (16C1CAA1-C746-4C21-8AE6-4CD30C39C33C)', Time: '2020-10-14T12:00:40', User OID: 'PatientReportedOutcome (US3312605)', ODM File OID: 'f3df480f-3e47-421a-9e5a-4f850d80640a' User entered 'None (1)'	System	14 Oct 2020 17:01:08
	System	14 Oct 2020 17:01:08

**US3312605**

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

**Form: Injection Site\_Day(7)**

**Generated On: 26 Nov 2020 10:55:55**

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (16C1CAA1-C746-4C21-8AE6-4CD30C39C33C)', Time: '2020-10-14T12:00:42', User OID: 'PatientReportedOutcome (US3312605)', ODM File OID: 'f3df480f-3e47-421a-9e5a-4f850d80640a' User entered '14 Oct 2020 12:00'	System	14 Oct 2020 17:01:08
	System	14 Oct 2020 17:01:08



**US3312605**

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

**Form: Injection Site\_Day(7)**

**Generated On: 26 Nov 2020 10:55:55**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '14 Oct 2020 12:00'	System	08 Oct 2020 19:33:08

**US3312605**

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

**Form: Injection Site\_Day(7)**

**Generated On: 26 Nov 2020 10:55:55**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '15 Oct 2020 11:59'	System	08 Oct 2020 19:33:08

**US3312605**

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

**Form: General\_Day(1/1)**

**Generated On: 26 Nov 2020 10:55:55**

**TIMEPOINT**

Audit	User	Time (GMT)
Data entry locked.	System	08 Oct 2020 19:33:08
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	08 Oct 2020 19:33:08

**US3312605**

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

**Form: General\_Day(1/1)**

**Generated On: 26 Nov 2020 10:55:55**

**HEADACHE**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (16C1CAA1-C746-4C21-8AE6-4CD30C39C33C)', Time: '2020-10-08T15:02:07', User OID: 'PatientReportedOutcome (US3312605)', ODM File OID: 'c530d4b2-9753-47e8-961f-e79cfb727375'	System	08 Oct 2020 20:02:24
User entered 'None (0)'	System	08 Oct 2020 20:02:24

**US3312605**

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

**Form: General\_Day(1/1)**

**Generated On: 26 Nov 2020 10:55:55**

**FATIGUE**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (16C1CAA1-C746-4C21-8AE6-4CD30C39C33C)', Time: '2020-10-08T15:02:09', User OID: 'PatientReportedOutcome (US3312605)', ODM File OID: 'c530d4b2-9753-47e8-961f-e79cfb727375'	System	08 Oct 2020 20:02:24
User entered 'None (0)'	System	08 Oct 2020 20:02:24

**US3312605**

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

**Form: General\_Day(1/1)**

**Generated On: 26 Nov 2020 10:55:55**

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (16C1CAA1-C746-4C21-8AE6-4CD30C39C33C)', Time: '2020-10-08T15:02:10', User OID: 'PatientReportedOutcome (US3312605)', ODM File OID: 'c530d4b2-9753-47e8-961f-e79cfb727375'	System	08 Oct 2020 20:02:24
User entered 'None (0)'	System	08 Oct 2020 20:02:24

**US3312605**

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

**Form: General\_Day(1/1)**

**Generated On: 26 Nov 2020 10:55:55**

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (16C1CAA1-C746-4C21-8AE6-4CD30C39C33C)', Time: '2020-10-08T15:02:12', User OID: 'PatientReportedOutcome (US3312605)', ODM File OID: 'c530d4b2-9753-47e8-961f-e79cfb727375'	System	08 Oct 2020 20:02:24
User entered 'None (0)'	System	08 Oct 2020 20:02:24

**US3312605**

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

**Form: General\_Day(1/1)**

**Generated On: 26 Nov 2020 10:55:55**

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (16C1CAA1-C746-4C21-8AE6-4CD30C39C33C)', Time: '2020-10-08T15:02:13', User OID: 'PatientReportedOutcome (US3312605)', ODM File OID: 'c530d4b2-9753-47e8-961f-e79cfb727375'	System	08 Oct 2020 20:02:24
User entered 'None (0)'	System	08 Oct 2020 20:02:24



**US3312605**

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

**Form: General\_Day(1/1)**

**Generated On: 26 Nov 2020 10:55:55**

**CHILLS**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (16C1CAA1-C746-4C21-8AE6-4CD30C39C33C)', Time: '2020-10-08T15:02:14', User OID: 'PatientReportedOutcome (US3312605)', ODM File OID: 'c530d4b2-9753-47e8-961f-e79cfb727375'	System	08 Oct 2020 20:02:24
User entered 'None (0)'	System	08 Oct 2020 20:02:24

US3312605

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 26 Nov 2020 10:55:55

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 (16C1CAA1-C746-4C21-8AE6-4CD30C39C33C)', Time: '2020-10-08T15:02:18', User OID: 'PatientReportedOutcome (US3312605)', ODM File OID: 'c530d4b2-9753-47e8-961f-e79cfb727375'	System	08 Oct 2020 20:02:24
User entered 'No (N)'	System	08 Oct 2020 20:02:24

**US3312605**

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

**Form: General\_Day(1/1)**

**Generated On: 26 Nov 2020 10:55:55**

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (16C1CAA1-C746-4C21-8AE6-4CD30C39C33C)', Time: '2020-10-08T15:02:22', User OID: 'PatientReportedOutcome (US3312605)', ODM File OID: 'c530d4b2-9753-47e8-961f-e79cfb727375' User entered '08 Oct 2020 15:02'	System	08 Oct 2020 20:02:24
	System	08 Oct 2020 20:02:24

**US3312605**

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

**Form: General\_Day(1/1)**

**Generated On: 26 Nov 2020 10:55:55**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '08 Oct 2020 14:49'	System	08 Oct 2020 19:33:08

**US3312605**

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

**Form: General\_Day(1/1)**

**Generated On: 26 Nov 2020 10:55:55**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '08 Oct 2020 17:19'	System	08 Oct 2020 19:33:08

**US3312605**

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

**Form: General\_Day(1/2)**

**Generated On: 26 Nov 2020 10:55:55**

**TIMEPOINT**

Audit	User	Time (GMT)
Data entry locked.	System	08 Oct 2020 19:33:08
User entered 'Day 1, after vaccination (at home)'	System	08 Oct 2020 19:33:08

**US3312605**

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

**Form: General\_Day(1/2)**

**Generated On: 26 Nov 2020 10:55:55**

**HEADACHE**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (16C1CAA1-C746-4C21-8AE6-4CD30C39C33C)', Time: '2020-10-09T09:37:56', User OID: 'PatientReportedOutcome (US3312605)', ODM File OID: 'c3edfc34-c8a9-4a2b-908f-42a25c31d92a'	System	09 Oct 2020 14:38:13
User entered 'None (0)'	System	09 Oct 2020 14:38:13

**US3312605**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(1/2)**

**Generated On: 26 Nov 2020 10:55:55**

**FATIGUE**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (16C1CAA1-C746-4C21-8AE6-4CD30C39C33C)', Time: '2020-10-09T09:37:58', User OID: 'PatientReportedOutcome (US3312605)', ODM File OID: 'c3edfc34-c8a9-4a2b-908f-42a25c31d92a'	System	09 Oct 2020 14:38:13
User entered 'None (0)'	System	09 Oct 2020 14:38:13



**US3312605**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(1/2)**

**Generated On: 26 Nov 2020 10:55:55**

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (16C1CAA1-C746-4C21-8AE6-4CD30C39C33C)', Time: '2020-10-09T09:37:59', User OID: 'PatientReportedOutcome (US3312605)', ODM File OID: 'c3edfc34-c8a9-4a2b-908f-42a25c31d92a'	System	09 Oct 2020 14:38:13
User entered 'None (0)'	System	09 Oct 2020 14:38:13

US3312605

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 26 Nov 2020 10:55:55

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (16C1CAA1-C746-4C21-8AE6-4CD30C39C33C)', Time: '2020-10-09T09:38:00', User OID: 'PatientReportedOutcome (US3312605)', ODM File OID: 'c3edfc34-c8a9-4a2b-908f-42a25c31d92a'	System	09 Oct 2020 14:38:13
User entered 'None (0)'	System	09 Oct 2020 14:38:13

**US3312605**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(1/2)**

**Generated On: 26 Nov 2020 10:55:55**

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (16C1CAA1-C746-4C21-8AE6-4CD30C39C33C)', Time: '2020-10-09T09:38:01', User OID: 'PatientReportedOutcome (US3312605)', ODM File OID: 'c3edfc34-c8a9-4a2b-908f-42a25c31d92a'	System	09 Oct 2020 14:38:13
User entered 'None (0)'	System	09 Oct 2020 14:38:13

**US3312605**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(1/2)**

**Generated On: 26 Nov 2020 10:55:55**

**CHILLS**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (16C1CAA1-C746-4C21-8AE6-4CD30C39C33C)', Time: '2020-10-09T09:38:02', User OID: 'PatientReportedOutcome (US3312605)', ODM File OID: 'c3edfc34-c8a9-4a2b-908f-42a25c31d92a'	System	09 Oct 2020 14:38:13
User entered 'None (0)'	System	09 Oct 2020 14:38:13

US3312605

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 26 Nov 2020 10:55:55

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 (16C1CAA1-C746-4C21-8AE6-4CD30C39C33C)', Time: '2020-10-09T09:38:05', User OID: 'PatientReportedOutcome (US3312605)', ODM File OID: 'c3edfc34-c8a9-4a2b-908f-42a25c31d92a'	System	09 Oct 2020 14:38:13
User entered 'No (N)'	System	09 Oct 2020 14:38:13

**US3312605**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(1/2)**

**Generated On: 26 Nov 2020 10:55:55**

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (16C1CAA1-C746-4C21-8AE6-4CD30C39C33C)', Time: '2020-10-09T09:38:10', User OID: 'PatientReportedOutcome (US3312605)', ODM File OID: 'c3edfc34-c8a9-4a2b-908f-42a25c31d92a' User entered '09 Oct 2020 09:38'	System	09 Oct 2020 14:38:13
	System	09 Oct 2020 14:38:13

**US3312605**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(1/2)**

**Generated On: 26 Nov 2020 10:55:55**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '08 Oct 2020 18:14'	System	08 Oct 2020 19:33:08

**US3312605**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(1/2)**

**Generated On: 26 Nov 2020 10:55:55**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '09 Oct 2020 11:59'	System	08 Oct 2020 19:33:08



**US3312605**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(2)**

**Generated On: 26 Nov 2020 10:55:55**

**TIMEPOINT**

Audit	User	Time (GMT)
Data entry locked.	System	08 Oct 2020 19:33:08
User entered 'Day 2'	System	08 Oct 2020 19:33:08

**US3312605**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(2)**

**Generated On: 26 Nov 2020 10:55:55**

**HEADACHE**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (16C1CAA1-C746-4C21-8AE6-4CD30C39C33C)', Time: '2020-10-10T00:11:41', User OID: 'PatientReportedOutcome (US3312605)', ODM File OID: '8f80559f-75c5-4db5-9e48-025c3d0f8f0b'	System	10 Oct 2020 05:11:55
User entered 'None (0)'	System	10 Oct 2020 05:11:55

**US3312605**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(2)**

**Generated On: 26 Nov 2020 10:55:55**

**FATIGUE**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (16C1CAA1-C746-4C21-8AE6-4CD30C39C33C)', Time: '2020-10-10T00:11:42', User OID: 'PatientReportedOutcome (US3312605)', ODM File OID: '8f80559f-75c5-4db5-9e48-025c3d0f8f0b'	System	10 Oct 2020 05:11:55
User entered 'None (0)'	System	10 Oct 2020 05:11:55

US3312605

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 26 Nov 2020 10:55:55

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (16C1CAA1-C746-4C21-8AE6-4CD30C39C33C)', Time: '2020-10-10T00:11:43', User OID: 'PatientReportedOutcome (US3312605)', ODM File OID: '8f80559f-75c5-4db5-9e48-025c3d0f8f0b'	System	10 Oct 2020 05:11:55
User entered 'None (0)'	System	10 Oct 2020 05:11:55

**US3312605**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(2)**

**Generated On: 26 Nov 2020 10:55:55**

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (16C1CAA1-C746-4C21-8AE6-4CD30C39C33C)', Time: '2020-10-10T00:11:44', User OID: 'PatientReportedOutcome (US3312605)', ODM File OID: '8f80559f-75c5-4db5-9e48-025c3d0f8f0b'	System	10 Oct 2020 05:11:55
User entered 'None (0)'	System	10 Oct 2020 05:11:55

**US3312605**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(2)**

**Generated On: 26 Nov 2020 10:55:55**

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (16C1CAA1-C746-4C21-8AE6-4CD30C39C33C)', Time: '2020-10-10T00:11:46', User OID: 'PatientReportedOutcome (US3312605)', ODM File OID: '8f80559f-75c5-4db5-9e48-025c3d0f8f0b'	System	10 Oct 2020 05:11:55
User entered 'None (0)'	System	10 Oct 2020 05:11:55

**US3312605**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(2)**

**Generated On: 26 Nov 2020 10:55:55**

**CHILLS**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (16C1CAA1-C746-4C21-8AE6-4CD30C39C33C)', Time: '2020-10-10T00:11:48', User OID: 'PatientReportedOutcome (US3312605)', ODM File OID: '8f80559f-75c5-4db5-9e48-025c3d0f8f0b'	System	10 Oct 2020 05:11:55
User entered 'None (0)'	System	10 Oct 2020 05:11:55

US3312605

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 26 Nov 2020 10:55:55

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 (16C1CAA1-C746-4C21-8AE6-4CD30C39C33C)', Time: '2020-10-10T00:11:50', User OID: 'PatientReportedOutcome (US3312605)', ODM File OID: '8f80559f-75c5-4db5-9e48-025c3d0f8f0b'	System	10 Oct 2020 05:11:55
User entered 'No (N)'	System	10 Oct 2020 05:11:55



**US3312605**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(2)**

**Generated On: 26 Nov 2020 10:55:55**

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (16C1CAA1-C746-4C21-8AE6-4CD30C39C33C)', Time: '2020-10-10T00:11:53', User OID: 'PatientReportedOutcome (US3312605)', ODM File OID: '8f80559f-75c5-4db5-9e48-025c3d0f8f0b' User entered '10 Oct 2020 00:11'	System	10 Oct 2020 05:11:55
	System	10 Oct 2020 05:11:55

**US3312605**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(2)**

**Generated On: 26 Nov 2020 10:55:55**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '09 Oct 2020 12:00'	System	08 Oct 2020 19:33:08

**US3312605**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(2)**

**Generated On: 26 Nov 2020 10:55:55**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '10 Oct 2020 11:59'	System	08 Oct 2020 19:33:08

**US3312605**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(3)**

**Generated On: 26 Nov 2020 10:55:55**

**TIMEPOINT**

Audit	User	Time (GMT)
Data entry locked.	System	08 Oct 2020 19:33:08
User entered 'Day 3'	System	08 Oct 2020 19:33:08

**US3312605**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(3)**

**Generated On: 26 Nov 2020 10:55:55**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '10 Oct 2020 12:00'	System	08 Oct 2020 19:33:08

**US3312605**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(3)**

**Generated On: 26 Nov 2020 10:55:55**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '11 Oct 2020 11:59'	System	08 Oct 2020 19:33:08

**US3312605**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(4)**

**Generated On: 26 Nov 2020 10:55:55**

**TIMEPOINT**

Audit	User	Time (GMT)
Data entry locked.	System	08 Oct 2020 19:33:08
User entered 'Day 4'	System	08 Oct 2020 19:33:08

**US3312605**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(4)**

**Generated On: 26 Nov 2020 10:55:55**

**HEADACHE**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (16C1CAA1-C746-4C21-8AE6-4CD30C39C33C)', Time: '2020-10-12T08:39:58', User OID: 'PatientReportedOutcome (US3312605)', ODM File OID: '8822799d-f80f-413c-b98d-2bdedd229daa'	System	12 Oct 2020 13:40:13
User entered 'None (0)'	System	12 Oct 2020 13:40:13



**US3312605**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(4)**

**Generated On: 26 Nov 2020 10:55:55**

**FATIGUE**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (16C1CAA1-C746-4C21-8AE6-4CD30C39C33C)', Time: '2020-10-12T08:40:00', User OID: 'PatientReportedOutcome (US3312605)', ODM File OID: '8822799d-f80f-413c-b98d-2bdedd229daa'	System	12 Oct 2020 13:40:13
User entered 'None (0)'	System	12 Oct 2020 13:40:13

US3312605

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 26 Nov 2020 10:55:55

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (16C1CAA1-C746-4C21-8AE6-4CD30C39C33C)', Time: '2020-10-12T08:40:03', User OID: 'PatientReportedOutcome (US3312605)', ODM File OID: '8822799d-f80f-413c-b98d-2bdedd229daa'	System	12 Oct 2020 13:40:13
User entered 'None (0)'	System	12 Oct 2020 13:40:13

US3312605

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 26 Nov 2020 10:55:55

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (16C1CAA1-C746-4C21-8AE6-4CD30C39C33C)', Time: '2020-10-12T08:40:04', User OID: 'PatientReportedOutcome (US3312605)', ODM File OID: '8822799d-f80f-413c-b98d-2bdedd229daa'	System	12 Oct 2020 13:40:13
User entered 'None (0)'	System	12 Oct 2020 13:40:13

**US3312605**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(4)**

**Generated On: 26 Nov 2020 10:55:55**

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (16C1CAA1-C746-4C21-8AE6-4CD30C39C33C)', Time: '2020-10-12T08:40:06', User OID: 'PatientReportedOutcome (US3312605)', ODM File OID: '8822799d-f80f-413c-b98d-2bdedd229daa'	System	12 Oct 2020 13:40:13
User entered 'None (0)'	System	12 Oct 2020 13:40:13

**US3312605**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(4)**

**Generated On: 26 Nov 2020 10:55:55**

**CHILLS**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (16C1CAA1-C746-4C21-8AE6-4CD30C39C33C)', Time: '2020-10-12T08:40:07', User OID: 'PatientReportedOutcome (US3312605)', ODM File OID: '8822799d-f80f-413c-b98d-2bdedd229daa'	System	12 Oct 2020 13:40:13
User entered 'None (0)'	System	12 Oct 2020 13:40:13

US3312605

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 26 Nov 2020 10:55:55

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 (16C1CAA1-C746-4C21-8AE6-4CD30C39C33C)', Time: '2020-10-12T08:40:10', User OID: 'PatientReportedOutcome (US3312605)', ODM File OID: '8822799d-f80f-413c-b98d-2bdedd229daa'	System	12 Oct 2020 13:40:13
User entered 'No (N)'	System	12 Oct 2020 13:40:13

**US3312605**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(4)**

**Generated On: 26 Nov 2020 10:55:55**

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (16C1CAA1-C746-4C21-8AE6-4CD30C39C33C)', Time: '2020-10-12T08:40:11', User OID: 'PatientReportedOutcome (US3312605)', ODM File OID: '8822799d-f80f-413c-b98d-2bdedd229daa'	System	12 Oct 2020 13:40:13
User entered '12 Oct 2020 08:40'	System	12 Oct 2020 13:40:13

**US3312605**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(4)**

**Generated On: 26 Nov 2020 10:55:55**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '11 Oct 2020 12:00'	System	08 Oct 2020 19:33:08



**US3312605**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(4)**

**Generated On: 26 Nov 2020 10:55:55**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '12 Oct 2020 11:59'	System	08 Oct 2020 19:33:08

**US3312605**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(5)**

**Generated On: 26 Nov 2020 10:55:55**

**TIMEPOINT**

Audit	User	Time (GMT)
Data entry locked.	System	08 Oct 2020 19:33:08
User entered 'Day 5'	System	08 Oct 2020 19:33:08

**US3312605**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(5)**

**Generated On: 26 Nov 2020 10:55:55**

**HEADACHE**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (16C1CAA1-C746-4C21-8AE6-4CD30C39C33C)', Time: '2020-10-12T12:34:24', User OID: 'PatientReportedOutcome (US3312605)', ODM File OID: '21dc775c-1836-4a8c-81b9-96066bee1ac2'	System	12 Oct 2020 17:34:39
User entered 'None (0)'	System	12 Oct 2020 17:34:39

**US3312605**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(5)**

**Generated On: 26 Nov 2020 10:55:55**

**FATIGUE**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (16C1CAA1-C746-4C21-8AE6-4CD30C39C33C)', Time: '2020-10-12T12:34:26', User OID: 'PatientReportedOutcome (US3312605)', ODM File OID: '21dc775c-1836-4a8c-81b9-96066bee1ac2'	System	12 Oct 2020 17:34:39
User entered 'None (0)'	System	12 Oct 2020 17:34:39

**US3312605**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(5)**

**Generated On: 26 Nov 2020 10:55:55**

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (16C1CAA1-C746-4C21-8AE6-4CD30C39C33C)', Time: '2020-10-12T12:34:27', User OID: 'PatientReportedOutcome (US3312605)', ODM File OID: '21dc775c-1836-4a8c-81b9-96066bee1ac2'	System	12 Oct 2020 17:34:39
User entered 'None (0)'	System	12 Oct 2020 17:34:39

**US3312605**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(5)**

**Generated On: 26 Nov 2020 10:55:55**

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (16C1CAA1-C746-4C21-8AE6-4CD30C39C33C)', Time: '2020-10-12T12:34:28', User OID: 'PatientReportedOutcome (US3312605)', ODM File OID: '21dc775c-1836-4a8c-81b9-96066bee1ac2'	System	12 Oct 2020 17:34:39
User entered 'None (0)'	System	12 Oct 2020 17:34:39

**US3312605**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(5)**

**Generated On: 26 Nov 2020 10:55:55**

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (16C1CAA1-C746-4C21-8AE6-4CD30C39C33C)', Time: '2020-10-12T12:34:30', User OID: 'PatientReportedOutcome (US3312605)', ODM File OID: '21dc775c-1836-4a8c-81b9-96066bee1ac2'	System	12 Oct 2020 17:34:39
User entered 'None (0)'	System	12 Oct 2020 17:34:39

**US3312605**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(5)**

**Generated On: 26 Nov 2020 10:55:55**

**CHILLS**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (16C1CAA1-C746-4C21-8AE6-4CD30C39C33C)', Time: '2020-10-12T12:34:32', User OID: 'PatientReportedOutcome (US3312605)', ODM File OID: '21dc775c-1836-4a8c-81b9-96066bee1ac2'	System	12 Oct 2020 17:34:39
User entered 'None (0)'	System	12 Oct 2020 17:34:39



US3312605

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 26 Nov 2020 10:55:55

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 (16C1CAA1-C746-4C21-8AE6-4CD30C39C33C)', Time: '2020-10-12T12:34:35', User OID: 'PatientReportedOutcome (US3312605)', ODM File OID: '21dc775c-1836-4a8c-81b9-96066bee1ac2'	System	12 Oct 2020 17:34:39
User entered 'No (N)'	System	12 Oct 2020 17:34:39

**US3312605**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(5)**

**Generated On: 26 Nov 2020 10:55:55**

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (16C1CAA1-C746-4C21-8AE6-4CD30C39C33C)', Time: '2020-10-12T12:34:37', User OID: 'PatientReportedOutcome (US3312605)', ODM File OID: '21dc775c-1836-4a8c-81b9-96066bee1ac2'	System	12 Oct 2020 17:34:39
User entered '12 Oct 2020 12:34'	System	12 Oct 2020 17:34:39

**US3312605**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(5)**

**Generated On: 26 Nov 2020 10:55:55**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '12 Oct 2020 12:00'	System	08 Oct 2020 19:33:08

**US3312605**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(5)**

**Generated On: 26 Nov 2020 10:55:55**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '13 Oct 2020 11:59'	System	08 Oct 2020 19:33:08

**US3312605**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(6)**

**Generated On: 26 Nov 2020 10:55:55**

**TIMEPOINT**

Audit	User	Time (GMT)
Data entry locked.	System	08 Oct 2020 19:33:08
User entered 'Day 6'	System	08 Oct 2020 19:33:08

**US3312605**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(6)**

**Generated On: 26 Nov 2020 10:55:55**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '13 Oct 2020 12:00'	System	08 Oct 2020 19:33:08

**US3312605**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(6)**

**Generated On: 26 Nov 2020 10:55:55**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '14 Oct 2020 11:59'	System	08 Oct 2020 19:33:08

**US3312605**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(7)**

**Generated On: 26 Nov 2020 10:55:55**

**TIMEPOINT**

Audit	User	Time (GMT)
Data entry locked.	System	08 Oct 2020 19:33:08
User entered 'Day 7'	System	08 Oct 2020 19:33:08



**US3312605**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(7)**

**Generated On: 26 Nov 2020 10:55:55**

**HEADACHE**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (16C1CAA1-C746-4C21-8AE6-4CD30C39C33C)', Time: '2020-10-14T12:00:14', User OID: 'PatientReportedOutcome (US3312605)', ODM File OID: 'f9f65b43-42cd-4fb5-b4db-a0c4b483105c'	System	14 Oct 2020 17:00:31
User entered 'None (0)'	System	14 Oct 2020 17:00:31

**US3312605**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(7)**

**Generated On: 26 Nov 2020 10:55:55**

**FATIGUE**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (16C1CAA1-C746-4C21-8AE6-4CD30C39C33C)', Time: '2020-10-14T12:00:15', User OID: 'PatientReportedOutcome (US3312605)', ODM File OID: 'f9f65b43-42cd-4fb5-b4db-a0c4b483105c'	System	14 Oct 2020 17:00:31
User entered 'None (0)'	System	14 Oct 2020 17:00:31

**US3312605**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(7)**

**Generated On: 26 Nov 2020 10:55:55**

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (16C1CAA1-C746-4C21-8AE6-4CD30C39C33C)', Time: '2020-10-14T12:00:16', User OID: 'PatientReportedOutcome (US3312605)', ODM File OID: 'f9f65b43-42cd-4fb5-b4db-a0c4b483105c'	System	14 Oct 2020 17:00:31
User entered 'None (0)'	System	14 Oct 2020 17:00:31

US3312605

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 26 Nov 2020 10:55:55

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (16C1CAA1-C746-4C21-8AE6-4CD30C39C33C)', Time: '2020-10-14T12:00:17', User OID: 'PatientReportedOutcome (US3312605)', ODM File OID: 'f9f65b43-42cd-4fb5-b4db-a0c4b483105c' User entered 'None (0)'	System	14 Oct 2020 17:00:31
	System	14 Oct 2020 17:00:31

**US3312605**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(7)**

**Generated On: 26 Nov 2020 10:55:55**

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (16C1CAA1-C746-4C21-8AE6-4CD30C39C33C)', Time: '2020-10-14T12:00:18', User OID: 'PatientReportedOutcome (US3312605)', ODM File OID: 'f9f65b43-42cd-4fb5-b4db-a0c4b483105c'	System	14 Oct 2020 17:00:31
User entered 'None (0)'	System	14 Oct 2020 17:00:31

**US3312605**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(7)**

**Generated On: 26 Nov 2020 10:55:55**

**CHILLS**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (16C1CAA1-C746-4C21-8AE6-4CD30C39C33C)', Time: '2020-10-14T12:00:19', User OID: 'PatientReportedOutcome (US3312605)', ODM File OID: 'f9f65b43-42cd-4fb5-b4db-a0c4b483105c'	System	14 Oct 2020 17:00:31
User entered 'None (0)'	System	14 Oct 2020 17:00:31

US3312605

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 26 Nov 2020 10:55:55

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 (16C1CAA1-C746-4C21-8AE6-4CD30C39C33C)', Time: '2020-10-14T12:00:21', User OID: 'PatientReportedOutcome (US3312605)', ODM File OID: 'f9f65b43-42cd-4fb5-b4db-a0c4b483105c'	System	14 Oct 2020 17:00:31
User entered 'No (N)'	System	14 Oct 2020 17:00:31

**US3312605**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(7)**

**Generated On: 26 Nov 2020 10:55:55**

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (16C1CAA1-C746-4C21-8AE6-4CD30C39C33C)', Time: '2020-10-14T12:00:22', User OID: 'PatientReportedOutcome (US3312605)', ODM File OID: 'f9f65b43-42cd-4fb5-b4db-a0c4b483105c' User entered '14 Oct 2020 12:00'	System	14 Oct 2020 17:00:31
	System	14 Oct 2020 17:00:31



**US3312605**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(7)**

**Generated On: 26 Nov 2020 10:55:55**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '14 Oct 2020 12:00'	System	08 Oct 2020 19:33:08

**US3312605**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(7)**

**Generated On: 26 Nov 2020 10:55:55**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '15 Oct 2020 11:59'	System	08 Oct 2020 19:33:08

US3312605

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 26 Nov 2020 10:55:55

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	20 Oct 2020 15:27:36

US3312605

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 26 Nov 2020 10:55:55

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered '15 Oct 2020'	(b) (4), (b) (6)	20 Oct 2020 15:27:36

**US3312605**

**Folder: Safety Call Day 36 (1)**

**Form: Safety Call**

**Generated On: 26 Nov 2020 10:55:55**

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
User entered 'Contact Made (CONTACT MADE)'	(b) (4), (b) (6)	20 Oct 2020 15:27:36

**US3312605**

**Folder: Safety Call Day 36 (1)**

**Form: Safety Call**

**Generated On: 26 Nov 2020 10:55:55**

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	20 Oct 2020 15:27:36

US3312605

Folder: Safety Call Day 36 (1)

Form: Continuing

Generated On: 26 Nov 2020 10:55:55

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	20 Oct 2020 15:27:39

**US3312605**

**Folder: Safety Call Day 36 (1)**

**Form: Continuing**

**Generated On: 26 Nov 2020 10:55:55**

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered 'I'	System	20 Oct 2020 15:27:39



**US3312605**

**Folder: Safety Call Day 43 (1)**

**Form: Safety Call**

**Generated On: 26 Nov 2020 10:55:55**

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	04 Nov 2020 15:31:32

US3312605

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 26 Nov 2020 10:55:55

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered '22 Oct 2020'	(b) (4), (b) (6)	04 Nov 2020 15:31:32

US3312605

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 26 Nov 2020 10:55:55

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
User entered 'Contact Not Made (CONTACT NOT MADE)'	(b) (4), (b) (6)	04 Nov 2020 15:31:32

**US3312605**

**Folder: Safety Call Day 43 (1)**

**Form: Safety Call**

**Generated On: 26 Nov 2020 10:55:55**

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
User entered 'UNABLE TO REACH SUBJECT. PROTOCOL DEVIATION NOTED. NOT REPORABLE TO IRB'	(b) (4), (b) (6)	04 Nov 2020 15:31:32

US3312605

Folder: Safety Call Day 43 (1)

Form: Continuing

Generated On: 26 Nov 2020 10:55:55

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	04 Nov 2020 15:31:35

**US3312605**

**Folder: Safety Call Day 43 (1)**

**Form: Continuing**

**Generated On: 26 Nov 2020 10:55:55**

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered 'I'	System	04 Nov 2020 15:31:35

**US3312605**

**Folder: Safety Call Day 50 (1)**

**Form: Safety Call**

**Generated On: 26 Nov 2020 10:55:55**

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	04 Nov 2020 15:32:02

US3312605

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 26 Nov 2020 10:55:55

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered '29 Oct 2020'	(b) (4), (b) (6)	04 Nov 2020 15:32:02



**US3312605**

**Folder: Safety Call Day 50 (1)**

**Form: Safety Call**

**Generated On: 26 Nov 2020 10:55:55**

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
User entered 'Contact Not Made (CONTACT NOT MADE)'	(b) (4), (b) (6)	04 Nov 2020 15:32:02

**US3312605**

**Folder: Safety Call Day 50 (1)**

**Form: Safety Call**

**Generated On: 26 Nov 2020 10:55:55**

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
User entered 'UNABLE TO REACH SUBJECT. PROTOCOL DEVIATION NOTED. NOT REPORABLE TO IRB.'	(b) (4), (b) (6)	04 Nov 2020 15:32:02

US3312605

Folder: Safety Call Day 50 (1)

Form: Continuing

Generated On: 26 Nov 2020 10:55:55

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	04 Nov 2020 15:32:07

**US3312605**

**Folder: Safety Call Day 50 (1)**

**Form: Continuing**

**Generated On: 26 Nov 2020 10:55:55**

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered 'I'	System	04 Nov 2020 15:32:07

US3312605

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 26 Nov 2020 10:55:55

[Was this visit performed?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Karol Moore (b) (4) (b) (4)	10 Nov 2020 13:56:36

US3312605

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 26 Nov 2020 10:55:55

[Visit date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User entered '04 Nov 2020'	Karol Moore (b) (4) (b) (4)	10 Nov 2020 13:56:36

US3312605

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 26 Nov 2020 10:55:55

Was visit performed at the participant's home or at the clinic?

Audit	User	Time (GMT)
User entered 'Clinic (Clinic)'	Karol Moore (b) (4) (b) (4)	10 Nov 2020 13:56:36

**US3312605**

**Folder: Visit 3 Day 57 (1)**

**Form: Visit Date**

**Generated On: 26 Nov 2020 10:55:55**

[Folder OID](#)

Audit	User	Time (GMT)
User entered 'VISIT3'	System	10 Nov 2020 13:56:36



US3312605

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 10:55:55

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Karol Moore (b) (4) (b) (4)	10 Nov 2020 13:57:01

US3312605

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 10:55:55

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered '04 Nov 2020'	Karol Moore (b) (4) (b) (4)	10 Nov 2020 13:57:01

**US3312605**

**Folder: Visit 3 Day 57 (1)**

**Form: Vital Signs**

**Generated On: 26 Nov 2020 10:55:55**

**Time of assessment (00:00-23:59)**

Audit	User	Time (GMT)
User entered '14:29'	Karol Moore (b) (4) (b) (4)	10 Nov 2020 13:57:01

**US3312605**

**Folder: Visit 3 Day 57 (1)**

**Form: Vital Signs**

**Generated On: 26 Nov 2020 10:55:55**

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered '04 Nov 2020 14:29'	System	10 Nov 2020 13:57:01

US3312605

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 10:55:55

Temperature (xxx.x)

Audit	User	Time (GMT)
User entered '98.7' F	Karol Moore (b) (4) (b) (4)	10 Nov 2020 13:57:01

US3312605

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 10:55:55

[Route of measurement](#)

Audit	User	Time (GMT)
User entered 'Oral (Oral)'	Karol Moore (b) (4) (b) (4)	10 Nov 2020 13:57:01

US3312605

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 10:55:55

[If Other, specify](#)

Audit	User	Time (GMT)
User entered empty.	Karol Moore (b) (4) (b) (4)	10 Nov 2020 13:57:01

US3312605

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 10:55:55

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
User entered '74'	Karol Moore (b) (4) (b) (4)	10 Nov 2020 13:57:01



**US3312605**

**Folder: Visit 3 Day 57 (1)**

**Form: Vital Signs**

**Generated On: 26 Nov 2020 10:55:55**

[Pulse units](#)

Audit	User	Time (GMT)
User entered 'bpm'	System	10 Nov 2020 13:57:01

US3312605

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 10:55:55

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
User entered '16'	Karol Moore (b) (4) (b) (4)	10 Nov 2020 13:57:01

**US3312605**

**Folder: Visit 3 Day 57 (1)**

**Form: Vital Signs**

**Generated On: 26 Nov 2020 10:55:55**

[Respiratory Rate units](#)

Audit	User	Time (GMT)
User entered 'breaths/min'	System	10 Nov 2020 13:57:01

US3312605

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 10:55:55

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
User entered '129'	Karol Moore (b) (4) (b) (4)	10 Nov 2020 13:57:01

US3312605

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 10:55:55

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	10 Nov 2020 13:57:01

US3312605

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 10:55:55

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
User entered '69' reason for change: Data Entry Error	Karol Moore (b) (4)	10 Nov 2020 13:57:07
User entered '68'	Karol Moore (b) (4)	10 Nov 2020 13:57:01

**US3312605**

**Folder: Visit 3 Day 57 (1)**

**Form: Vital Signs**

**Generated On: 26 Nov 2020 10:55:55**

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	10 Nov 2020 13:57:01

US3312605

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Generated On: 26 Nov 2020 10:55:55

Was the physical examination performed?

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Karol Moore (b) (4) (b) (4)	10 Nov 2020 13:57:19



US3312605

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Generated On: 26 Nov 2020 10:55:55

Date of examination (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered '04 Nov 2020'	Karol Moore (b) (4) (b) (4)	10 Nov 2020 13:57:19

US3312605

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 10:55:55

[Was the sample collected?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Karol Moore (b) (4) (b) (4)	10 Nov 2020 13:57:32

US3312605

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 10:55:55

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered '04 Nov 2020'	Karol Moore (b) (4) (b) (4)	10 Nov 2020 13:57:32

US3312605

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 10:55:55

Collection time (00:00-23:59)

Audit	User	Time (GMT)
User entered '14:53'	Karol Moore (b) (4) (b) (4)	10 Nov 2020 13:57:32

**US3312605**

**Folder: Visit 3 Day 57 (1)**

**Form: Immunogenicity Assessment**

**Generated On: 26 Nov 2020 10:55:55**

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered '04 Nov 2020 14:53'	System	10 Nov 2020 13:57:32

US3312605

Folder: Visit 3 Day 57 (1)

Form: Continuing

Generated On: 26 Nov 2020 10:55:55

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Karol Moore (b) (4) (b) (4)	10 Nov 2020 13:57:39

**US3312605**

**Folder: Visit 3 Day 57 (1)**

**Form: Continuing**

**Generated On: 26 Nov 2020 10:55:55**

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered 'I'	System	10 Nov 2020 13:57:39

**US3312605**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:55:55**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:17:11
Amendment Manager: User entered 'Day 61'	System	20 Nov 2020 07:17:11



**US3312605**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:55:55**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:17:11
Amendment Manager: User entered '07 Nov 2020 00:01'	System	20 Nov 2020 07:17:11

**US3312605**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:55:55**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:17:11
Amendment Manager: User entered '11 Nov 2020 23:59'	System	20 Nov 2020 07:17:11

**US3312605**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:55:55**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:17:11
Amendment Manager: User entered 'Day 68'	System	20 Nov 2020 07:17:11

**US3312605**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:55:55**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:17:11
Amendment Manager: User entered '14 Nov 2020 00:01'	System	20 Nov 2020 07:17:11

**US3312605**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:55:55**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:17:11
Amendment Manager: User entered '18 Nov 2020 23:59'	System	20 Nov 2020 07:17:11

**US3312605**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:55:55**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:17:11
Amendment Manager: User entered 'Day 75'	System	20 Nov 2020 07:17:11

**US3312605**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:55:55**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:17:11
Amendment Manager: User entered '21 Nov 2020 00:01'	System	20 Nov 2020 07:17:11

**US3312605**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:55:55**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:17:11
Amendment Manager: User entered '25 Nov 2020 23:59'	System	20 Nov 2020 07:17:11



**US3312605**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:55:55**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:17:11
Amendment Manager: User entered 'Day 82'	System	20 Nov 2020 07:17:11

**US3312605**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:55:55**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:17:11
Amendment Manager: User entered '28 Nov 2020 00:01'	System	20 Nov 2020 07:17:11

**US3312605**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:55:55**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:17:11
Amendment Manager: User entered '02 Dec 2020 23:59'	System	20 Nov 2020 07:17:11

**US3312605**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:55:55**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:17:11
Amendment Manager: User entered 'Day 89'	System	20 Nov 2020 07:17:11

**US3312605**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:55:55**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:17:11
Amendment Manager: User entered '05 Dec 2020 00:01'	System	20 Nov 2020 07:17:11

**US3312605**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:55:55**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:17:11
Amendment Manager: User entered '09 Dec 2020 23:59'	System	20 Nov 2020 07:17:11

**US3312605**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:55:55**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:17:11
Amendment Manager: User entered 'Day 96'	System	20 Nov 2020 07:17:11

**US3312605**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:55:55**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:17:11
Amendment Manager: User entered '12 Dec 2020 00:01'	System	20 Nov 2020 07:17:11



**US3312605**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:55:55**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:17:11
Amendment Manager: User entered '16 Dec 2020 23:59'	System	20 Nov 2020 07:17:11

**US3312605**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:55:55**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:17:11
Amendment Manager: User entered 'Day 103'	System	20 Nov 2020 07:17:11

**US3312605**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:55:55**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:17:11
Amendment Manager: User entered '19 Dec 2020 00:01'	System	20 Nov 2020 07:17:11

**US3312605**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:55:55**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:17:11
Amendment Manager: User entered '23 Dec 2020 23:59'	System	20 Nov 2020 07:17:11

**US3312605**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:55:55**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:17:11
Amendment Manager: User entered 'Day 110'	System	20 Nov 2020 07:17:11

**US3312605**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:55:55**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:17:11
Amendment Manager: User entered '26 Dec 2020 00:01'	System	20 Nov 2020 07:17:11

**US3312605**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:55:55**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:17:11
Amendment Manager: User entered '30 Dec 2020 23:59'	System	20 Nov 2020 07:17:11

**US3312605**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:55:55**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:17:11
Amendment Manager: User entered 'Day 117'	System	20 Nov 2020 07:17:11



**US3312605**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:55:55**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:17:11
Amendment Manager: User entered '02 Jan 2021 00:01'	System	20 Nov 2020 07:17:11

**US3312605**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:55:55**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:17:11
Amendment Manager: User entered '06 Jan 2021 23:59'	System	20 Nov 2020 07:17:11

**US3312605**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:55:55**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:17:11
Amendment Manager: User entered 'Day 124'	System	20 Nov 2020 07:17:11

**US3312605**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:55:55**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:17:11
Amendment Manager: User entered '09 Jan 2021 00:01'	System	20 Nov 2020 07:17:11

**US3312605**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:55:55**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:17:11
Amendment Manager: User entered '13 Jan 2021 23:59'	System	20 Nov 2020 07:17:11

**US3312605**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:55:55**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:17:11
Amendment Manager: User entered 'Day 131'	System	20 Nov 2020 07:17:11

**US3312605**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:55:55**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:17:11
Amendment Manager: User entered '16 Jan 2021 00:01'	System	20 Nov 2020 07:17:11

**US3312605**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:55:55**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:17:11
Amendment Manager: User entered '20 Jan 2021 23:59'	System	20 Nov 2020 07:17:11



**US3312605**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:55:55**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:17:11
Amendment Manager: User entered 'Day 138'	System	20 Nov 2020 07:17:11

**US3312605**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:55:55**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:17:11
Amendment Manager: User entered '23 Jan 2021 00:01'	System	20 Nov 2020 07:17:11

**US3312605**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:55:55**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:17:11
Amendment Manager: User entered '27 Jan 2021 23:59'	System	20 Nov 2020 07:17:11

**US3312605**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:55:55**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:17:11
Amendment Manager: User entered 'Day 145'	System	20 Nov 2020 07:17:11

**US3312605**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:55:55**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:17:11
Amendment Manager: User entered '30 Jan 2021 00:01'	System	20 Nov 2020 07:17:11

**US3312605**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:55:55**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:17:11
Amendment Manager: User entered '03 Feb 2021 23:59'	System	20 Nov 2020 07:17:11

**US3312605**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:55:55**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:17:11
Amendment Manager: User entered 'Day 152'	System	20 Nov 2020 07:17:11

**US3312605**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:55:55**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:17:11
Amendment Manager: User entered '06 Feb 2021 00:01'	System	20 Nov 2020 07:17:11



**US3312605**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:55:55**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:17:11
Amendment Manager: User entered '10 Feb 2021 23:59'	System	20 Nov 2020 07:17:11

**US3312605**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:55:55**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:17:11
Amendment Manager: User entered 'Day 159'	System	20 Nov 2020 07:17:11

**US3312605**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:55:55**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:17:11
Amendment Manager: User entered '13 Feb 2021 00:01'	System	20 Nov 2020 07:17:11

**US3312605**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:55:55**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:17:11
Amendment Manager: User entered '17 Feb 2021 23:59'	System	20 Nov 2020 07:17:11

**US3312605**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:55:55**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:17:11
Amendment Manager: User entered 'Day 166'	System	20 Nov 2020 07:17:11

**US3312605**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:55:55**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:17:11
Amendment Manager: User entered '20 Feb 2021 00:01'	System	20 Nov 2020 07:17:11

**US3312605**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:55:55**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:17:11
Amendment Manager: User entered '24 Feb 2021 23:59'	System	20 Nov 2020 07:17:11

**US3312605**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:55:55**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:17:11
Amendment Manager: User entered 'Day 173'	System	20 Nov 2020 07:17:11



**US3312605**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:55:55**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:17:11
Amendment Manager: User entered '27 Feb 2021 00:01'	System	20 Nov 2020 07:17:11

**US3312605**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:55:55**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:17:11
Amendment Manager: User entered '03 Mar 2021 23:59'	System	20 Nov 2020 07:17:11

**US3312605**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:55:55**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:17:11
Amendment Manager: User entered 'Day 180'	System	20 Nov 2020 07:17:11

**US3312605**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:55:55**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:17:11
Amendment Manager: User entered '06 Mar 2021 00:01'	System	20 Nov 2020 07:17:11

**US3312605**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:55:55**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:17:11
Amendment Manager: User entered '10 Mar 2021 23:59'	System	20 Nov 2020 07:17:11

**US3312605**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:55:55**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:17:11
Amendment Manager: User entered 'Day 187'	System	20 Nov 2020 07:17:11

**US3312605**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:55:55**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:17:11
Amendment Manager: User entered '13 Mar 2021 00:01'	System	20 Nov 2020 07:17:11

**US3312605**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:55:55**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:17:11
Amendment Manager: User entered '17 Mar 2021 23:59'	System	20 Nov 2020 07:17:11



**US3312605**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:55:55**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:17:11
Amendment Manager: User entered 'Day 194'	System	20 Nov 2020 07:17:11

**US3312605**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:55:55**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:17:11
Amendment Manager: User entered '20 Mar 2021 00:01'	System	20 Nov 2020 07:17:11

**US3312605**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:55:55**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:17:11
Amendment Manager: User entered '24 Mar 2021 23:59'	System	20 Nov 2020 07:17:11

**US3312605**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:55:55**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:17:11
Amendment Manager: User entered 'Day 201'	System	20 Nov 2020 07:17:11

**US3312605**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:55:55**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:17:11
Amendment Manager: User entered '27 Mar 2021 00:01'	System	20 Nov 2020 07:17:11

**US3312605**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:55:55**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:17:11
Amendment Manager: User entered '31 Mar 2021 23:59'	System	20 Nov 2020 07:17:11

**US3312605**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:55:55**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:17:11
Amendment Manager: User entered 'Day 208'	System	20 Nov 2020 07:17:11

**US3312605**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:55:55**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:17:11
Amendment Manager: User entered '03 Apr 2021 00:01'	System	20 Nov 2020 07:17:11



**US3312605**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:55:55**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:17:11
Amendment Manager: User entered '07 Apr 2021 23:59'	System	20 Nov 2020 07:17:11

**US3312605**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:55:55**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:17:11
Amendment Manager: User entered 'Day 215'	System	20 Nov 2020 07:17:11

**US3312605**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:55:55**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:17:11
Amendment Manager: User entered '10 Apr 2021 00:01'	System	20 Nov 2020 07:17:11

**US3312605**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:55:55**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:17:11
Amendment Manager: User entered '14 Apr 2021 23:59'	System	20 Nov 2020 07:17:11

**US3312605**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:55:55**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:17:11
Amendment Manager: User entered 'Day 222'	System	20 Nov 2020 07:17:11

**US3312605**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:55:55**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:17:11
Amendment Manager: User entered '17 Apr 2021 00:01'	System	20 Nov 2020 07:17:11

**US3312605**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:55:55**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:17:11
Amendment Manager: User entered '21 Apr 2021 23:59'	System	20 Nov 2020 07:17:11

**US3312605**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:55:55**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:17:11
Amendment Manager: User entered 'Day 229'	System	20 Nov 2020 07:17:11



**US3312605**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:55:55**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:17:11
Amendment Manager: User entered '24 Apr 2021 00:01'	System	20 Nov 2020 07:17:11

**US3312605**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:55:55**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:17:11
Amendment Manager: User entered '28 Apr 2021 23:59'	System	20 Nov 2020 07:17:11

**US3312605**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:55:55**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:17:11
Amendment Manager: User entered 'Day 236'	System	20 Nov 2020 07:17:11

**US3312605**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:55:55**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:17:11
Amendment Manager: User entered '01 May 2021 00:01'	System	20 Nov 2020 07:17:11

**US3312605**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:55:55**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:17:11
Amendment Manager: User entered '05 May 2021 23:59'	System	20 Nov 2020 07:17:11

**US3312605**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:55:55**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:17:11
Amendment Manager: User entered 'Day 243'	System	20 Nov 2020 07:17:11

**US3312605**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:55:55**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:17:11
Amendment Manager: User entered '08 May 2021 00:01'	System	20 Nov 2020 07:17:11

**US3312605**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:55:55**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:17:11
Amendment Manager: User entered '12 May 2021 23:59'	System	20 Nov 2020 07:17:11



**US3312605**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:55:55**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:17:11
Amendment Manager: User entered 'Day 250'	System	20 Nov 2020 07:17:11

**US3312605**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:55:55**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:17:11
Amendment Manager: User entered '15 May 2021 00:01'	System	20 Nov 2020 07:17:11

**US3312605**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:55:55**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:17:11
Amendment Manager: User entered '19 May 2021 23:59'	System	20 Nov 2020 07:17:11

**US3312605**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:55:55**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:17:11
Amendment Manager: User entered 'Day 257'	System	20 Nov 2020 07:17:11

**US3312605**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:55:55**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:17:11
Amendment Manager: User entered '22 May 2021 00:01'	System	20 Nov 2020 07:17:11

**US3312605**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:55:55**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:17:11
Amendment Manager: User entered '26 May 2021 23:59'	System	20 Nov 2020 07:17:11

**US3312605**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:55:55**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:17:11
Amendment Manager: User entered 'Day 264'	System	20 Nov 2020 07:17:11

**US3312605**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:55:55**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:17:11
Amendment Manager: User entered '29 May 2021 00:01'	System	20 Nov 2020 07:17:11



**US3312605**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:55:55**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:17:11
Amendment Manager: User entered '02 Jun 2021 23:59'	System	20 Nov 2020 07:17:11

**US3312605**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:55:55**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:17:11
Amendment Manager: User entered 'Day 271'	System	20 Nov 2020 07:17:11

**US3312605**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:55:55**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:17:11
Amendment Manager: User entered '05 Jun 2021 00:01'	System	20 Nov 2020 07:17:11

**US3312605**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:55:55**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:17:11
Amendment Manager: User entered '09 Jun 2021 23:59'	System	20 Nov 2020 07:17:11

**US3312605**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:55:55**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:17:11
Amendment Manager: User entered 'Day 278'	System	20 Nov 2020 07:17:11

**US3312605**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:55:55**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:17:11
Amendment Manager: User entered '12 Jun 2021 00:01'	System	20 Nov 2020 07:17:11

**US3312605**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:55:55**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:17:11
Amendment Manager: User entered '16 Jun 2021 23:59'	System	20 Nov 2020 07:17:11

**US3312605**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:55:55**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:17:11
Amendment Manager: User entered 'Day 285'	System	20 Nov 2020 07:17:11



**US3312605**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:55:55**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:17:11
Amendment Manager: User entered '19 Jun 2021 00:01'	System	20 Nov 2020 07:17:11

**US3312605**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:55:55**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:17:11
Amendment Manager: User entered '23 Jun 2021 23:59'	System	20 Nov 2020 07:17:11

**US3312605**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:55:55**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:17:11
Amendment Manager: User entered 'Day 292'	System	20 Nov 2020 07:17:11

**US3312605**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:55:55**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:17:11
Amendment Manager: User entered '26 Jun 2021 00:01'	System	20 Nov 2020 07:17:11

**US3312605**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:55:55**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:17:11
Amendment Manager: User entered '30 Jun 2021 23:59'	System	20 Nov 2020 07:17:11

**US3312605**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:55:55**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:17:11
Amendment Manager: User entered 'Day 299'	System	20 Nov 2020 07:17:11

**US3312605**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:55:55**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:17:11
Amendment Manager: User entered '03 Jul 2021 00:01'	System	20 Nov 2020 07:17:11

**US3312605**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:55:55**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:17:11
Amendment Manager: User entered '07 Jul 2021 23:59'	System	20 Nov 2020 07:17:11



**US3312605**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:55:55**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:17:11
Amendment Manager: User entered 'Day 306'	System	20 Nov 2020 07:17:11

**US3312605**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:55:55**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:17:11
Amendment Manager: User entered '10 Jul 2021 00:01'	System	20 Nov 2020 07:17:11

**US3312605**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:55:55**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:17:11
Amendment Manager: User entered '14 Jul 2021 23:59'	System	20 Nov 2020 07:17:11

**US3312605**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:55:55**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:17:11
Amendment Manager: User entered 'Day 313'	System	20 Nov 2020 07:17:11

**US3312605**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:55:55**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:17:11
Amendment Manager: User entered '17 Jul 2021 00:01'	System	20 Nov 2020 07:17:11

**US3312605**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:55:55**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:17:11
Amendment Manager: User entered '21 Jul 2021 23:59'	System	20 Nov 2020 07:17:11

**US3312605**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:55:55**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:17:11
Amendment Manager: User entered 'Day 320'	System	20 Nov 2020 07:17:11

**US3312605**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:55:55**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:17:11
Amendment Manager: User entered '24 Jul 2021 00:01'	System	20 Nov 2020 07:17:11



**US3312605**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:55:55**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:17:11
Amendment Manager: User entered '28 Jul 2021 23:59'	System	20 Nov 2020 07:17:11

**US3312605**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:55:55**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:17:11
Amendment Manager: User entered 'Day 327'	System	20 Nov 2020 07:17:11

**US3312605**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:55:55**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:17:11
Amendment Manager: User entered '31 Jul 2021 00:01'	System	20 Nov 2020 07:17:11

**US3312605**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:55:55**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:17:11
Amendment Manager: User entered '04 Aug 2021 23:59'	System	20 Nov 2020 07:17:11

**US3312605**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:55:55**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:17:11
Amendment Manager: User entered 'Day 334'	System	20 Nov 2020 07:17:11

**US3312605**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:55:55**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:17:11
Amendment Manager: User entered '07 Aug 2021 00:01'	System	20 Nov 2020 07:17:11

**US3312605**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:55:55**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:17:11
Amendment Manager: User entered '11 Aug 2021 23:59'	System	20 Nov 2020 07:17:11

**US3312605**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:55:55**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:17:11
Amendment Manager: User entered 'Day 341'	System	20 Nov 2020 07:17:11



**US3312605**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:55:55**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:17:11
Amendment Manager: User entered '14 Aug 2021 00:01'	System	20 Nov 2020 07:17:11

**US3312605**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:55:55**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:17:11
Amendment Manager: User entered '18 Aug 2021 23:59'	System	20 Nov 2020 07:17:11

**US3312605**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:55:55**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:17:11
Amendment Manager: User entered 'Day 348'	System	20 Nov 2020 07:17:11

**US3312605**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:55:55**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:17:11
Amendment Manager: User entered '21 Aug 2021 00:01'	System	20 Nov 2020 07:17:11

**US3312605**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:55:55**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:17:11
Amendment Manager: User entered '25 Aug 2021 23:59'	System	20 Nov 2020 07:17:11

**US3312605**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:55:55**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:17:11
Amendment Manager: User entered 'Day 355'	System	20 Nov 2020 07:17:11

**US3312605**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:55:55**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:17:11
Amendment Manager: User entered '28 Aug 2021 00:01'	System	20 Nov 2020 07:17:11

**US3312605**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:55:55**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:17:11
Amendment Manager: User entered '01 Sep 2021 23:59'	System	20 Nov 2020 07:17:11



**US3312605**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:55:55**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:17:11
Amendment Manager: User entered 'Day 362'	System	20 Nov 2020 07:17:11

**US3312605**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:55:55**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:17:11
Amendment Manager: User entered '04 Sep 2021 00:01'	System	20 Nov 2020 07:17:11

**US3312605**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:55:55**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:17:11
Amendment Manager: User entered '08 Sep 2021 23:59'	System	20 Nov 2020 07:17:11

**US3312605**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:55:55**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:17:11
Amendment Manager: User entered 'Day 369'	System	20 Nov 2020 07:17:11

**US3312605**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:55:55**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:17:11
Amendment Manager: User entered '11 Sep 2021 00:01'	System	20 Nov 2020 07:17:11

**US3312605**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:55:55**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:17:11
Amendment Manager: User entered '15 Sep 2021 23:59'	System	20 Nov 2020 07:17:11

**US3312605**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:55:55**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:17:11
Amendment Manager: User entered 'Day 376'	System	20 Nov 2020 07:17:11

**US3312605**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:55:55**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:17:11
Amendment Manager: User entered '18 Sep 2021 00:01'	System	20 Nov 2020 07:17:11



**US3312605**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:55:55**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:17:11
Amendment Manager: User entered '22 Sep 2021 23:59'	System	20 Nov 2020 07:17:11

**US3312605**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:55:55**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:17:11
Amendment Manager: User entered 'Day 383'	System	20 Nov 2020 07:17:11

**US3312605**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:55:55**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:17:11
Amendment Manager: User entered '25 Sep 2021 00:01'	System	20 Nov 2020 07:17:11

**US3312605**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:55:55**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:17:11
Amendment Manager: User entered '29 Sep 2021 23:59'	System	20 Nov 2020 07:17:11

**US3312605**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:55:55**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:17:11
Amendment Manager: User entered 'Day 390'	System	20 Nov 2020 07:17:11

**US3312605**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:55:55**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:17:11
Amendment Manager: User entered '02 Oct 2021 00:01'	System	20 Nov 2020 07:17:11

**US3312605**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:55:55**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:17:11
Amendment Manager: User entered '06 Oct 2021 23:59'	System	20 Nov 2020 07:17:11

**US3312605**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:55:55**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:17:11
Amendment Manager: User entered 'Day 397'	System	20 Nov 2020 07:17:11



**US3312605**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:55:55**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:17:11
Amendment Manager: User entered '09 Oct 2021 00:01'	System	20 Nov 2020 07:17:11

**US3312605**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:55:55**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:17:11
Amendment Manager: User entered '13 Oct 2021 23:59'	System	20 Nov 2020 07:17:11

**US3312605**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:55:55**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:17:11
Amendment Manager: User entered 'Day 404'	System	20 Nov 2020 07:17:11

**US3312605**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:55:55**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:17:11
Amendment Manager: User entered '16 Oct 2021 00:01'	System	20 Nov 2020 07:17:11

**US3312605**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:55:55**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:17:11
Amendment Manager: User entered '20 Oct 2021 23:59'	System	20 Nov 2020 07:17:11

**US3312605**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:55:55**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:17:11
Amendment Manager: User entered 'Day 411'	System	20 Nov 2020 07:17:11

**US3312605**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:55:55**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:17:11
Amendment Manager: User entered '23 Oct 2021 00:01'	System	20 Nov 2020 07:17:11

**US3312605**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:55:55**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:17:11
Amendment Manager: User entered '27 Oct 2021 23:59'	System	20 Nov 2020 07:17:11



**US3312605**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:55:55**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:17:11
Amendment Manager: User entered 'Day 418'	System	20 Nov 2020 07:17:11

**US3312605**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:55:55**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:17:11
Amendment Manager: User entered '30 Oct 2021 00:01'	System	20 Nov 2020 07:17:11

**US3312605**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:55:55**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:17:11
Amendment Manager: User entered '03 Nov 2021 23:59'	System	20 Nov 2020 07:17:11

**US3312605**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:55:55**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:17:11
Amendment Manager: User entered 'Day 425'	System	20 Nov 2020 07:17:11

**US3312605**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:55:55**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:17:11
Amendment Manager: User entered '06 Nov 2021 00:01'	System	20 Nov 2020 07:17:11

**US3312605**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:55:55**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:17:11
Amendment Manager: User entered '10 Nov 2021 23:59'	System	20 Nov 2020 07:17:11

**US3312605**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:55:55**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:17:11
Amendment Manager: User entered 'Day 432'	System	20 Nov 2020 07:17:11

**US3312605**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:55:55**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:17:11
Amendment Manager: User entered '13 Nov 2021 00:01'	System	20 Nov 2020 07:17:11



**US3312605**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:55:55**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:17:11
Amendment Manager: User entered '17 Nov 2021 23:59'	System	20 Nov 2020 07:17:11

**US3312605**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:55:55**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:17:11
Amendment Manager: User entered 'Day 439'	System	20 Nov 2020 07:17:11

**US3312605**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:55:55**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:17:11
Amendment Manager: User entered '20 Nov 2021 00:01'	System	20 Nov 2020 07:17:11

**US3312605**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:55:55**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:17:11
Amendment Manager: User entered '24 Nov 2021 23:59'	System	20 Nov 2020 07:17:11

**US3312605**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:55:55**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:17:11
Amendment Manager: User entered 'Day 446'	System	20 Nov 2020 07:17:11

**US3312605**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:55:55**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:17:11
Amendment Manager: User entered '27 Nov 2021 00:01'	System	20 Nov 2020 07:17:11

**US3312605**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:55:55**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:17:11
Amendment Manager: User entered '01 Dec 2021 23:59'	System	20 Nov 2020 07:17:11

**US3312605**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:55:55**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:17:11
Amendment Manager: User entered 'Day 453'	System	20 Nov 2020 07:17:11



**US3312605**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:55:55**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:17:11
Amendment Manager: User entered '04 Dec 2021 00:01'	System	20 Nov 2020 07:17:11

**US3312605**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:55:55**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:17:11
Amendment Manager: User entered '08 Dec 2021 23:59'	System	20 Nov 2020 07:17:11

**US3312605**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:55:55**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:17:11
Amendment Manager: User entered 'Day 460'	System	20 Nov 2020 07:17:11

**US3312605**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:55:55**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:17:11
Amendment Manager: User entered '11 Dec 2021 00:01'	System	20 Nov 2020 07:17:11

**US3312605**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:55:55**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:17:11
Amendment Manager: User entered '15 Dec 2021 23:59'	System	20 Nov 2020 07:17:11

**US3312605**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:55:55**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:17:11
Amendment Manager: User entered 'Day 467'	System	20 Nov 2020 07:17:11

**US3312605**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:55:55**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:17:11
Amendment Manager: User entered '18 Dec 2021 00:01'	System	20 Nov 2020 07:17:11

**US3312605**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:55:55**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:17:11
Amendment Manager: User entered '22 Dec 2021 23:59'	System	20 Nov 2020 07:17:11



**US3312605**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:55:55**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:17:11
Amendment Manager: User entered 'Day 474'	System	20 Nov 2020 07:17:11

**US3312605**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:55:55**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:17:11
Amendment Manager: User entered '25 Dec 2021 00:01'	System	20 Nov 2020 07:17:11

**US3312605**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:55:55**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:17:11
Amendment Manager: User entered '29 Dec 2021 23:59'	System	20 Nov 2020 07:17:11

**US3312605**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:55:55**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:17:11
Amendment Manager: User entered 'Day 481'	System	20 Nov 2020 07:17:11

**US3312605**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:55:55**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:17:11
Amendment Manager: User entered '01 Jan 2022 00:01'	System	20 Nov 2020 07:17:11

**US3312605**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:55:55**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:17:11
Amendment Manager: User entered '05 Jan 2022 23:59'	System	20 Nov 2020 07:17:11

**US3312605**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:55:55**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:17:11
Amendment Manager: User entered 'Day 488'	System	20 Nov 2020 07:17:11

**US3312605**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:55:55**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:17:11
Amendment Manager: User entered '08 Jan 2022 00:01'	System	20 Nov 2020 07:17:11



**US3312605**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:55:55**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:17:11
Amendment Manager: User entered '12 Jan 2022 23:59'	System	20 Nov 2020 07:17:11

**US3312605**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:55:55**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:17:11
Amendment Manager: User entered 'Day 495'	System	20 Nov 2020 07:17:11

**US3312605**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:55:55**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:17:11
Amendment Manager: User entered '15 Jan 2022 00:01'	System	20 Nov 2020 07:17:11

**US3312605**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:55:55**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:17:11
Amendment Manager: User entered '19 Jan 2022 23:59'	System	20 Nov 2020 07:17:11

**US3312605**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:55:55**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:17:11
Amendment Manager: User entered 'Day 502'	System	20 Nov 2020 07:17:11

**US3312605**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:55:55**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:17:11
Amendment Manager: User entered '22 Jan 2022 00:01'	System	20 Nov 2020 07:17:11

**US3312605**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:55:55**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:17:11
Amendment Manager: User entered '26 Jan 2022 23:59'	System	20 Nov 2020 07:17:11

**US3312605**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:55:55**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:17:11
Amendment Manager: User entered 'Day 509'	System	20 Nov 2020 07:17:11



**US3312605**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:55:55**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:17:11
Amendment Manager: User entered '29 Jan 2022 00:01'	System	20 Nov 2020 07:17:11

**US3312605**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:55:55**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:17:11
Amendment Manager: User entered '02 Feb 2022 23:59'	System	20 Nov 2020 07:17:11

**US3312605**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:55:55**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:17:11
Amendment Manager: User entered 'Day 516'	System	20 Nov 2020 07:17:11

**US3312605**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:55:55**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:17:11
Amendment Manager: User entered '05 Feb 2022 00:01'	System	20 Nov 2020 07:17:11

**US3312605**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:55:55**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:17:11
Amendment Manager: User entered '09 Feb 2022 23:59'	System	20 Nov 2020 07:17:11

**US3312605**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:55:55**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:17:11
Amendment Manager: User entered 'Day 523'	System	20 Nov 2020 07:17:11

**US3312605**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:55:55**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:17:11
Amendment Manager: User entered '12 Feb 2022 00:01'	System	20 Nov 2020 07:17:11

**US3312605**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:55:55**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:17:11
Amendment Manager: User entered '16 Feb 2022 23:59'	System	20 Nov 2020 07:17:11



**US3312605**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:55:55**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:17:11
Amendment Manager: User entered 'Day 530'	System	20 Nov 2020 07:17:11

**US3312605**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:55:55**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:17:11
Amendment Manager: User entered '19 Feb 2022 00:01'	System	20 Nov 2020 07:17:11

**US3312605**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:55:55**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:17:11
Amendment Manager: User entered '23 Feb 2022 23:59'	System	20 Nov 2020 07:17:11

**US3312605**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:55:55**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:17:11
Amendment Manager: User entered 'Day 537'	System	20 Nov 2020 07:17:11

**US3312605**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:55:55**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:17:11
Amendment Manager: User entered '26 Feb 2022 00:01'	System	20 Nov 2020 07:17:11

**US3312605**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:55:55**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:17:11
Amendment Manager: User entered '02 Mar 2022 23:59'	System	20 Nov 2020 07:17:11

**US3312605**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:55:55**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:17:11
Amendment Manager: User entered 'Day 544'	System	20 Nov 2020 07:17:11

**US3312605**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:55:55**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:17:11
Amendment Manager: User entered '05 Mar 2022 00:01'	System	20 Nov 2020 07:17:11



**US3312605**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:55:55**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:17:11
Amendment Manager: User entered '09 Mar 2022 23:59'	System	20 Nov 2020 07:17:11

**US3312605**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:55:55**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:17:11
Amendment Manager: User entered 'Day 551'	System	20 Nov 2020 07:17:11

**US3312605**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:55:55**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:17:11
Amendment Manager: User entered '12 Mar 2022 00:01'	System	20 Nov 2020 07:17:11

**US3312605**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:55:55**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:17:11
Amendment Manager: User entered '16 Mar 2022 23:59'	System	20 Nov 2020 07:17:11

**US3312605**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:55:55**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:17:11
Amendment Manager: User entered 'Day 558'	System	20 Nov 2020 07:17:11

**US3312605**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:55:55**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:17:11
Amendment Manager: User entered '19 Mar 2022 00:01'	System	20 Nov 2020 07:17:11

**US3312605**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:55:55**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:17:11
Amendment Manager: User entered '23 Mar 2022 23:59'	System	20 Nov 2020 07:17:11

**US3312605**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:55:55**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:17:11
Amendment Manager: User entered 'Day 565'	System	20 Nov 2020 07:17:11



**US3312605**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:55:55**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:17:11
Amendment Manager: User entered '26 Mar 2022 00:01'	System	20 Nov 2020 07:17:11

**US3312605**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:55:55**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:17:11
Amendment Manager: User entered '30 Mar 2022 23:59'	System	20 Nov 2020 07:17:11

**US3312605**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:55:55**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:17:11
Amendment Manager: User entered 'Day 572'	System	20 Nov 2020 07:17:11

**US3312605**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:55:55**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:17:11
Amendment Manager: User entered '02 Apr 2022 00:01'	System	20 Nov 2020 07:17:11

**US3312605**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:55:55**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:17:11
Amendment Manager: User entered '06 Apr 2022 23:59'	System	20 Nov 2020 07:17:11

**US3312605**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:55:55**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:17:11
Amendment Manager: User entered 'Day 579'	System	20 Nov 2020 07:17:11

**US3312605**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:55:55**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:17:11
Amendment Manager: User entered '09 Apr 2022 00:01'	System	20 Nov 2020 07:17:11

**US3312605**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:55:55**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:17:11
Amendment Manager: User entered '13 Apr 2022 23:59'	System	20 Nov 2020 07:17:11



**US3312605**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:55:55**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:17:11
Amendment Manager: User entered 'Day 586'	System	20 Nov 2020 07:17:11

**US3312605**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:55:55**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:17:11
Amendment Manager: User entered '16 Apr 2022 00:01'	System	20 Nov 2020 07:17:11

**US3312605**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:55:55**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:17:11
Amendment Manager: User entered '20 Apr 2022 23:59'	System	20 Nov 2020 07:17:11

**US3312605**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:55:55**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:17:11
Amendment Manager: User entered 'Day 593'	System	20 Nov 2020 07:17:11

**US3312605**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:55:55**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:17:11
Amendment Manager: User entered '23 Apr 2022 00:01'	System	20 Nov 2020 07:17:11

**US3312605**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:55:55**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:17:11
Amendment Manager: User entered '27 Apr 2022 23:59'	System	20 Nov 2020 07:17:11

**US3312605**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:55:55**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:17:11
Amendment Manager: User entered 'Day 600'	System	20 Nov 2020 07:17:11

**US3312605**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:55:55**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:17:11
Amendment Manager: User entered '30 Apr 2022 00:01'	System	20 Nov 2020 07:17:11



**US3312605**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:55:55**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:17:11
Amendment Manager: User entered '04 May 2022 23:59'	System	20 Nov 2020 07:17:11

**US3312605**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:55:55**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:17:11
Amendment Manager: User entered 'Day 607'	System	20 Nov 2020 07:17:11

**US3312605**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:55:55**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:17:11
Amendment Manager: User entered '07 May 2022 00:01'	System	20 Nov 2020 07:17:11

**US3312605**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:55:55**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:17:11
Amendment Manager: User entered '11 May 2022 23:59'	System	20 Nov 2020 07:17:11

**US3312605**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:55:55**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:17:11
Amendment Manager: User entered 'Day 614'	System	20 Nov 2020 07:17:11

**US3312605**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:55:55**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:17:11
Amendment Manager: User entered '14 May 2022 00:01'	System	20 Nov 2020 07:17:11

**US3312605**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:55:55**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:17:11
Amendment Manager: User entered '18 May 2022 23:59'	System	20 Nov 2020 07:17:11

**US3312605**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:55:55**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:17:11
Amendment Manager: User entered 'Day 621'	System	20 Nov 2020 07:17:11



**US3312605**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:55:55**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:17:11
Amendment Manager: User entered '21 May 2022 00:01'	System	20 Nov 2020 07:17:11

**US3312605**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:55:55**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:17:11
Amendment Manager: User entered '25 May 2022 23:59'	System	20 Nov 2020 07:17:11

**US3312605**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:55:55**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:17:11
Amendment Manager: User entered 'Day 628'	System	20 Nov 2020 07:17:11

**US3312605**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:55:55**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:17:11
Amendment Manager: User entered '28 May 2022 00:01'	System	20 Nov 2020 07:17:11

**US3312605**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:55:55**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:17:11
Amendment Manager: User entered '01 Jun 2022 23:59'	System	20 Nov 2020 07:17:11

**US3312605**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:55:55**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:17:11
Amendment Manager: User entered 'Day 635'	System	20 Nov 2020 07:17:11

**US3312605**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:55:55**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:17:11
Amendment Manager: User entered '04 Jun 2022 00:01'	System	20 Nov 2020 07:17:11

**US3312605**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:55:55**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:17:11
Amendment Manager: User entered '08 Jun 2022 23:59'	System	20 Nov 2020 07:17:11



**US3312605**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:55:55**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:17:11
Amendment Manager: User entered 'Day 642'	System	20 Nov 2020 07:17:11

**US3312605**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:55:55**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:17:11
Amendment Manager: User entered '11 Jun 2022 00:01'	System	20 Nov 2020 07:17:11

**US3312605**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:55:55**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:17:11
Amendment Manager: User entered '15 Jun 2022 23:59'	System	20 Nov 2020 07:17:11

**US3312605**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:55:55**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:17:11
Amendment Manager: User entered 'Day 649'	System	20 Nov 2020 07:17:11

**US3312605**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:55:55**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:17:11
Amendment Manager: User entered '18 Jun 2022 00:01'	System	20 Nov 2020 07:17:11

**US3312605**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:55:55**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:17:11
Amendment Manager: User entered '22 Jun 2022 23:59'	System	20 Nov 2020 07:17:11

**US3312605**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:55:55**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:17:11
Amendment Manager: User entered 'Day 656'	System	20 Nov 2020 07:17:11

**US3312605**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:55:55**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:17:11
Amendment Manager: User entered '25 Jun 2022 00:01'	System	20 Nov 2020 07:17:11



**US3312605**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:55:55**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:17:11
Amendment Manager: User entered '29 Jun 2022 23:59'	System	20 Nov 2020 07:17:11

**US3312605**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:55:55**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:17:11
Amendment Manager: User entered 'Day 663'	System	20 Nov 2020 07:17:11

**US3312605**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:55:55**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:17:11
Amendment Manager: User entered '02 Jul 2022 00:01'	System	20 Nov 2020 07:17:11

**US3312605**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:55:55**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:17:11
Amendment Manager: User entered '06 Jul 2022 23:59'	System	20 Nov 2020 07:17:11

**US3312605**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:55:55**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:17:11
Amendment Manager: User entered 'Day 670'	System	20 Nov 2020 07:17:11

**US3312605**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:55:55**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:17:11
Amendment Manager: User entered '09 Jul 2022 00:01'	System	20 Nov 2020 07:17:11

**US3312605**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:55:55**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:17:11
Amendment Manager: User entered '13 Jul 2022 23:59'	System	20 Nov 2020 07:17:11

**US3312605**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:55:55**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:17:11
Amendment Manager: User entered 'Day 677'	System	20 Nov 2020 07:17:11



**US3312605**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:55:55**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:17:11
Amendment Manager: User entered '16 Jul 2022 00:01'	System	20 Nov 2020 07:17:11

**US3312605**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:55:55**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:17:11
Amendment Manager: User entered '20 Jul 2022 23:59'	System	20 Nov 2020 07:17:11

**US3312605**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:55:55**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:17:11
Amendment Manager: User entered 'Day 684'	System	20 Nov 2020 07:17:11

**US3312605**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:55:55**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:17:11
Amendment Manager: User entered '23 Jul 2022 00:01'	System	20 Nov 2020 07:17:11

**US3312605**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:55:55**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:17:11
Amendment Manager: User entered '27 Jul 2022 23:59'	System	20 Nov 2020 07:17:11

**US3312605**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:55:55**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:17:11
Amendment Manager: User entered 'Day 691'	System	20 Nov 2020 07:17:11

**US3312605**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:55:55**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:17:11
Amendment Manager: User entered '30 Jul 2022 00:01'	System	20 Nov 2020 07:17:11

**US3312605**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:55:55**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:17:11
Amendment Manager: User entered '03 Aug 2022 23:59'	System	20 Nov 2020 07:17:11



**US3312605**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:55:55**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:17:11
Amendment Manager: User entered 'Day 698'	System	20 Nov 2020 07:17:11

**US3312605**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:55:55**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:17:11
Amendment Manager: User entered '06 Aug 2022 00:01'	System	20 Nov 2020 07:17:11

**US3312605**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:55:55**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:17:11
Amendment Manager: User entered '10 Aug 2022 23:59'	System	20 Nov 2020 07:17:11

**US3312605**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:55:55**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:17:11
Amendment Manager: User entered 'Day 705'	System	20 Nov 2020 07:17:11

**US3312605**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:55:55**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:17:11
Amendment Manager: User entered '13 Aug 2022 00:01'	System	20 Nov 2020 07:17:11

**US3312605**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:55:55**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:17:11
Amendment Manager: User entered '17 Aug 2022 23:59'	System	20 Nov 2020 07:17:11

**US3312605**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:55:55**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:17:11
Amendment Manager: User entered 'Day 712'	System	20 Nov 2020 07:17:11

**US3312605**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:55:55**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:17:11
Amendment Manager: User entered '20 Aug 2022 00:01'	System	20 Nov 2020 07:17:11



**US3312605**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:55:55**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:17:11
Amendment Manager: User entered '24 Aug 2022 23:59'	System	20 Nov 2020 07:17:11

**US3312605**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:55:55**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:17:11
Amendment Manager: User entered 'Day 719'	System	20 Nov 2020 07:17:11

**US3312605**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:55:55**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:17:11
Amendment Manager: User entered '27 Aug 2022 00:01'	System	20 Nov 2020 07:17:11

**US3312605**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:55:55**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:17:11
Amendment Manager: User entered '31 Aug 2022 23:59'	System	20 Nov 2020 07:17:11

**US3312605**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:55:55**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:17:11
Amendment Manager: User entered 'Day 726'	System	20 Nov 2020 07:17:11

**US3312605**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:55:55**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:17:11
Amendment Manager: User entered '03 Sep 2022 00:01'	System	20 Nov 2020 07:17:11

**US3312605**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:55:55**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:17:11
Amendment Manager: User entered '07 Sep 2022 23:59'	System	20 Nov 2020 07:17:11

**US3312605**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:55:55**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:17:11
Amendment Manager: User entered 'Day 733'	System	20 Nov 2020 07:17:11



**US3312605**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:55:55**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:17:11
Amendment Manager: User entered '10 Sep 2022 00:01'	System	20 Nov 2020 07:17:11

**US3312605**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:55:55**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:17:11
Amendment Manager: User entered '14 Sep 2022 23:59'	System	20 Nov 2020 07:17:11

**US3312605**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:55:55**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:17:11
Amendment Manager: User entered 'Day 740'	System	20 Nov 2020 07:17:11

**US3312605**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:55:55**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:17:11
Amendment Manager: User entered '17 Sep 2022 00:01'	System	20 Nov 2020 07:17:11

**US3312605**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:55:55**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:17:11
Amendment Manager: User entered '21 Sep 2022 23:59'	System	20 Nov 2020 07:17:11

**US3312605**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:55:55**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:17:11
Amendment Manager: User entered 'Day 747'	System	20 Nov 2020 07:17:11

**US3312605**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:55:55**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:17:11
Amendment Manager: User entered '24 Sep 2022 00:01'	System	20 Nov 2020 07:17:11

**US3312605**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:55:55**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:17:11
Amendment Manager: User entered '28 Sep 2022 23:59'	System	20 Nov 2020 07:17:11



**US3312605**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:55:55**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:17:11
Amendment Manager: User entered 'Day 754'	System	20 Nov 2020 07:17:11

**US3312605**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:55:55**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:17:11
Amendment Manager: User entered '01 Oct 2022 00:01'	System	20 Nov 2020 07:17:11

**US3312605**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:55:55**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:17:11
Amendment Manager: User entered '05 Oct 2022 23:59'	System	20 Nov 2020 07:17:11

**US3312605**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:55:55**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:17:11
Amendment Manager: User entered 'Day 761'	System	20 Nov 2020 07:17:11

**US3312605**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:55:55**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:17:11
Amendment Manager: User entered '08 Oct 2022 00:01'	System	20 Nov 2020 07:17:11

**US3312605**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:55:55**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:17:11
Amendment Manager: User entered '12 Oct 2022 23:59'	System	20 Nov 2020 07:17:11

**US3312605**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:55:55**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:17:11
Amendment Manager: User entered 'Day 768'	System	20 Nov 2020 07:17:11

**US3312605**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:55:55**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:17:11
Amendment Manager: User entered '15 Oct 2022 00:01'	System	20 Nov 2020 07:17:11



**US3312605**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:55:55**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:17:11
Amendment Manager: User entered '19 Oct 2022 23:59'	System	20 Nov 2020 07:17:11

**US3312605**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:55:55**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:17:11
Amendment Manager: User entered 'Day 775'	System	20 Nov 2020 07:17:11

**US3312605**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:55:55**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:17:11
Amendment Manager: User entered '22 Oct 2022 00:01'	System	20 Nov 2020 07:17:11

**US3312605**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:55:55**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:17:11
Amendment Manager: User entered '26 Oct 2022 23:59'	System	20 Nov 2020 07:17:11

**US3312605**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:55:55**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:17:11
Amendment Manager: User entered 'Day 782'	System	20 Nov 2020 07:17:11

**US3312605**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:55:55**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:17:11
Amendment Manager: User entered '29 Oct 2022 00:01'	System	20 Nov 2020 07:17:11

**US3312605**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:55:55**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:17:11
Amendment Manager: User entered '02 Nov 2022 23:59'	System	20 Nov 2020 07:17:11

**US3312605**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:55:55**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:17:11
Amendment Manager: User entered 'Day 789'	System	20 Nov 2020 07:17:11



**US3312605**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:55:55**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:17:11
Amendment Manager: User entered '05 Nov 2022 00:01'	System	20 Nov 2020 07:17:11

**US3312605**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:55:55**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:17:11
Amendment Manager: User entered '09 Nov 2022 23:59'	System	20 Nov 2020 07:17:11

**US3312605**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:55:55**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:17:11
Amendment Manager: User entered 'Day 796'	System	20 Nov 2020 07:17:11

**US3312605**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:55:55**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:17:11
Amendment Manager: User entered '12 Nov 2022 00:01'	System	20 Nov 2020 07:17:11

**US3312605**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:55:55**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:17:11
Amendment Manager: User entered '16 Nov 2022 23:59'	System	20 Nov 2020 07:17:11

**US3312605**

**Folder: Covid-19 Assessment 04 Nov 2020**

**Form: COVID-19 Contact**

**Generated On: 26 Nov 2020 10:55:55**

[Date of Contact](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 15:22:50
User entered '04 Nov 2020'	(b) (4), (b) (6)	04 Nov 2020 23:46:58

US3312605

Folder: Covid-19 Assessment 04 Nov 2020

Form: COVID-19 Contact

Generated On: 26 Nov 2020 10:55:55

[Time of Contact](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 13:11:49
User closed query 'Source does not state a time of 14:00. closes time recorded for this visit was 14:29. please verify and update as needed. Thanks ' (Site from CRA).	(b) (4), (b) (6)	18 Nov 2020 14:39:38
Query 'Source does not state a time of 14:00. closes time recorded for this visit was 14:29. please verify and update as needed. Thanks ' answered with 'UPDATED PER SOURCE NOTES' (Site from CRA).	Karol Moore (b) (4) (b) (4)	17 Nov 2020 21:49:49
User entered '14:20' reason for change: Data Entry Error	Karol Moore (b) (4) (b) (4)	17 Nov 2020 21:49:42
User opened query 'Source does not state a time of 14:00. closes time recorded for this visit was 14:29. please verify and update as needed. Thanks ' (Site from CRA).	(b) (4), (b) (6)	10 Nov 2020 15:26:04
DataPoint Un-verified.	(b) (4), (b) (6)	10 Nov 2020 15:24:34
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 15:22:50
User entered '14:00'	(b) (4), (b) (6)	04 Nov 2020 23:46:58

**US3312605**

**Folder: Covid-19 Assessment 04 Nov 2020**

**Form: COVID-19 Contact**

**Generated On: 26 Nov 2020 10:55:55**

[Date and Time of Contact \(derived\)](#)

Audit	User	Time (GMT)
User entered '04 Nov 2020 14:20'	System	17 Nov 2020 21:49:42
User entered '04 Nov 2020 14:00'	System	04 Nov 2020 23:46:58



**US3312605**

**Folder: Covid-19 Assessment 04 Nov 2020**

**Form: COVID-19 Contact**

**Generated On: 26 Nov 2020 10:55:55**

[Type of Contact](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 15:22:50
User entered 'Clinic Visit - Scheduled (Clinic Visit - Scheduled)'	(b) (4), (b) (6)	04 Nov 2020 23:46:58

**US3312605**

**Folder: Covid-19 Assessment 04 Nov 2020**

**Form: COVID-19 Contact**

**Generated On: 26 Nov 2020 10:55:55**

[Has the subject reported symptoms of SARS-COV-2?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 15:22:50
User entered 'Yes (Y)'	(b) (4), (b) (6)	04 Nov 2020 23:46:58

US3312605

Folder: Covid-19 Assessment 04 Nov 2020

Form: Symptom Log (1)

Generated On: 26 Nov 2020 10:55:55

[Symptom Day](#)

Audit	User	Time (GMT)
User entered 'Day 1 (Day 1)'	Karol Moore (b) (4) (b) (4)	05 Nov 2020 01:13:57

**US3312605**

**Folder: Covid-19 Assessment 04 Nov 2020**

**Form: Symptom Log (1)**

**Generated On: 26 Nov 2020 10:55:55**

[Date](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 16:43:43
User entered '19 Oct 2020'	Karol Moore (b) (4) (b) (4)	05 Nov 2020 01:13:57

US3312605

Folder: Covid-19 Assessment 04 Nov 2020

Form: Symptom Log (1)

Generated On: 26 Nov 2020 10:55:55

[Assessment Not Done](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 16:43:43
User entered '0'	Karol Moore (b) (4) (b) (4)	05 Nov 2020 01:13:57

US3312605

Folder: Covid-19 Assessment 04 Nov 2020

Form: Symptom Log (1)

Generated On: 26 Nov 2020 10:55:55

[O2 Saturation](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 16:43:43
User entered empty.	Karol Moore (b) (4) (b) (4)	05 Nov 2020 01:13:57

**US3312605**

**Folder: Covid-19 Assessment 04 Nov 2020**

**Form: Symptom Log (1)**

**Generated On: 26 Nov 2020 10:55:55**

[O2 Saturation Units](#)

Audit	User	Time (GMT)
User entered empty.	System	05 Nov 2020 01:13:57

US3312605

Folder: Covid-19 Assessment 04 Nov 2020

Form: Symptom Log (1)

Generated On: 26 Nov 2020 10:55:55

[Temperature](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 16:43:43
User entered empty.	Karol Moore (b) (4) (b) (4)	05 Nov 2020 01:13:57



US3312605

Folder: Covid-19 Assessment 04 Nov 2020

Form: Symptom Log (1)

Generated On: 26 Nov 2020 10:55:55

[Chills](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 16:43:43
User entered 'None (None)'	Karol Moore (b) (4) (b) (4)	05 Nov 2020 01:13:57

**US3312605**

**Folder: Covid-19 Assessment 04 Nov 2020**

**Form: Symptom Log (1)**

**Generated On: 26 Nov 2020 10:55:55**

[Cough](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 16:43:43
User entered 'Moderate (Moderate)'	Karol Moore (b) (4) (b) (4)	05 Nov 2020 01:13:57

US3312605

Folder: Covid-19 Assessment 04 Nov 2020

Form: Symptom Log (1)

Generated On: 26 Nov 2020 10:55:55

[Shortness of Breath](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 16:43:43
User entered 'None (None)'	Karol Moore (b) (4) (b) (4)	05 Nov 2020 01:13:57

US3312605

Folder: Covid-19 Assessment 04 Nov 2020

Form: Symptom Log (1)

Generated On: 26 Nov 2020 10:55:55

[Difficulty Breathing](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 16:43:43
User entered 'None (None)'	Karol Moore (b) (4) (b) (4)	05 Nov 2020 01:13:57

US3312605

Folder: Covid-19 Assessment 04 Nov 2020

Form: Symptom Log (1)

Generated On: 26 Nov 2020 10:55:55

[Fatigue](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 16:43:43
User entered 'Severe (Severe)'	Karol Moore (b) (4) (b) (4)	05 Nov 2020 01:13:57

US3312605

Folder: Covid-19 Assessment 04 Nov 2020

Form: Symptom Log (1)

Generated On: 26 Nov 2020 10:55:55

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 16:43:43
User entered 'Severe (Severe)'	Karol Moore (b) (4) (b) (4)	05 Nov 2020 01:13:57

US3312605

Folder: Covid-19 Assessment 04 Nov 2020

Form: Symptom Log (1)

Generated On: 26 Nov 2020 10:55:55

[Body Aches](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 16:43:43
User entered 'Severe (Severe)'	Karol Moore (b) (4) (b) (4)	05 Nov 2020 01:13:57

US3312605

Folder: Covid-19 Assessment 04 Nov 2020

Form: Symptom Log (1)

Generated On: 26 Nov 2020 10:55:55

[Headache](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 16:43:43
User entered 'Not Done (Not Done)'	Karol Moore (b) (4) (b) (4)	05 Nov 2020 01:13:57



US3312605

Folder: Covid-19 Assessment 04 Nov 2020

Form: Symptom Log (1)

Generated On: 26 Nov 2020 10:55:55

[New Loss of Taste](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 16:43:43
User entered 'None (None)'	Karol Moore (b) (4) (b) (4)	05 Nov 2020 01:13:57

US3312605

Folder: Covid-19 Assessment 04 Nov 2020

Form: Symptom Log (1)

Generated On: 26 Nov 2020 10:55:55

[New Loss of Smell](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 16:43:43
User entered 'None (None)'	Karol Moore (b) (4) (b) (4)	05 Nov 2020 01:13:57

US3312605

Folder: Covid-19 Assessment 04 Nov 2020

Form: Symptom Log (1)

Generated On: 26 Nov 2020 10:55:55

[Nasal Congestion](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 16:43:43
User entered 'None (None)'	Karol Moore (b) (4) (b) (4)	05 Nov 2020 01:13:57

US3312605

Folder: Covid-19 Assessment 04 Nov 2020

Form: Symptom Log (1)

Generated On: 26 Nov 2020 10:55:55

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 16:43:43
User entered 'None (None)'	Karol Moore (b) (4) (b) (4)	05 Nov 2020 01:13:57

US3312605

Folder: Covid-19 Assessment 04 Nov 2020

Form: Symptom Log (1)

Generated On: 26 Nov 2020 10:55:55

[Nausea](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 16:43:43
User entered 'Severe (Severe)'	Karol Moore (b) (4) (b) (4)	05 Nov 2020 01:13:57

**US3312605**

**Folder: Covid-19 Assessment 04 Nov 2020**

**Form: Symptom Log (1)**

**Generated On: 26 Nov 2020 10:55:55**

[Vomiting](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 16:43:43
User entered 'Severe (Severe)'	Karol Moore (b) (4) (b) (4)	05 Nov 2020 01:13:57

US3312605

Folder: Covid-19 Assessment 04 Nov 2020

Form: Symptom Log (1)

Generated On: 26 Nov 2020 10:55:55

[Diarrhea](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 16:43:43
User entered 'Severe (Severe)'	Karol Moore (b) (4) (b) (4)	05 Nov 2020 01:13:57

US3312605

Folder: Covid-19 Assessment 04 Nov 2020

Form: Symptom Log (1)

Generated On: 26 Nov 2020 10:55:55

[Sore Throat](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 16:43:43
User entered 'Severe (Severe)'	Karol Moore (b) (4) (b) (4)	05 Nov 2020 01:13:57



US3312605

Folder: Covid-19 Assessment 04 Nov 2020

Form: Symptom Log (2)

Generated On: 26 Nov 2020 10:55:55

[Symptom Day](#)

Audit	User	Time (GMT)
User entered 'Day 2 (Day 2)'	Karol Moore (b) (4) (b) (4)	05 Nov 2020 01:14:41

**US3312605**

**Folder: Covid-19 Assessment 04 Nov 2020**

**Form: Symptom Log (2)**

**Generated On: 26 Nov 2020 10:55:55**

[Date](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 16:43:43
User entered '20 Oct 2020'	Karol Moore (b) (4) (b) (4)	05 Nov 2020 01:14:41

US3312605

Folder: Covid-19 Assessment 04 Nov 2020

Form: Symptom Log (2)

Generated On: 26 Nov 2020 10:55:55

[Assessment Not Done](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 16:43:43
User entered '0'	Karol Moore (b) (4) (b) (4)	05 Nov 2020 01:14:41

US3312605

Folder: Covid-19 Assessment 04 Nov 2020

Form: Symptom Log (2)

Generated On: 26 Nov 2020 10:55:55

[O2 Saturation](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 16:43:43
User entered empty.	Karol Moore (b) (4) (b) (4)	05 Nov 2020 01:14:41

**US3312605**

**Folder: Covid-19 Assessment 04 Nov 2020**

**Form: Symptom Log (2)**

**Generated On: 26 Nov 2020 10:55:55**

[O2 Saturation Units](#)

Audit	User	Time (GMT)
User entered empty.	System	05 Nov 2020 01:14:41

US3312605

Folder: Covid-19 Assessment 04 Nov 2020

Form: Symptom Log (2)

Generated On: 26 Nov 2020 10:55:55

[Temperature](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 16:43:43
User entered empty.	Karol Moore (b) (4) (b) (4)	05 Nov 2020 01:14:41

US3312605

Folder: Covid-19 Assessment 04 Nov 2020

Form: Symptom Log (2)

Generated On: 26 Nov 2020 10:55:55

[Chills](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 16:43:43
User entered 'None (None)'	Karol Moore (b) (4) (b) (4)	05 Nov 2020 01:14:41

US3312605

Folder: Covid-19 Assessment 04 Nov 2020

Form: Symptom Log (2)

Generated On: 26 Nov 2020 10:55:55

[Cough](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 16:43:43
User entered 'Moderate (Moderate)'	Karol Moore (b) (4) (b) (4)	05 Nov 2020 01:14:41



US3312605

Folder: Covid-19 Assessment 04 Nov 2020

Form: Symptom Log (2)

Generated On: 26 Nov 2020 10:55:55

[Shortness of Breath](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 16:43:43
User entered 'None (None)'	Karol Moore (b) (4) (b) (4)	05 Nov 2020 01:14:41

US3312605

Folder: Covid-19 Assessment 04 Nov 2020

Form: Symptom Log (2)

Generated On: 26 Nov 2020 10:55:55

[Difficulty Breathing](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 16:43:43
User entered 'None (None)'	Karol Moore (b) (4) (b) (4)	05 Nov 2020 01:14:41

US3312605

Folder: Covid-19 Assessment 04 Nov 2020

Form: Symptom Log (2)

Generated On: 26 Nov 2020 10:55:55

[Fatigue](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 16:43:43
User entered 'Severe (Severe)'	Karol Moore (b) (4) (b) (4)	05 Nov 2020 01:14:41

US3312605

Folder: Covid-19 Assessment 04 Nov 2020

Form: Symptom Log (2)

Generated On: 26 Nov 2020 10:55:55

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 16:43:43
User entered 'Severe (Severe)'	Karol Moore (b) (4) (b) (4)	05 Nov 2020 01:14:41

US3312605

Folder: Covid-19 Assessment 04 Nov 2020

Form: Symptom Log (2)

Generated On: 26 Nov 2020 10:55:55

[Body Aches](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 16:43:43
User entered 'Severe (Severe)'	Karol Moore (b) (4) (b) (4)	05 Nov 2020 01:14:41

US3312605

Folder: Covid-19 Assessment 04 Nov 2020

Form: Symptom Log (2)

Generated On: 26 Nov 2020 10:55:55

[Headache](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 16:43:43
User entered 'Moderate (Moderate)'	Karol Moore (b) (4) (b) (4)	05 Nov 2020 01:14:41

US3312605

Folder: Covid-19 Assessment 04 Nov 2020

Form: Symptom Log (2)

Generated On: 26 Nov 2020 10:55:55

[New Loss of Taste](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 16:43:43
User entered 'None (None)'	Karol Moore (b) (4) (b) (4)	05 Nov 2020 01:14:41

US3312605

Folder: Covid-19 Assessment 04 Nov 2020

Form: Symptom Log (2)

Generated On: 26 Nov 2020 10:55:55

[New Loss of Smell](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 16:43:43
User entered 'None (None)'	Karol Moore (b) (4) (b) (4)	05 Nov 2020 01:14:41



US3312605

Folder: Covid-19 Assessment 04 Nov 2020

Form: Symptom Log (2)

Generated On: 26 Nov 2020 10:55:55

[Nasal Congestion](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 16:43:43
User entered 'None (None)'	Karol Moore (b) (4) (b) (4)	05 Nov 2020 01:14:41

US3312605

Folder: Covid-19 Assessment 04 Nov 2020

Form: Symptom Log (2)

Generated On: 26 Nov 2020 10:55:55

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 16:43:43
User entered 'None (None)'	Karol Moore (b) (4) (b) (4)	05 Nov 2020 01:14:41

US3312605

Folder: Covid-19 Assessment 04 Nov 2020

Form: Symptom Log (2)

Generated On: 26 Nov 2020 10:55:55

[Nausea](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 16:43:43
User entered 'Severe (Severe)'	Karol Moore (b) (4) (b) (4)	05 Nov 2020 01:14:41

US3312605

Folder: Covid-19 Assessment 04 Nov 2020

Form: Symptom Log (2)

Generated On: 26 Nov 2020 10:55:55

[Vomiting](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 16:43:43
User entered 'Severe (Severe)'	Karol Moore (b) (4) (b) (4)	05 Nov 2020 01:14:41

US3312605

Folder: Covid-19 Assessment 04 Nov 2020

Form: Symptom Log (2)

Generated On: 26 Nov 2020 10:55:55

[Diarrhea](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 16:43:43
User entered 'Severe (Severe)'	Karol Moore (b) (4) (b) (4)	05 Nov 2020 01:14:41

US3312605

Folder: Covid-19 Assessment 04 Nov 2020

Form: Symptom Log (2)

Generated On: 26 Nov 2020 10:55:55

[Sore Throat](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 16:43:43
User entered 'Severe (Severe)'	Karol Moore (b) (4) (b) (4)	05 Nov 2020 01:14:41

US3312605

Folder: Covid-19 Assessment 04 Nov 2020

Form: Symptom Log (3)

Generated On: 26 Nov 2020 10:55:55

[Symptom Day](#)

Audit	User	Time (GMT)
User entered 'Day 3 (Day 3)'	Karol Moore (b) (4) (b) (4)	05 Nov 2020 01:15:54

US3312605

Folder: Covid-19 Assessment 04 Nov 2020

Form: Symptom Log (3)

Generated On: 26 Nov 2020 10:55:55

[Date](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 16:43:43
User entered '21 Oct 2020'	Karol Moore (b) (4) (b) (4)	05 Nov 2020 01:15:54



US3312605

Folder: Covid-19 Assessment 04 Nov 2020

Form: Symptom Log (3)

Generated On: 26 Nov 2020 10:55:55

[Assessment Not Done](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 16:43:43
User entered '0'	Karol Moore (b) (4) (b) (4)	05 Nov 2020 01:15:54

US3312605

Folder: Covid-19 Assessment 04 Nov 2020

Form: Symptom Log (3)

Generated On: 26 Nov 2020 10:55:55

[O2 Saturation](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 16:43:43
User entered empty.	Karol Moore (b) (4) (b) (4)	05 Nov 2020 01:15:54

**US3312605**

**Folder: Covid-19 Assessment 04 Nov 2020**

**Form: Symptom Log (3)**

**Generated On: 26 Nov 2020 10:55:55**

[O2 Saturation Units](#)

Audit	User	Time (GMT)
User entered empty.	System	05 Nov 2020 01:15:54

US3312605

Folder: Covid-19 Assessment 04 Nov 2020

Form: Symptom Log (3)

Generated On: 26 Nov 2020 10:55:55

[Temperature](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 16:43:43
User entered empty.	Karol Moore (b) (4) (b) (4)	05 Nov 2020 01:15:54

US3312605

Folder: Covid-19 Assessment 04 Nov 2020

Form: Symptom Log (3)

Generated On: 26 Nov 2020 10:55:55

[Chills](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 16:43:43
User entered 'Moderate (Moderate)'	Karol Moore (b) (4) (b) (4)	05 Nov 2020 01:15:54

**US3312605**

**Folder: Covid-19 Assessment 04 Nov 2020**

**Form: Symptom Log (3)**

**Generated On: 26 Nov 2020 10:55:55**

[Cough](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 16:43:43
User entered 'Moderate (Moderate)'	Karol Moore (b) (4) (b) (4)	05 Nov 2020 01:15:54

US3312605

Folder: Covid-19 Assessment 04 Nov 2020

Form: Symptom Log (3)

Generated On: 26 Nov 2020 10:55:55

[Shortness of Breath](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 16:43:43
User entered 'Severe (Severe)'	Karol Moore (b) (4) (b) (4)	05 Nov 2020 01:15:54

US3312605

Folder: Covid-19 Assessment 04 Nov 2020

Form: Symptom Log (3)

Generated On: 26 Nov 2020 10:55:55

[Difficulty Breathing](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 16:43:43
User entered 'Severe (Severe)'	Karol Moore (b) (4) (b) (4)	05 Nov 2020 01:15:54



US3312605

Folder: Covid-19 Assessment 04 Nov 2020

Form: Symptom Log (3)

Generated On: 26 Nov 2020 10:55:55

[Fatigue](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 16:43:43
User entered 'Severe (Severe)'	Karol Moore (b) (4) (b) (4)	05 Nov 2020 01:15:54

US3312605

Folder: Covid-19 Assessment 04 Nov 2020

Form: Symptom Log (3)

Generated On: 26 Nov 2020 10:55:55

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 16:43:43
User entered 'Severe (Severe)'	Karol Moore (b) (4) (b) (4)	05 Nov 2020 01:15:54

US3312605

Folder: Covid-19 Assessment 04 Nov 2020

Form: Symptom Log (3)

Generated On: 26 Nov 2020 10:55:55

[Body Aches](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 16:43:43
User entered 'Severe (Severe)'	Karol Moore (b) (4) (b) (4)	05 Nov 2020 01:15:54

US3312605

Folder: Covid-19 Assessment 04 Nov 2020

Form: Symptom Log (3)

Generated On: 26 Nov 2020 10:55:55

[Headache](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 16:43:43
User entered 'Moderate (Moderate)'	Karol Moore (b) (4) (b) (4)	05 Nov 2020 01:15:54

US3312605

Folder: Covid-19 Assessment 04 Nov 2020

Form: Symptom Log (3)

Generated On: 26 Nov 2020 10:55:55

[New Loss of Taste](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 16:43:43
User entered 'None (None)'	Karol Moore (b) (4) (b) (4)	05 Nov 2020 01:15:54

US3312605

Folder: Covid-19 Assessment 04 Nov 2020

Form: Symptom Log (3)

Generated On: 26 Nov 2020 10:55:55

[New Loss of Smell](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 16:43:43
User entered 'None (None)'	Karol Moore (b) (4) (b) (4)	05 Nov 2020 01:15:54

**US3312605**

**Folder: Covid-19 Assessment 04 Nov 2020**

**Form: Symptom Log (3)**

**Generated On: 26 Nov 2020 10:55:55**

[Nasal Congestion](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 16:43:43
User entered 'Severe (Severe)'	Karol Moore (b) (4) (b) (4)	05 Nov 2020 01:15:54

US3312605

Folder: Covid-19 Assessment 04 Nov 2020

Form: Symptom Log (3)

Generated On: 26 Nov 2020 10:55:55

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 16:43:43
User entered 'None (None)'	Karol Moore (b) (4) (b) (4)	05 Nov 2020 01:15:54



**US3312605**

**Folder: Covid-19 Assessment 04 Nov 2020**

**Form: Symptom Log (3)**

**Generated On: 26 Nov 2020 10:55:55**

[Nausea](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 16:43:43
User entered 'Severe (Severe)'	Karol Moore (b) (4) (b) (4)	05 Nov 2020 01:15:54

US3312605

Folder: Covid-19 Assessment 04 Nov 2020

Form: Symptom Log (3)

Generated On: 26 Nov 2020 10:55:55

[Vomiting](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 16:43:43
User entered 'Severe (Severe)'	Karol Moore (b) (4) (b) (4)	05 Nov 2020 01:15:54

US3312605

Folder: Covid-19 Assessment 04 Nov 2020

Form: Symptom Log (3)

Generated On: 26 Nov 2020 10:55:55

[Diarrhea](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 16:43:43
User entered 'Severe (Severe)'	Karol Moore (b) (4) (b) (4)	05 Nov 2020 01:15:54

US3312605

Folder: Covid-19 Assessment 04 Nov 2020

Form: Symptom Log (3)

Generated On: 26 Nov 2020 10:55:55

[Sore Throat](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 16:43:43
User entered 'Severe (Severe)'	Karol Moore (b) (4) (b) (4)	05 Nov 2020 01:15:54

US3312605

Folder: Covid-19 Assessment 04 Nov 2020

Form: Symptom Log (4)

Generated On: 26 Nov 2020 10:55:55

[Symptom Day](#)

Audit	User	Time (GMT)
User entered 'Day 4 (Day 4)'	Karol Moore (b) (4) (b) (4)	05 Nov 2020 01:18:06

US3312605

Folder: Covid-19 Assessment 04 Nov 2020

Form: Symptom Log (4)

Generated On: 26 Nov 2020 10:55:55

[Date](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 16:43:43
User entered '22 Oct 2020'	Karol Moore (b) (4) (b) (4)	05 Nov 2020 01:18:06

US3312605

Folder: Covid-19 Assessment 04 Nov 2020

Form: Symptom Log (4)

Generated On: 26 Nov 2020 10:55:55

[Assessment Not Done](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 16:43:43
User entered '0'	Karol Moore (b) (4) (b) (4)	05 Nov 2020 01:18:06

US3312605

Folder: Covid-19 Assessment 04 Nov 2020

Form: Symptom Log (4)

Generated On: 26 Nov 2020 10:55:55

[O2 Saturation](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 16:43:43
User entered empty.	Karol Moore (b) (4) (b) (4)	05 Nov 2020 01:18:06



**US3312605**

**Folder: Covid-19 Assessment 04 Nov 2020**

**Form: Symptom Log (4)**

**Generated On: 26 Nov 2020 10:55:55**

[O2 Saturation Units](#)

Audit	User	Time (GMT)
User entered empty.	System	05 Nov 2020 01:18:06

US3312605

Folder: Covid-19 Assessment 04 Nov 2020

Form: Symptom Log (4)

Generated On: 26 Nov 2020 10:55:55

[Temperature](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 16:43:43
User entered empty.	Karol Moore (b) (4) (b) (4)	05 Nov 2020 01:18:06

US3312605

Folder: Covid-19 Assessment 04 Nov 2020

Form: Symptom Log (4)

Generated On: 26 Nov 2020 10:55:55

[Chills](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 16:43:43
User entered 'Moderate (Moderate)'	Karol Moore (b) (4) (b) (4)	05 Nov 2020 01:18:06

US3312605

Folder: Covid-19 Assessment 04 Nov 2020

Form: Symptom Log (4)

Generated On: 26 Nov 2020 10:55:55

[Cough](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 16:43:43
User entered 'Moderate (Moderate)'	Karol Moore (b) (4) (b) (4)	05 Nov 2020 01:18:06

US3312605

Folder: Covid-19 Assessment 04 Nov 2020

Form: Symptom Log (4)

Generated On: 26 Nov 2020 10:55:55

[Shortness of Breath](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 16:43:43
User entered 'Severe (Severe)'	Karol Moore (b) (4) (b) (4)	05 Nov 2020 01:18:06

US3312605

Folder: Covid-19 Assessment 04 Nov 2020

Form: Symptom Log (4)

Generated On: 26 Nov 2020 10:55:55

[Difficulty Breathing](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 16:43:43
User entered 'Severe (Severe)'	Karol Moore (b) (4) (b) (4)	05 Nov 2020 01:18:06

US3312605

Folder: Covid-19 Assessment 04 Nov 2020

Form: Symptom Log (4)

Generated On: 26 Nov 2020 10:55:55

[Fatigue](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 16:43:43
User entered 'Severe (Severe)'	Karol Moore (b) (4) (b) (4)	05 Nov 2020 01:18:06

US3312605

Folder: Covid-19 Assessment 04 Nov 2020

Form: Symptom Log (4)

Generated On: 26 Nov 2020 10:55:55

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 16:43:43
User entered 'Severe (Severe)'	Karol Moore (b) (4) (b) (4)	05 Nov 2020 01:18:06



US3312605

Folder: Covid-19 Assessment 04 Nov 2020

Form: Symptom Log (4)

Generated On: 26 Nov 2020 10:55:55

[Body Aches](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 16:43:43
User entered 'Severe (Severe)'	Karol Moore (b) (4) (b) (4)	05 Nov 2020 01:18:06

US3312605

Folder: Covid-19 Assessment 04 Nov 2020

Form: Symptom Log (4)

Generated On: 26 Nov 2020 10:55:55

[Headache](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 16:43:43
User entered 'Moderate (Moderate)'	Karol Moore (b) (4) (b) (4)	05 Nov 2020 01:18:06

US3312605

Folder: Covid-19 Assessment 04 Nov 2020

Form: Symptom Log (4)

Generated On: 26 Nov 2020 10:55:55

[New Loss of Taste](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 16:43:43
User entered 'None (None)'	Karol Moore (b) (4) (b) (4)	05 Nov 2020 01:18:06

US3312605

Folder: Covid-19 Assessment 04 Nov 2020

Form: Symptom Log (4)

Generated On: 26 Nov 2020 10:55:55

[New Loss of Smell](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 16:43:43
User entered 'None (None)'	Karol Moore (b) (4) (b) (4)	05 Nov 2020 01:18:06

US3312605

Folder: Covid-19 Assessment 04 Nov 2020

Form: Symptom Log (4)

Generated On: 26 Nov 2020 10:55:55

[Nasal Congestion](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 16:43:43
User entered 'Severe (Severe)'	Karol Moore (b) (4) (b) (4)	05 Nov 2020 01:18:06

US3312605

Folder: Covid-19 Assessment 04 Nov 2020

Form: Symptom Log (4)

Generated On: 26 Nov 2020 10:55:55

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 16:43:43
User entered 'None (None)'	Karol Moore (b) (4) (b) (4)	05 Nov 2020 01:18:06

US3312605

Folder: Covid-19 Assessment 04 Nov 2020

Form: Symptom Log (4)

Generated On: 26 Nov 2020 10:55:55

[Nausea](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 16:43:43
User entered 'Severe (Severe)'	Karol Moore (b) (4) (b) (4)	05 Nov 2020 01:18:06

US3312605

Folder: Covid-19 Assessment 04 Nov 2020

Form: Symptom Log (4)

Generated On: 26 Nov 2020 10:55:55

[Vomiting](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 16:43:43
User entered 'Severe (Severe)'	Karol Moore (b) (4) (b) (4)	05 Nov 2020 01:18:06



US3312605

Folder: Covid-19 Assessment 04 Nov 2020

Form: Symptom Log (4)

Generated On: 26 Nov 2020 10:55:55

[Diarrhea](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 16:43:43
User entered 'Severe (Severe)'	Karol Moore (b) (4) (b) (4)	05 Nov 2020 01:18:06

US3312605

Folder: Covid-19 Assessment 04 Nov 2020

Form: Symptom Log (4)

Generated On: 26 Nov 2020 10:55:55

[Sore Throat](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 16:43:43
User entered 'Severe (Severe)'	Karol Moore (b) (4) (b) (4)	05 Nov 2020 01:18:06

US3312605

Folder: Covid-19 Assessment 04 Nov 2020

Form: Symptom Log (5)

Generated On: 26 Nov 2020 10:55:55

[Symptom Day](#)

Audit	User	Time (GMT)
User entered 'Day 5 (Day 5)'	Karol Moore (b) (4) (b) (4)	05 Nov 2020 01:28:29

US3312605

Folder: Covid-19 Assessment 04 Nov 2020

Form: Symptom Log (5)

Generated On: 26 Nov 2020 10:55:55

[Date](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 16:43:43
User entered '23 Oct 2020'	Karol Moore (b) (4) (b) (4)	05 Nov 2020 01:28:29

US3312605

Folder: Covid-19 Assessment 04 Nov 2020

Form: Symptom Log (5)

Generated On: 26 Nov 2020 10:55:55

[Assessment Not Done](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 16:43:43
User entered '0'	Karol Moore (b) (4) (b) (4)	05 Nov 2020 01:28:29

US3312605

Folder: Covid-19 Assessment 04 Nov 2020

Form: Symptom Log (5)

Generated On: 26 Nov 2020 10:55:55

[O2 Saturation](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 16:43:43
User entered empty.	Karol Moore (b) (4) (b) (4)	05 Nov 2020 01:28:29

**US3312605**

**Folder: Covid-19 Assessment 04 Nov 2020**

**Form: Symptom Log (5)**

**Generated On: 26 Nov 2020 10:55:55**

[O2 Saturation Units](#)

Audit	User	Time (GMT)
User entered empty.	System	05 Nov 2020 01:28:29

US3312605

Folder: Covid-19 Assessment 04 Nov 2020

Form: Symptom Log (5)

Generated On: 26 Nov 2020 10:55:55

[Temperature](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 16:43:43
User entered empty.	Karol Moore (b) (4) (b) (4)	05 Nov 2020 01:28:29



US3312605

Folder: Covid-19 Assessment 04 Nov 2020

Form: Symptom Log (5)

Generated On: 26 Nov 2020 10:55:55

[Chills](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 16:43:43
User entered 'Moderate (Moderate)'	Karol Moore (b) (4) (b) (4)	05 Nov 2020 01:28:29

US3312605

Folder: Covid-19 Assessment 04 Nov 2020

Form: Symptom Log (5)

Generated On: 26 Nov 2020 10:55:55

[Cough](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 16:43:43
User entered 'Moderate (Moderate)'	Karol Moore (b) (4) (b) (4)	05 Nov 2020 01:28:29

US3312605

Folder: Covid-19 Assessment 04 Nov 2020

Form: Symptom Log (5)

Generated On: 26 Nov 2020 10:55:55

[Shortness of Breath](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 16:43:43
User entered 'Severe (Severe)'	Karol Moore (b) (4) (b) (4)	05 Nov 2020 01:28:29

US3312605

Folder: Covid-19 Assessment 04 Nov 2020

Form: Symptom Log (5)

Generated On: 26 Nov 2020 10:55:55

[Difficulty Breathing](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 16:43:43
User entered 'Severe (Severe)'	Karol Moore (b) (4) (b) (4)	05 Nov 2020 01:28:29

US3312605

Folder: Covid-19 Assessment 04 Nov 2020

Form: Symptom Log (5)

Generated On: 26 Nov 2020 10:55:55

[Fatigue](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 16:43:43
User entered 'Severe (Severe)'	Karol Moore (b) (4) (b) (4)	05 Nov 2020 01:28:29

US3312605

Folder: Covid-19 Assessment 04 Nov 2020

Form: Symptom Log (5)

Generated On: 26 Nov 2020 10:55:55

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 16:43:43
User entered 'Severe (Severe)'	Karol Moore (b) (4) (b) (4)	05 Nov 2020 01:28:29

US3312605

Folder: Covid-19 Assessment 04 Nov 2020

Form: Symptom Log (5)

Generated On: 26 Nov 2020 10:55:55

[Body Aches](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 16:43:43
User entered 'Severe (Severe)'	Karol Moore (b) (4) (b) (4)	05 Nov 2020 01:28:29

US3312605

Folder: Covid-19 Assessment 04 Nov 2020

Form: Symptom Log (5)

Generated On: 26 Nov 2020 10:55:55

[Headache](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 16:43:43
User entered 'Severe (Severe)'	Karol Moore (b) (4) (b) (4)	05 Nov 2020 01:28:29



US3312605

Folder: Covid-19 Assessment 04 Nov 2020

Form: Symptom Log (5)

Generated On: 26 Nov 2020 10:55:55

[New Loss of Taste](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 16:43:43
User entered 'None (None)'	Karol Moore (b) (4) (b) (4)	05 Nov 2020 01:28:29

US3312605

Folder: Covid-19 Assessment 04 Nov 2020

Form: Symptom Log (5)

Generated On: 26 Nov 2020 10:55:55

[New Loss of Smell](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 16:43:43
User entered 'None (None)'	Karol Moore (b) (4) (b) (4)	05 Nov 2020 01:28:29

US3312605

Folder: Covid-19 Assessment 04 Nov 2020

Form: Symptom Log (5)

Generated On: 26 Nov 2020 10:55:55

[Nasal Congestion](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 16:43:43
User entered 'Severe (Severe)'	Karol Moore (b) (4) (b) (4)	05 Nov 2020 01:28:29

US3312605

Folder: Covid-19 Assessment 04 Nov 2020

Form: Symptom Log (5)

Generated On: 26 Nov 2020 10:55:55

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 16:43:43
User entered 'None (None)'	Karol Moore (b) (4) (b) (4)	05 Nov 2020 01:28:29

US3312605

Folder: Covid-19 Assessment 04 Nov 2020

Form: Symptom Log (5)

Generated On: 26 Nov 2020 10:55:55

[Nausea](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 16:43:43
User entered 'Severe (Severe)'	Karol Moore (b) (4) (b) (4)	05 Nov 2020 01:28:29

US3312605

Folder: Covid-19 Assessment 04 Nov 2020

Form: Symptom Log (5)

Generated On: 26 Nov 2020 10:55:55

[Vomiting](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 16:43:43
User entered 'Severe (Severe)'	Karol Moore (b) (4) (b) (4)	05 Nov 2020 01:28:29

US3312605

Folder: Covid-19 Assessment 04 Nov 2020

Form: Symptom Log (5)

Generated On: 26 Nov 2020 10:55:55

[Diarrhea](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 16:43:43
User entered 'Severe (Severe)'	Karol Moore (b) (4) (b) (4)	05 Nov 2020 01:28:29

US3312605

Folder: Covid-19 Assessment 04 Nov 2020

Form: Symptom Log (5)

Generated On: 26 Nov 2020 10:55:55

[Sore Throat](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 16:43:43
User entered 'Severe (Severe)'	Karol Moore (b) (4) (b) (4)	05 Nov 2020 01:28:29



US3312605

Folder: Covid-19 Assessment 04 Nov 2020

Form: Symptom Log (6)

Generated On: 26 Nov 2020 10:55:55

[Symptom Day](#)

Audit	User	Time (GMT)
User entered 'Day 6 (Day 6)'	Karol Moore (b) (4) (b) (4)	05 Nov 2020 01:30:23

**US3312605**

**Folder: Covid-19 Assessment 04 Nov 2020**

**Form: Symptom Log (6)**

**Generated On: 26 Nov 2020 10:55:55**

[Date](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 16:43:43
User entered '24 Oct 2020'	Karol Moore (b) (4) (b) (4)	05 Nov 2020 01:30:23

US3312605

Folder: Covid-19 Assessment 04 Nov 2020

Form: Symptom Log (6)

Generated On: 26 Nov 2020 10:55:55

[Assessment Not Done](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 16:43:43
User entered '0'	Karol Moore (b) (4) (b) (4)	05 Nov 2020 01:30:23

US3312605

Folder: Covid-19 Assessment 04 Nov 2020

Form: Symptom Log (6)

Generated On: 26 Nov 2020 10:55:55

[O2 Saturation](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 16:43:43
User entered empty.	Karol Moore (b) (4) (b) (4)	05 Nov 2020 01:30:23

**US3312605**

**Folder: Covid-19 Assessment 04 Nov 2020**

**Form: Symptom Log (6)**

**Generated On: 26 Nov 2020 10:55:55**

[O2 Saturation Units](#)

Audit	User	Time (GMT)
User entered empty.	System	05 Nov 2020 01:30:23

US3312605

Folder: Covid-19 Assessment 04 Nov 2020

Form: Symptom Log (6)

Generated On: 26 Nov 2020 10:55:55

[Temperature](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 16:43:43
User entered empty.	Karol Moore (b) (4) (b) (4)	05 Nov 2020 01:30:23

US3312605

Folder: Covid-19 Assessment 04 Nov 2020

Form: Symptom Log (6)

Generated On: 26 Nov 2020 10:55:55

[Chills](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 16:43:43
User entered 'Moderate (Moderate)'	Karol Moore (b) (4) (b) (4)	05 Nov 2020 01:30:23

US3312605

Folder: Covid-19 Assessment 04 Nov 2020

Form: Symptom Log (6)

Generated On: 26 Nov 2020 10:55:55

[Cough](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 16:43:43
User entered 'Moderate (Moderate)'	Karol Moore (b) (4) (b) (4)	05 Nov 2020 01:30:23



US3312605

Folder: Covid-19 Assessment 04 Nov 2020

Form: Symptom Log (6)

Generated On: 26 Nov 2020 10:55:55

[Shortness of Breath](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 16:43:43
User entered 'Severe (Severe)'	Karol Moore (b) (4) (b) (4)	05 Nov 2020 01:30:23

US3312605

Folder: Covid-19 Assessment 04 Nov 2020

Form: Symptom Log (6)

Generated On: 26 Nov 2020 10:55:55

[Difficulty Breathing](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 16:43:43
User entered 'Severe (Severe)'	Karol Moore (b) (4) (b) (4)	05 Nov 2020 01:30:23

US3312605

Folder: Covid-19 Assessment 04 Nov 2020

Form: Symptom Log (6)

Generated On: 26 Nov 2020 10:55:55

[Fatigue](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 16:43:43
User entered 'Severe (Severe)'	Karol Moore (b) (4) (b) (4)	05 Nov 2020 01:30:23

US3312605

Folder: Covid-19 Assessment 04 Nov 2020

Form: Symptom Log (6)

Generated On: 26 Nov 2020 10:55:55

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 16:43:43
User entered 'Severe (Severe)'	Karol Moore (b) (4) (b) (4)	05 Nov 2020 01:30:23

US3312605

Folder: Covid-19 Assessment 04 Nov 2020

Form: Symptom Log (6)

Generated On: 26 Nov 2020 10:55:55

[Body Aches](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 16:43:43
User entered 'Severe (Severe)'	Karol Moore (b) (4) (b) (4)	05 Nov 2020 01:30:23

US3312605

Folder: Covid-19 Assessment 04 Nov 2020

Form: Symptom Log (6)

Generated On: 26 Nov 2020 10:55:55

[Headache](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 16:43:43
User entered 'Moderate (Moderate)'	Karol Moore (b) (4) (b) (4)	05 Nov 2020 01:30:23

US3312605

Folder: Covid-19 Assessment 04 Nov 2020

Form: Symptom Log (6)

Generated On: 26 Nov 2020 10:55:55

[New Loss of Taste](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 16:43:43
User entered 'None (None)'	Karol Moore (b) (4) (b) (4)	05 Nov 2020 01:30:23

US3312605

Folder: Covid-19 Assessment 04 Nov 2020

Form: Symptom Log (6)

Generated On: 26 Nov 2020 10:55:55

[New Loss of Smell](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 16:43:43
User entered 'None (None)'	Karol Moore (b) (4) (b) (4)	05 Nov 2020 01:30:23



US3312605

Folder: Covid-19 Assessment 04 Nov 2020

Form: Symptom Log (6)

Generated On: 26 Nov 2020 10:55:55

[Nasal Congestion](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 16:43:43
User entered 'Severe (Severe)'	Karol Moore (b) (4) (b) (4)	05 Nov 2020 01:30:23

US3312605

Folder: Covid-19 Assessment 04 Nov 2020

Form: Symptom Log (6)

Generated On: 26 Nov 2020 10:55:55

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 16:43:43
User entered 'None (None)'	Karol Moore (b) (4) (b) (4)	05 Nov 2020 01:30:23

US3312605

Folder: Covid-19 Assessment 04 Nov 2020

Form: Symptom Log (6)

Generated On: 26 Nov 2020 10:55:55

[Nausea](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 16:43:43
User entered 'Severe (Severe)'	Karol Moore (b) (4) (b) (4)	05 Nov 2020 01:30:23

US3312605

Folder: Covid-19 Assessment 04 Nov 2020

Form: Symptom Log (6)

Generated On: 26 Nov 2020 10:55:55

[Vomiting](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 16:43:43
User entered 'Severe (Severe)'	Karol Moore (b) (4) (b) (4)	05 Nov 2020 01:30:23

US3312605

Folder: Covid-19 Assessment 04 Nov 2020

Form: Symptom Log (6)

Generated On: 26 Nov 2020 10:55:55

[Diarrhea](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 16:43:43
User entered 'Severe (Severe)'	Karol Moore (b) (4) (b) (4)	05 Nov 2020 01:30:23

US3312605

Folder: Covid-19 Assessment 04 Nov 2020

Form: Symptom Log (6)

Generated On: 26 Nov 2020 10:55:55

[Sore Throat](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 16:43:43
User entered 'Severe (Severe)'	Karol Moore (b) (4) (b) (4)	05 Nov 2020 01:30:23

US3312605

Folder: Covid-19 Assessment 04 Nov 2020

Form: Symptom Log (7)

Generated On: 26 Nov 2020 10:55:55

[Symptom Day](#)

Audit	User	Time (GMT)
User entered 'Day 7 (Day 7)'	Karol Moore (b) (4) (b) (4)	05 Nov 2020 01:32:13

**US3312605**

**Folder: Covid-19 Assessment 04 Nov 2020**

**Form: Symptom Log (7)**

**Generated On: 26 Nov 2020 10:55:55**

[Date](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 16:43:43
User entered '25 Oct 2020'	Karol Moore (b) (4) (b) (4)	05 Nov 2020 01:32:13



US3312605

Folder: Covid-19 Assessment 04 Nov 2020

Form: Symptom Log (7)

Generated On: 26 Nov 2020 10:55:55

[Assessment Not Done](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 16:43:43
User entered '0'	Karol Moore (b) (4) (b) (4)	05 Nov 2020 01:32:13

US3312605

Folder: Covid-19 Assessment 04 Nov 2020

Form: Symptom Log (7)

Generated On: 26 Nov 2020 10:55:55

[O2 Saturation](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 16:43:43
User entered empty.	Karol Moore (b) (4) (b) (4)	05 Nov 2020 01:32:13

**US3312605**

**Folder: Covid-19 Assessment 04 Nov 2020**

**Form: Symptom Log (7)**

**Generated On: 26 Nov 2020 10:55:55**

[O2 Saturation Units](#)

Audit	User	Time (GMT)
User entered empty.	System	05 Nov 2020 01:32:13

US3312605

Folder: Covid-19 Assessment 04 Nov 2020

Form: Symptom Log (7)

Generated On: 26 Nov 2020 10:55:55

[Temperature](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 16:43:43
User entered empty.	Karol Moore (b) (4) (b) (4)	05 Nov 2020 01:32:13

**US3312605**

**Folder: Covid-19 Assessment 04 Nov 2020**

**Form: Symptom Log (7)**

**Generated On: 26 Nov 2020 10:55:55**

[Chills](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 16:43:43
User entered 'Moderate (Moderate)'	Karol Moore (b) (4) (b) (4)	05 Nov 2020 01:32:13

US3312605

Folder: Covid-19 Assessment 04 Nov 2020

Form: Symptom Log (7)

Generated On: 26 Nov 2020 10:55:55

[Cough](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 16:43:43
User entered 'Moderate (Moderate)'	Karol Moore (b) (4) (b) (4)	05 Nov 2020 01:32:13

US3312605

Folder: Covid-19 Assessment 04 Nov 2020

Form: Symptom Log (7)

Generated On: 26 Nov 2020 10:55:55

[Shortness of Breath](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 16:43:43
User entered 'Severe (Severe)'	Karol Moore (b) (4) (b) (4)	05 Nov 2020 01:32:13

US3312605

Folder: Covid-19 Assessment 04 Nov 2020

Form: Symptom Log (7)

Generated On: 26 Nov 2020 10:55:55

[Difficulty Breathing](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 16:43:43
User entered 'Severe (Severe)'	Karol Moore (b) (4) (b) (4)	05 Nov 2020 01:32:13



US3312605

Folder: Covid-19 Assessment 04 Nov 2020

Form: Symptom Log (7)

Generated On: 26 Nov 2020 10:55:55

[Fatigue](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 16:43:43
User entered 'Severe (Severe)'	Karol Moore (b) (4) (b) (4)	05 Nov 2020 01:32:13

US3312605

Folder: Covid-19 Assessment 04 Nov 2020

Form: Symptom Log (7)

Generated On: 26 Nov 2020 10:55:55

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 16:43:43
User entered 'Severe (Severe)'	Karol Moore (b) (4) (b) (4)	05 Nov 2020 01:32:13

US3312605

Folder: Covid-19 Assessment 04 Nov 2020

Form: Symptom Log (7)

Generated On: 26 Nov 2020 10:55:55

[Body Aches](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 16:43:43
User entered 'Severe (Severe)'	Karol Moore (b) (4) (b) (4)	05 Nov 2020 01:32:13

US3312605

Folder: Covid-19 Assessment 04 Nov 2020

Form: Symptom Log (7)

Generated On: 26 Nov 2020 10:55:55

[Headache](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 16:43:43
User entered 'Moderate (Moderate)'	Karol Moore (b) (4) (b) (4)	05 Nov 2020 01:32:13

US3312605

Folder: Covid-19 Assessment 04 Nov 2020

Form: Symptom Log (7)

Generated On: 26 Nov 2020 10:55:55

[New Loss of Taste](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 16:43:43
User entered 'None (None)'	Karol Moore (b) (4) (b) (4)	05 Nov 2020 01:32:13

US3312605

Folder: Covid-19 Assessment 04 Nov 2020

Form: Symptom Log (7)

Generated On: 26 Nov 2020 10:55:55

[New Loss of Smell](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 16:43:43
User entered 'None (None)'	Karol Moore (b) (4) (b) (4)	05 Nov 2020 01:32:13

**US3312605**

**Folder: Covid-19 Assessment 04 Nov 2020**

**Form: Symptom Log (7)**

**Generated On: 26 Nov 2020 10:55:55**

[Nasal Congestion](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 16:43:43
User entered 'Severe (Severe)'	Karol Moore (b) (4) (b) (4)	05 Nov 2020 01:32:13

US3312605

Folder: Covid-19 Assessment 04 Nov 2020

Form: Symptom Log (7)

Generated On: 26 Nov 2020 10:55:55

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 16:43:43
User entered 'None (None)'	Karol Moore (b) (4) (b) (4)	05 Nov 2020 01:32:13



**US3312605**

**Folder: Covid-19 Assessment 04 Nov 2020**

**Form: Symptom Log (7)**

**Generated On: 26 Nov 2020 10:55:55**

[Nausea](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 16:43:43
User entered 'Severe (Severe)'	Karol Moore (b) (4) (b) (4)	05 Nov 2020 01:32:13

US3312605

Folder: Covid-19 Assessment 04 Nov 2020

Form: Symptom Log (7)

Generated On: 26 Nov 2020 10:55:55

[Vomiting](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 16:43:43
User entered 'Severe (Severe)'	Karol Moore (b) (4) (b) (4)	05 Nov 2020 01:32:13

US3312605

Folder: Covid-19 Assessment 04 Nov 2020

Form: Symptom Log (7)

Generated On: 26 Nov 2020 10:55:55

[Diarrhea](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 16:43:43
User entered 'Severe (Severe)'	Karol Moore (b) (4) (b) (4)	05 Nov 2020 01:32:13

**US3312605**

**Folder: Covid-19 Assessment 04 Nov 2020**

**Form: Symptom Log (7)**

**Generated On: 26 Nov 2020 10:55:55**

[Sore Throat](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 16:43:43
User entered 'Severe (Severe)'	Karol Moore (b) (4) (b) (4)	05 Nov 2020 01:32:13

US3312605

Folder: Covid-19 Assessment 04 Nov 2020

Form: Symptom Log (8)

Generated On: 26 Nov 2020 10:55:55

[Symptom Day](#)

Audit	User	Time (GMT)
User entered 'Day 8 (Day 8)'	Karol Moore (b) (4) (b) (4)	05 Nov 2020 01:33:16

**US3312605**

**Folder: Covid-19 Assessment 04 Nov 2020**

**Form: Symptom Log (8)**

**Generated On: 26 Nov 2020 10:55:55**

[Date](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 16:43:43
User entered '26 Oct 2020'	Karol Moore (b) (4) (b) (4)	05 Nov 2020 01:33:16

US3312605

Folder: Covid-19 Assessment 04 Nov 2020

Form: Symptom Log (8)

Generated On: 26 Nov 2020 10:55:55

[Assessment Not Done](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 16:43:43
User entered '0'	Karol Moore (b) (4) (b) (4)	05 Nov 2020 01:33:16

US3312605

Folder: Covid-19 Assessment 04 Nov 2020

Form: Symptom Log (8)

Generated On: 26 Nov 2020 10:55:55

[O2 Saturation](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 16:43:43
User entered empty.	Karol Moore (b) (4) (b) (4)	05 Nov 2020 01:33:16



**US3312605**

**Folder: Covid-19 Assessment 04 Nov 2020**

**Form: Symptom Log (8)**

**Generated On: 26 Nov 2020 10:55:55**

[O2 Saturation Units](#)

Audit	User	Time (GMT)
User entered empty.	System	05 Nov 2020 01:33:16

US3312605

Folder: Covid-19 Assessment 04 Nov 2020

Form: Symptom Log (8)

Generated On: 26 Nov 2020 10:55:55

[Temperature](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 16:43:43
User entered empty.	Karol Moore (b) (4) (b) (4)	05 Nov 2020 01:33:16

**US3312605**

**Folder: Covid-19 Assessment 04 Nov 2020**

**Form: Symptom Log (8)**

**Generated On: 26 Nov 2020 10:55:55**

[Chills](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 16:43:43
User entered 'Moderate (Moderate)'	Karol Moore (b) (4) (b) (4)	05 Nov 2020 01:33:16

**US3312605**

**Folder: Covid-19 Assessment 04 Nov 2020**

**Form: Symptom Log (8)**

**Generated On: 26 Nov 2020 10:55:55**

[Cough](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 16:43:43
User entered 'Moderate (Moderate)'	Karol Moore (b) (4) (b) (4)	05 Nov 2020 01:33:16

US3312605

Folder: Covid-19 Assessment 04 Nov 2020

Form: Symptom Log (8)

Generated On: 26 Nov 2020 10:55:55

[Shortness of Breath](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 16:43:43
User entered 'Severe (Severe)'	Karol Moore (b) (4) (b) (4)	05 Nov 2020 01:33:16

US3312605

Folder: Covid-19 Assessment 04 Nov 2020

Form: Symptom Log (8)

Generated On: 26 Nov 2020 10:55:55

[Difficulty Breathing](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 16:43:43
User entered 'Severe (Severe)'	Karol Moore (b) (4) (b) (4)	05 Nov 2020 01:33:16

US3312605

Folder: Covid-19 Assessment 04 Nov 2020

Form: Symptom Log (8)

Generated On: 26 Nov 2020 10:55:55

[Fatigue](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 16:43:43
User entered 'Severe (Severe)'	Karol Moore (b) (4) (b) (4)	05 Nov 2020 01:33:16

US3312605

Folder: Covid-19 Assessment 04 Nov 2020

Form: Symptom Log (8)

Generated On: 26 Nov 2020 10:55:55

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 16:43:43
User entered 'Severe (Severe)'	Karol Moore (b) (4) (b) (4)	05 Nov 2020 01:33:16



US3312605

Folder: Covid-19 Assessment 04 Nov 2020

Form: Symptom Log (8)

Generated On: 26 Nov 2020 10:55:55

[Body Aches](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 16:43:43
User entered 'Severe (Severe)'	Karol Moore (b) (4) (b) (4)	05 Nov 2020 01:33:16

US3312605

Folder: Covid-19 Assessment 04 Nov 2020

Form: Symptom Log (8)

Generated On: 26 Nov 2020 10:55:55

[Headache](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 16:43:43
User entered 'Moderate (Moderate)'	Karol Moore (b) (4) (b) (4)	05 Nov 2020 01:33:16

**US3312605**

**Folder: Covid-19 Assessment 04 Nov 2020**

**Form: Symptom Log (8)**

**Generated On: 26 Nov 2020 10:55:55**

[New Loss of Taste](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 16:43:43
User entered 'Severe (Severe)'	Karol Moore (b) (4) (b) (4)	05 Nov 2020 01:33:16

US3312605

Folder: Covid-19 Assessment 04 Nov 2020

Form: Symptom Log (8)

Generated On: 26 Nov 2020 10:55:55

[New Loss of Smell](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 16:43:43
User entered 'Severe (Severe)'	Karol Moore (b) (4) (b) (4)	05 Nov 2020 01:33:16

US3312605

Folder: Covid-19 Assessment 04 Nov 2020

Form: Symptom Log (8)

Generated On: 26 Nov 2020 10:55:55

[Nasal Congestion](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 16:43:43
User entered 'Severe (Severe)'	Karol Moore (b) (4) (b) (4)	05 Nov 2020 01:33:16

US3312605

Folder: Covid-19 Assessment 04 Nov 2020

Form: Symptom Log (8)

Generated On: 26 Nov 2020 10:55:55

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 16:43:43
User entered 'None (None)'	Karol Moore (b) (4) (b) (4)	05 Nov 2020 01:33:16

**US3312605**

**Folder: Covid-19 Assessment 04 Nov 2020**

**Form: Symptom Log (8)**

**Generated On: 26 Nov 2020 10:55:55**

[Nausea](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 16:43:43
User entered 'None (None)'	Karol Moore (b) (4) (b) (4)	05 Nov 2020 01:33:16

**US3312605**

**Folder: Covid-19 Assessment 04 Nov 2020**

**Form: Symptom Log (8)**

**Generated On: 26 Nov 2020 10:55:55**

[Vomiting](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 16:43:43
User entered 'None (None)'	Karol Moore (b) (4) (b) (4)	05 Nov 2020 01:33:16



US3312605

Folder: Covid-19 Assessment 04 Nov 2020

Form: Symptom Log (8)

Generated On: 26 Nov 2020 10:55:55

[Diarrhea](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 16:43:43
User entered 'None (None)'	Karol Moore (b) (4) (b) (4)	05 Nov 2020 01:33:16

US3312605

Folder: Covid-19 Assessment 04 Nov 2020

Form: Symptom Log (8)

Generated On: 26 Nov 2020 10:55:55

[Sore Throat](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 16:43:43
User entered 'Severe (Severe)'	Karol Moore (b) (4) (b) (4)	05 Nov 2020 01:33:16

US3312605

Folder: Covid-19 Assessment 04 Nov 2020

Form: Symptom Log (9)

Generated On: 26 Nov 2020 10:55:55

[Symptom Day](#)

Audit	User	Time (GMT)
User entered 'Day 9 (Day 9)'	Karol Moore (b) (4) (b) (4)	05 Nov 2020 01:34:02

**US3312605**

**Folder: Covid-19 Assessment 04 Nov 2020**

**Form: Symptom Log (9)**

**Generated On: 26 Nov 2020 10:55:55**

[Date](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 16:43:43
User entered '27 Oct 2020'	Karol Moore (b) (4) (b) (4)	05 Nov 2020 01:34:02

US3312605

Folder: Covid-19 Assessment 04 Nov 2020

Form: Symptom Log (9)

Generated On: 26 Nov 2020 10:55:55

[Assessment Not Done](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 16:43:43
User entered '0'	Karol Moore (b) (4) (b) (4)	05 Nov 2020 01:34:02

US3312605

Folder: Covid-19 Assessment 04 Nov 2020

Form: Symptom Log (9)

Generated On: 26 Nov 2020 10:55:55

[O2 Saturation](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 16:43:43
User entered empty.	Karol Moore (b) (4) (b) (4)	05 Nov 2020 01:34:02

**US3312605**

**Folder: Covid-19 Assessment 04 Nov 2020**

**Form: Symptom Log (9)**

**Generated On: 26 Nov 2020 10:55:55**

[O2 Saturation Units](#)

Audit	User	Time (GMT)
User entered empty.	System	05 Nov 2020 01:34:02

US3312605

Folder: Covid-19 Assessment 04 Nov 2020

Form: Symptom Log (9)

Generated On: 26 Nov 2020 10:55:55

[Temperature](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 16:43:43
User entered empty.	Karol Moore (b) (4) (b) (4)	05 Nov 2020 01:34:02



US3312605

Folder: Covid-19 Assessment 04 Nov 2020

Form: Symptom Log (9)

Generated On: 26 Nov 2020 10:55:55

[Chills](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 16:43:43
User entered 'Moderate (Moderate)'	Karol Moore (b) (4) (b) (4)	05 Nov 2020 01:34:02

US3312605

Folder: Covid-19 Assessment 04 Nov 2020

Form: Symptom Log (9)

Generated On: 26 Nov 2020 10:55:55

[Cough](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 16:43:43
User entered 'Moderate (Moderate)'	Karol Moore (b) (4) (b) (4)	05 Nov 2020 01:34:02

US3312605

Folder: Covid-19 Assessment 04 Nov 2020

Form: Symptom Log (9)

Generated On: 26 Nov 2020 10:55:55

[Shortness of Breath](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 16:43:43
User entered 'Severe (Severe)'	Karol Moore (b) (4) (b) (4)	05 Nov 2020 01:34:02

US3312605

Folder: Covid-19 Assessment 04 Nov 2020

Form: Symptom Log (9)

Generated On: 26 Nov 2020 10:55:55

[Difficulty Breathing](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 16:43:43
User entered 'Severe (Severe)'	Karol Moore (b) (4) (b) (4)	05 Nov 2020 01:34:02

US3312605

Folder: Covid-19 Assessment 04 Nov 2020

Form: Symptom Log (9)

Generated On: 26 Nov 2020 10:55:55

[Fatigue](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 16:43:43
User entered 'Severe (Severe)'	Karol Moore (b) (4) (b) (4)	05 Nov 2020 01:34:02

US3312605

Folder: Covid-19 Assessment 04 Nov 2020

Form: Symptom Log (9)

Generated On: 26 Nov 2020 10:55:55

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 16:43:43
User entered 'Severe (Severe)'	Karol Moore (b) (4) (b) (4)	05 Nov 2020 01:34:02

US3312605

Folder: Covid-19 Assessment 04 Nov 2020

Form: Symptom Log (9)

Generated On: 26 Nov 2020 10:55:55

[Body Aches](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 16:43:43
User entered 'Severe (Severe)'	Karol Moore (b) (4) (b) (4)	05 Nov 2020 01:34:02

US3312605

Folder: Covid-19 Assessment 04 Nov 2020

Form: Symptom Log (9)

Generated On: 26 Nov 2020 10:55:55

[Headache](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 16:43:43
User entered 'Moderate (Moderate)'	Karol Moore (b) (4) (b) (4)	05 Nov 2020 01:34:02



US3312605

Folder: Covid-19 Assessment 04 Nov 2020

Form: Symptom Log (9)

Generated On: 26 Nov 2020 10:55:55

[New Loss of Taste](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 16:43:43
User entered 'Severe (Severe)'	Karol Moore (b) (4) (b) (4)	05 Nov 2020 01:34:02

US3312605

Folder: Covid-19 Assessment 04 Nov 2020

Form: Symptom Log (9)

Generated On: 26 Nov 2020 10:55:55

[New Loss of Smell](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 16:43:43
User entered 'Severe (Severe)'	Karol Moore (b) (4) (b) (4)	05 Nov 2020 01:34:02

US3312605

Folder: Covid-19 Assessment 04 Nov 2020

Form: Symptom Log (9)

Generated On: 26 Nov 2020 10:55:55

[Nasal Congestion](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 16:43:43
User entered 'Severe (Severe)'	Karol Moore (b) (4) (b) (4)	05 Nov 2020 01:34:02

US3312605

Folder: Covid-19 Assessment 04 Nov 2020

Form: Symptom Log (9)

Generated On: 26 Nov 2020 10:55:55

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 16:43:43
User entered 'None (None)'	Karol Moore (b) (4) (b) (4)	05 Nov 2020 01:34:02

US3312605

Folder: Covid-19 Assessment 04 Nov 2020

Form: Symptom Log (9)

Generated On: 26 Nov 2020 10:55:55

[Nausea](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 16:43:43
User entered 'None (None)'	Karol Moore (b) (4) (b) (4)	05 Nov 2020 01:34:02

**US3312605**

**Folder: Covid-19 Assessment 04 Nov 2020**

**Form: Symptom Log (9)**

**Generated On: 26 Nov 2020 10:55:55**

[Vomiting](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 16:43:43
User entered 'None (None)'	Karol Moore (b) (4) (b) (4)	05 Nov 2020 01:34:02

US3312605

Folder: Covid-19 Assessment 04 Nov 2020

Form: Symptom Log (9)

Generated On: 26 Nov 2020 10:55:55

[Diarrhea](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 16:43:43
User entered 'None (None)'	Karol Moore (b) (4) (b) (4)	05 Nov 2020 01:34:02

US3312605

Folder: Covid-19 Assessment 04 Nov 2020

Form: Symptom Log (9)

Generated On: 26 Nov 2020 10:55:55

[Sore Throat](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 16:43:43
User entered 'Severe (Severe)'	Karol Moore (b) (4) (b) (4)	05 Nov 2020 01:34:02



US3312605

Folder: Covid-19 Assessment 04 Nov 2020

Form: Symptom Log (10)

Generated On: 26 Nov 2020 10:55:55

[Symptom Day](#)

Audit	User	Time (GMT)
User entered 'Day 10 (Day 10)'	Karol Moore (b) (4) (b) (4)	05 Nov 2020 01:34:43

**US3312605**

**Folder: Covid-19 Assessment 04 Nov 2020**

**Form: Symptom Log (10)**

**Generated On: 26 Nov 2020 10:55:55**

[Date](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 16:43:43
User entered '28 Oct 2020'	Karol Moore (b) (4) (b) (4)	05 Nov 2020 01:34:43

US3312605

Folder: Covid-19 Assessment 04 Nov 2020

Form: Symptom Log (10)

Generated On: 26 Nov 2020 10:55:55

[Assessment Not Done](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 16:43:43
User entered '0'	Karol Moore (b) (4) (b) (4)	05 Nov 2020 01:34:43

US3312605

Folder: Covid-19 Assessment 04 Nov 2020

Form: Symptom Log (10)

Generated On: 26 Nov 2020 10:55:55

[O2 Saturation](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 16:43:43
User entered empty.	Karol Moore (b) (4) (b) (4)	05 Nov 2020 01:34:43

**US3312605**

**Folder: Covid-19 Assessment 04 Nov 2020**

**Form: Symptom Log (10)**

**Generated On: 26 Nov 2020 10:55:55**

[O2 Saturation Units](#)

Audit	User	Time (GMT)
User entered empty.	System	05 Nov 2020 01:34:43

US3312605

Folder: Covid-19 Assessment 04 Nov 2020

Form: Symptom Log (10)

Generated On: 26 Nov 2020 10:55:55

[Temperature](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 16:43:43
User entered empty.	Karol Moore (b) (4) (b) (4)	05 Nov 2020 01:34:43

US3312605

Folder: Covid-19 Assessment 04 Nov 2020

Form: Symptom Log (10)

Generated On: 26 Nov 2020 10:55:55

[Chills](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 16:43:43
User entered 'Moderate (Moderate)'	Karol Moore (b) (4) (b) (4)	05 Nov 2020 01:34:43

US3312605

Folder: Covid-19 Assessment 04 Nov 2020

Form: Symptom Log (10)

Generated On: 26 Nov 2020 10:55:55

[Cough](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 16:43:43
User entered 'Moderate (Moderate)'	Karol Moore (b) (4) (b) (4)	05 Nov 2020 01:34:43



US3312605

Folder: Covid-19 Assessment 04 Nov 2020

Form: Symptom Log (10)

Generated On: 26 Nov 2020 10:55:55

[Shortness of Breath](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 16:43:43
User entered 'Severe (Severe)'	Karol Moore (b) (4) (b) (4)	05 Nov 2020 01:34:43

US3312605

Folder: Covid-19 Assessment 04 Nov 2020

Form: Symptom Log (10)

Generated On: 26 Nov 2020 10:55:55

[Difficulty Breathing](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 16:43:43
User entered 'Severe (Severe)'	Karol Moore (b) (4) (b) (4)	05 Nov 2020 01:34:43

US3312605

Folder: Covid-19 Assessment 04 Nov 2020

Form: Symptom Log (10)

Generated On: 26 Nov 2020 10:55:55

[Fatigue](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 16:43:43
User entered 'Severe (Severe)'	Karol Moore (b) (4) (b) (4)	05 Nov 2020 01:34:43

US3312605

Folder: Covid-19 Assessment 04 Nov 2020

Form: Symptom Log (10)

Generated On: 26 Nov 2020 10:55:55

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 16:43:43
User entered 'Severe (Severe)'	Karol Moore (b) (4) (b) (4)	05 Nov 2020 01:34:43

US3312605

Folder: Covid-19 Assessment 04 Nov 2020

Form: Symptom Log (10)

Generated On: 26 Nov 2020 10:55:55

[Body Aches](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 16:43:43
User entered 'Severe (Severe)'	Karol Moore (b) (4) (b) (4)	05 Nov 2020 01:34:43

US3312605

Folder: Covid-19 Assessment 04 Nov 2020

Form: Symptom Log (10)

Generated On: 26 Nov 2020 10:55:55

[Headache](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 16:43:43
User entered 'Moderate (Moderate)'	Karol Moore (b) (4) (b) (4)	05 Nov 2020 01:34:43

US3312605

Folder: Covid-19 Assessment 04 Nov 2020

Form: Symptom Log (10)

Generated On: 26 Nov 2020 10:55:55

[New Loss of Taste](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 16:43:43
User entered 'Severe (Severe)'	Karol Moore (b) (4) (b) (4)	05 Nov 2020 01:34:43

US3312605

Folder: Covid-19 Assessment 04 Nov 2020

Form: Symptom Log (10)

Generated On: 26 Nov 2020 10:55:55

[New Loss of Smell](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 16:43:43
User entered 'Severe (Severe)'	Karol Moore (b) (4) (b) (4)	05 Nov 2020 01:34:43



US3312605

Folder: Covid-19 Assessment 04 Nov 2020

Form: Symptom Log (10)

Generated On: 26 Nov 2020 10:55:55

[Nasal Congestion](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 16:43:43
User entered 'Severe (Severe)'	Karol Moore (b) (4) (b) (4)	05 Nov 2020 01:34:43

US3312605

Folder: Covid-19 Assessment 04 Nov 2020

Form: Symptom Log (10)

Generated On: 26 Nov 2020 10:55:55

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 16:43:43
User entered 'None (None)'	Karol Moore (b) (4) (b) (4)	05 Nov 2020 01:34:43

**US3312605**

**Folder: Covid-19 Assessment 04 Nov 2020**

**Form: Symptom Log (10)**

**Generated On: 26 Nov 2020 10:55:55**

[Nausea](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 16:43:43
User entered 'None (None)'	Karol Moore (b) (4) (b) (4)	05 Nov 2020 01:34:43

US3312605

Folder: Covid-19 Assessment 04 Nov 2020

Form: Symptom Log (10)

Generated On: 26 Nov 2020 10:55:55

[Vomiting](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 16:43:43
User entered 'None (None)'	Karol Moore (b) (4) (b) (4)	05 Nov 2020 01:34:43

US3312605

Folder: Covid-19 Assessment 04 Nov 2020

Form: Symptom Log (10)

Generated On: 26 Nov 2020 10:55:55

[Diarrhea](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 16:43:43
User entered 'None (None)'	Karol Moore (b) (4) (b) (4)	05 Nov 2020 01:34:43

US3312605

Folder: Covid-19 Assessment 04 Nov 2020

Form: Symptom Log (10)

Generated On: 26 Nov 2020 10:55:55

[Sore Throat](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 16:43:43
User entered 'Severe (Severe)'	Karol Moore (b) (4) (b) (4)	05 Nov 2020 01:34:43

US3312605

Folder: Covid-19 Assessment 04 Nov 2020

Form: Symptom Log (11)

Generated On: 26 Nov 2020 10:55:55

[Symptom Day](#)

Audit	User	Time (GMT)
User entered 'Day 11 (Day 11)'	Karol Moore (b) (4) (b) (4)	05 Nov 2020 01:35:41

US3312605

Folder: Covid-19 Assessment 04 Nov 2020

Form: Symptom Log (11)

Generated On: 26 Nov 2020 10:55:55

[Date](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 16:43:43
User entered '29 Oct 2020'	Karol Moore (b) (4) (b) (4)	05 Nov 2020 01:35:41



US3312605

Folder: Covid-19 Assessment 04 Nov 2020

Form: Symptom Log (11)

Generated On: 26 Nov 2020 10:55:55

[Assessment Not Done](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 16:43:43
User entered '0'	Karol Moore (b) (4) (b) (4)	05 Nov 2020 01:35:41

US3312605

Folder: Covid-19 Assessment 04 Nov 2020

Form: Symptom Log (11)

Generated On: 26 Nov 2020 10:55:55

[O2 Saturation](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 16:43:43
User entered empty.	Karol Moore (b) (4) (b) (4)	05 Nov 2020 01:35:41

**US3312605**

**Folder: Covid-19 Assessment 04 Nov 2020**

**Form: Symptom Log (11)**

**Generated On: 26 Nov 2020 10:55:55**

[O2 Saturation Units](#)

Audit	User	Time (GMT)
User entered empty.	System	05 Nov 2020 01:35:41

US3312605

Folder: Covid-19 Assessment 04 Nov 2020

Form: Symptom Log (11)

Generated On: 26 Nov 2020 10:55:55

[Temperature](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 16:43:43
User entered empty.	Karol Moore (b) (4) (b) (4)	05 Nov 2020 01:35:41

US3312605

Folder: Covid-19 Assessment 04 Nov 2020

Form: Symptom Log (11)

Generated On: 26 Nov 2020 10:55:55

[Chills](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 16:43:43
User entered 'Moderate (Moderate)'	Karol Moore (b) (4) (b) (4)	05 Nov 2020 01:35:41

**US3312605**

**Folder: Covid-19 Assessment 04 Nov 2020**

**Form: Symptom Log (11)**

**Generated On: 26 Nov 2020 10:55:55**

[Cough](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 16:43:43
User entered 'Moderate (Moderate)'	Karol Moore (b) (4) (b) (4)	05 Nov 2020 01:35:41

US3312605

Folder: Covid-19 Assessment 04 Nov 2020

Form: Symptom Log (11)

Generated On: 26 Nov 2020 10:55:55

[Shortness of Breath](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 16:43:43
User entered 'Severe (Severe)'	Karol Moore (b) (4) (b) (4)	05 Nov 2020 01:35:41

US3312605

Folder: Covid-19 Assessment 04 Nov 2020

Form: Symptom Log (11)

Generated On: 26 Nov 2020 10:55:55

[Difficulty Breathing](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 16:43:43
User entered 'Severe (Severe)'	Karol Moore (b) (4) (b) (4)	05 Nov 2020 01:35:41



US3312605

Folder: Covid-19 Assessment 04 Nov 2020

Form: Symptom Log (11)

Generated On: 26 Nov 2020 10:55:55

[Fatigue](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 16:43:43
User entered 'Severe (Severe)'	Karol Moore (b) (4) (b) (4)	05 Nov 2020 01:35:41

US3312605

Folder: Covid-19 Assessment 04 Nov 2020

Form: Symptom Log (11)

Generated On: 26 Nov 2020 10:55:55

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 16:43:43
User entered 'Severe (Severe)'	Karol Moore (b) (4) (b) (4)	05 Nov 2020 01:35:41

US3312605

Folder: Covid-19 Assessment 04 Nov 2020

Form: Symptom Log (11)

Generated On: 26 Nov 2020 10:55:55

[Body Aches](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 16:43:43
User entered 'Severe (Severe)'	Karol Moore (b) (4) (b) (4)	05 Nov 2020 01:35:41

US3312605

Folder: Covid-19 Assessment 04 Nov 2020

Form: Symptom Log (11)

Generated On: 26 Nov 2020 10:55:55

[Headache](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 16:43:43
User entered 'Moderate (Moderate)'	Karol Moore (b) (4) (b) (4)	05 Nov 2020 01:35:41

US3312605

Folder: Covid-19 Assessment 04 Nov 2020

Form: Symptom Log (11)

Generated On: 26 Nov 2020 10:55:55

[New Loss of Taste](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 16:43:43
User entered 'Severe (Severe)'	Karol Moore (b) (4) (b) (4)	05 Nov 2020 01:35:41

US3312605

Folder: Covid-19 Assessment 04 Nov 2020

Form: Symptom Log (11)

Generated On: 26 Nov 2020 10:55:55

[New Loss of Smell](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 16:43:43
User entered 'Severe (Severe)'	Karol Moore (b) (4) (b) (4)	05 Nov 2020 01:35:41

US3312605

Folder: Covid-19 Assessment 04 Nov 2020

Form: Symptom Log (11)

Generated On: 26 Nov 2020 10:55:55

[Nasal Congestion](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 16:43:43
User entered 'Severe (Severe)'	Karol Moore (b) (4) (b) (4)	05 Nov 2020 01:35:41

US3312605

Folder: Covid-19 Assessment 04 Nov 2020

Form: Symptom Log (11)

Generated On: 26 Nov 2020 10:55:55

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 16:43:43
User entered 'None (None)'	Karol Moore (b) (4) (b) (4)	05 Nov 2020 01:35:41



US3312605

Folder: Covid-19 Assessment 04 Nov 2020

Form: Symptom Log (11)

Generated On: 26 Nov 2020 10:55:55

[Nausea](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 16:43:43
User entered 'None (None)'	Karol Moore (b) (4) (b) (4)	05 Nov 2020 01:35:41

US3312605

Folder: Covid-19 Assessment 04 Nov 2020

Form: Symptom Log (11)

Generated On: 26 Nov 2020 10:55:55

[Vomiting](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 16:43:43
User entered 'None (None)'	Karol Moore (b) (4) (b) (4)	05 Nov 2020 01:35:41

US3312605

Folder: Covid-19 Assessment 04 Nov 2020

Form: Symptom Log (11)

Generated On: 26 Nov 2020 10:55:55

[Diarrhea](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 16:43:43
User entered 'None (None)'	Karol Moore (b) (4) (b) (4)	05 Nov 2020 01:35:41

US3312605

Folder: Covid-19 Assessment 04 Nov 2020

Form: Symptom Log (11)

Generated On: 26 Nov 2020 10:55:55

[Sore Throat](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 16:43:43
User entered 'Severe (Severe)'	Karol Moore (b) (4) (b) (4)	05 Nov 2020 01:35:41

US3312605

Folder: Covid-19 Assessment 04 Nov 2020

Form: Symptom Log (12)

Generated On: 26 Nov 2020 10:55:55

[Symptom Day](#)

Audit	User	Time (GMT)
User entered 'Day 12 (Day 12)'	Karol Moore (b) (4) (b) (4)	05 Nov 2020 01:36:27

**US3312605**

**Folder: Covid-19 Assessment 04 Nov 2020**

**Form: Symptom Log (12)**

**Generated On: 26 Nov 2020 10:55:55**

[Date](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 16:43:43
User entered '30 Oct 2020'	Karol Moore (b) (4) (b) (4)	05 Nov 2020 01:36:27

US3312605

Folder: Covid-19 Assessment 04 Nov 2020

Form: Symptom Log (12)

Generated On: 26 Nov 2020 10:55:55

[Assessment Not Done](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 16:43:43
User entered '0'	Karol Moore (b) (4) (b) (4)	05 Nov 2020 01:36:27

US3312605

Folder: Covid-19 Assessment 04 Nov 2020

Form: Symptom Log (12)

Generated On: 26 Nov 2020 10:55:55

[O2 Saturation](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 16:43:43
User entered empty.	Karol Moore (b) (4) (b) (4)	05 Nov 2020 01:36:27



**US3312605**

**Folder: Covid-19 Assessment 04 Nov 2020**

**Form: Symptom Log (12)**

**Generated On: 26 Nov 2020 10:55:55**

[O2 Saturation Units](#)

Audit	User	Time (GMT)
User entered empty.	System	05 Nov 2020 01:36:27

US3312605

Folder: Covid-19 Assessment 04 Nov 2020

Form: Symptom Log (12)

Generated On: 26 Nov 2020 10:55:55

[Temperature](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 16:43:43
User entered empty.	Karol Moore (b) (4) (b) (4)	05 Nov 2020 01:36:27

US3312605

Folder: Covid-19 Assessment 04 Nov 2020

Form: Symptom Log (12)

Generated On: 26 Nov 2020 10:55:55

[Chills](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 16:43:43
User entered 'Moderate (Moderate)'	Karol Moore (b) (4) (b) (4)	05 Nov 2020 01:36:27

**US3312605**

**Folder: Covid-19 Assessment 04 Nov 2020**

**Form: Symptom Log (12)**

**Generated On: 26 Nov 2020 10:55:55**

[Cough](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 16:43:43
User entered 'Moderate (Moderate)'	Karol Moore (b) (4) (b) (4)	05 Nov 2020 01:36:27

US3312605

Folder: Covid-19 Assessment 04 Nov 2020

Form: Symptom Log (12)

Generated On: 26 Nov 2020 10:55:55

[Shortness of Breath](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 16:43:43
User entered 'None (None)'	Karol Moore (b) (4) (b) (4)	05 Nov 2020 01:36:27

US3312605

Folder: Covid-19 Assessment 04 Nov 2020

Form: Symptom Log (12)

Generated On: 26 Nov 2020 10:55:55

[Difficulty Breathing](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 16:43:43
User entered 'None (None)'	Karol Moore (b) (4) (b) (4)	05 Nov 2020 01:36:27

US3312605

Folder: Covid-19 Assessment 04 Nov 2020

Form: Symptom Log (12)

Generated On: 26 Nov 2020 10:55:55

[Fatigue](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 16:43:43
User entered 'Severe (Severe)'	Karol Moore (b) (4) (b) (4)	05 Nov 2020 01:36:27

US3312605

Folder: Covid-19 Assessment 04 Nov 2020

Form: Symptom Log (12)

Generated On: 26 Nov 2020 10:55:55

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 16:43:43
User entered 'Severe (Severe)'	Karol Moore (b) (4) (b) (4)	05 Nov 2020 01:36:27



US3312605

Folder: Covid-19 Assessment 04 Nov 2020

Form: Symptom Log (12)

Generated On: 26 Nov 2020 10:55:55

[Body Aches](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 16:43:43
User entered 'Severe (Severe)'	Karol Moore (b) (4) (b) (4)	05 Nov 2020 01:36:27

US3312605

Folder: Covid-19 Assessment 04 Nov 2020

Form: Symptom Log (12)

Generated On: 26 Nov 2020 10:55:55

[Headache](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 16:43:43
User entered 'Moderate (Moderate)'	Karol Moore (b) (4) (b) (4)	05 Nov 2020 01:36:27

US3312605

Folder: Covid-19 Assessment 04 Nov 2020

Form: Symptom Log (12)

Generated On: 26 Nov 2020 10:55:55

[New Loss of Taste](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 16:43:43
User entered 'Severe (Severe)'	Karol Moore (b) (4) (b) (4)	05 Nov 2020 01:36:27

US3312605

Folder: Covid-19 Assessment 04 Nov 2020

Form: Symptom Log (12)

Generated On: 26 Nov 2020 10:55:55

[New Loss of Smell](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 16:43:43
User entered 'Severe (Severe)'	Karol Moore (b) (4) (b) (4)	05 Nov 2020 01:36:27

US3312605

Folder: Covid-19 Assessment 04 Nov 2020

Form: Symptom Log (12)

Generated On: 26 Nov 2020 10:55:55

[Nasal Congestion](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 16:43:43
User entered 'None (None)'	Karol Moore (b) (4) (b) (4)	05 Nov 2020 01:36:27

US3312605

Folder: Covid-19 Assessment 04 Nov 2020

Form: Symptom Log (12)

Generated On: 26 Nov 2020 10:55:55

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 16:43:43
User entered 'None (None)'	Karol Moore (b) (4) (b) (4)	05 Nov 2020 01:36:27

**US3312605**

**Folder: Covid-19 Assessment 04 Nov 2020**

**Form: Symptom Log (12)**

**Generated On: 26 Nov 2020 10:55:55**

[Nausea](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 16:43:43
User entered 'None (None)'	Karol Moore (b) (4) (b) (4)	05 Nov 2020 01:36:27

US3312605

Folder: Covid-19 Assessment 04 Nov 2020

Form: Symptom Log (12)

Generated On: 26 Nov 2020 10:55:55

[Vomiting](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 16:43:43
User entered 'None (None)'	Karol Moore (b) (4) (b) (4)	05 Nov 2020 01:36:27



US3312605

Folder: Covid-19 Assessment 04 Nov 2020

Form: Symptom Log (12)

Generated On: 26 Nov 2020 10:55:55

[Diarrhea](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 16:43:43
User entered 'None (None)'	Karol Moore (b) (4) (b) (4)	05 Nov 2020 01:36:27

US3312605

Folder: Covid-19 Assessment 04 Nov 2020

Form: Symptom Log (12)

Generated On: 26 Nov 2020 10:55:55

[Sore Throat](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 16:43:43
User entered 'Severe (Severe)'	Karol Moore (b) (4) (b) (4)	05 Nov 2020 01:36:27

US3312605

Folder: Covid-19 Assessment 04 Nov 2020

Form: Symptom Log (13)

Generated On: 26 Nov 2020 10:55:55

[Symptom Day](#)

Audit	User	Time (GMT)
User entered 'Day 13 (Day 13)'	Karol Moore (b) (4) (b) (4)	05 Nov 2020 01:37:11

US3312605

Folder: Covid-19 Assessment 04 Nov 2020

Form: Symptom Log (13)

Generated On: 26 Nov 2020 10:55:55

[Date](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 16:43:43
User entered '01 Nov 2020'	Karol Moore (b) (4) (b) (4)	05 Nov 2020 01:37:11

**US3312605**

**Folder: Covid-19 Assessment 04 Nov 2020**

**Form: Symptom Log (13)**

**Generated On: 26 Nov 2020 10:55:55**

[Assessment Not Done](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 16:43:43
User entered '0'	Karol Moore (b) (4) (b) (4)	05 Nov 2020 01:37:11

US3312605

Folder: Covid-19 Assessment 04 Nov 2020

Form: Symptom Log (13)

Generated On: 26 Nov 2020 10:55:55

[O2 Saturation](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 16:43:43
User entered empty.	Karol Moore (b) (4) (b) (4)	05 Nov 2020 01:37:11

**US3312605**

**Folder: Covid-19 Assessment 04 Nov 2020**

**Form: Symptom Log (13)**

**Generated On: 26 Nov 2020 10:55:55**

[O2 Saturation Units](#)

Audit	User	Time (GMT)
User entered empty.	System	05 Nov 2020 01:37:11

US3312605

Folder: Covid-19 Assessment 04 Nov 2020

Form: Symptom Log (13)

Generated On: 26 Nov 2020 10:55:55

[Temperature](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 16:43:43
User entered empty.	Karol Moore (b) (4) (b) (4)	05 Nov 2020 01:37:11



US3312605

Folder: Covid-19 Assessment 04 Nov 2020

Form: Symptom Log (13)

Generated On: 26 Nov 2020 10:55:55

[Chills](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 16:43:43
User entered 'None (None)'	Karol Moore (b) (4) (b) (4)	05 Nov 2020 01:37:11

US3312605

Folder: Covid-19 Assessment 04 Nov 2020

Form: Symptom Log (13)

Generated On: 26 Nov 2020 10:55:55

[Cough](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 16:43:43
User entered 'None (None)'	Karol Moore (b) (4) (b) (4)	05 Nov 2020 01:37:11

US3312605

Folder: Covid-19 Assessment 04 Nov 2020

Form: Symptom Log (13)

Generated On: 26 Nov 2020 10:55:55

[Shortness of Breath](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 16:43:43
User entered 'None (None)'	Karol Moore (b) (4) (b) (4)	05 Nov 2020 01:37:11

US3312605

Folder: Covid-19 Assessment 04 Nov 2020

Form: Symptom Log (13)

Generated On: 26 Nov 2020 10:55:55

[Difficulty Breathing](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 16:43:43
User entered 'None (None)'	Karol Moore (b) (4) (b) (4)	05 Nov 2020 01:37:11

US3312605

Folder: Covid-19 Assessment 04 Nov 2020

Form: Symptom Log (13)

Generated On: 26 Nov 2020 10:55:55

[Fatigue](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 16:43:43
User entered 'None (None)'	Karol Moore (b) (4) (b) (4)	05 Nov 2020 01:37:11

US3312605

Folder: Covid-19 Assessment 04 Nov 2020

Form: Symptom Log (13)

Generated On: 26 Nov 2020 10:55:55

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 16:43:43
User entered 'None (None)'	Karol Moore (b) (4) (b) (4)	05 Nov 2020 01:37:11

US3312605

Folder: Covid-19 Assessment 04 Nov 2020

Form: Symptom Log (13)

Generated On: 26 Nov 2020 10:55:55

[Body Aches](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 16:43:43
User entered 'None (None)'	Karol Moore (b) (4) (b) (4)	05 Nov 2020 01:37:11

US3312605

Folder: Covid-19 Assessment 04 Nov 2020

Form: Symptom Log (13)

Generated On: 26 Nov 2020 10:55:55

[Headache](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 16:43:43
User entered 'None (None)'	Karol Moore (b) (4) (b) (4)	05 Nov 2020 01:37:11



US3312605

Folder: Covid-19 Assessment 04 Nov 2020

Form: Symptom Log (13)

Generated On: 26 Nov 2020 10:55:55

[New Loss of Taste](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 16:43:43
User entered 'Severe (Severe)'	Karol Moore (b) (4) (b) (4)	05 Nov 2020 01:37:11

US3312605

Folder: Covid-19 Assessment 04 Nov 2020

Form: Symptom Log (13)

Generated On: 26 Nov 2020 10:55:55

[New Loss of Smell](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 16:43:43
User entered 'Severe (Severe)'	Karol Moore (b) (4) (b) (4)	05 Nov 2020 01:37:11

US3312605

Folder: Covid-19 Assessment 04 Nov 2020

Form: Symptom Log (13)

Generated On: 26 Nov 2020 10:55:55

[Nasal Congestion](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 16:43:43
User entered 'None (None)'	Karol Moore (b) (4) (b) (4)	05 Nov 2020 01:37:11

US3312605

Folder: Covid-19 Assessment 04 Nov 2020

Form: Symptom Log (13)

Generated On: 26 Nov 2020 10:55:55

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 16:43:43
User entered 'None (None)'	Karol Moore (b) (4) (b) (4)	05 Nov 2020 01:37:11

US3312605

Folder: Covid-19 Assessment 04 Nov 2020

Form: Symptom Log (13)

Generated On: 26 Nov 2020 10:55:55

[Nausea](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 16:43:43
User entered 'None (None)'	Karol Moore (b) (4) (b) (4)	05 Nov 2020 01:37:11

US3312605

Folder: Covid-19 Assessment 04 Nov 2020

Form: Symptom Log (13)

Generated On: 26 Nov 2020 10:55:55

[Vomiting](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 16:43:43
User entered 'None (None)'	Karol Moore (b) (4) (b) (4)	05 Nov 2020 01:37:11

US3312605

Folder: Covid-19 Assessment 04 Nov 2020

Form: Symptom Log (13)

Generated On: 26 Nov 2020 10:55:55

[Diarrhea](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 16:43:43
User entered 'None (None)'	Karol Moore (b) (4) (b) (4)	05 Nov 2020 01:37:11

US3312605

Folder: Covid-19 Assessment 04 Nov 2020

Form: Symptom Log (13)

Generated On: 26 Nov 2020 10:55:55

[Sore Throat](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 16:43:43
User entered 'None (None)'	Karol Moore (b) (4) (b) (4)	05 Nov 2020 01:37:11



US3312605

Folder: Covid-19 Assessment 04 Nov 2020

Form: COVID Diagnostic Test

Generated On: 26 Nov 2020 10:55:55

[Date of Visit](#)

Audit	User	Time (GMT)
User closed query 'Per GCL Lab recon: Swab: Sample collection date 27-OCT-2020 is recorded under Covid-19 Assessment; however, corresponding swab sample is missing in GCL. Kindly confirm if swab sample was collected on 27-OCT-2020 for Covid-19 Assessment visit to be updated in GCL records.' (Site from DM).	(b) (4), (b) (6)	23 Nov 2020 10:16:46
User opened query 'Per ETRTR, According to AE Narrative, "COVID TEST reported" on 22 Oct 2020. Please reconcile date entered in this page and update if needed.' (Site from CRA).	(b) (4), (b) (6)	21 Nov 2020 20:51:44
Query 'Per GCL Lab recon: Swab: Sample collection date 27-OCT-2020 is recorded under Covid-19 Assessment; however, corresponding swab sample is missing in GCL. Kindly confirm if swab sample was collected on 27-OCT-2020 for Covid-19 Assessment visit to be updated in GCL records.' answered with 'AS NOTED, NOT DONE AT SITE. COMPLETED AT DIFFERENT LAB/INSTITUTION' (Site from DM).	Karol Moore (b) (4) (b) (4)	17 Nov 2020 21:51:10
User opened query 'Per GCL Lab recon: Swab: Sample collection date 27-OCT-2020 is recorded under Covid-19 Assessment; however, corresponding swab sample is missing in GCL. Kindly confirm if swab sample was collected on 27-OCT-2020 for Covid-19 Assessment visit to be updated in GCL records.' (Site from DM).	(b) (4), (b) (6)	12 Nov 2020 06:15:48
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 22:34:55
User closed query 'Per CDM: Please complete an Illness Visit and Saliva Log' (Site from DM).	(b) (4), (b) (6)	10 Nov 2020 17:45:55
Query 'Per CDM: Please complete an Illness Visit and Saliva Log' answered with 'NA. ILLNESS VISIT NOT PERFORMED. SEE AE NARRATIVE' (Site from DM).	Karol Moore (b) (4) (b) (4)	10 Nov 2020 14:04:05
User opened query 'Per CDM: Please complete an Illness Visit and Saliva Log' (Site from DM).	(b) (4), (b) (6)	09 Nov 2020 03:18:48
User entered '27 Oct 2020'	(b) (4), (b) (6)	04 Nov 2020 23:49:02

**US3312605**

**Folder: Covid-19 Assessment 04 Nov 2020**

**Form: COVID Diagnostic Test**

**Generated On: 26 Nov 2020 10:55:55**

[Was the Subject Tested For SARS-CoV-2 by RT-PCR?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 22:34:55
User entered 'Yes (Y)'	(b) (4), (b) (6)	04 Nov 2020 23:49:02

US3312605

Folder: Covid-19 Assessment 04 Nov 2020

Form: COVID Diagnostic Test

Generated On: 26 Nov 2020 10:55:55

[Did Subject Test Positive For SARS-CoV-2 by RT-PCR?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 22:34:55
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)	06 Nov 2020 12:26:33
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 'updated' (Site from System).	(b) (4), (b) (6)	04 Nov 2020 23:49:12
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	04 Nov 2020 23:49:02
User entered 'Yes (Y)'	(b) (4), (b) (6)	04 Nov 2020 23:49:02

**US3312605**

**Folder: Covid-19 Assessment 04 Nov 2020**

**Form: COVID Diagnostic Test**

**Generated On: 26 Nov 2020 10:55:55**

[Date of Test](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 22:34:55
User entered '27 Oct 2020'	(b) (4), (b) (6)	04 Nov 2020 23:49:02

**US3312605**

**Folder: Covid-19 Assessment 04 Nov 2020**

**Form: COVID Diagnostic Test**

**Generated On: 26 Nov 2020 10:55:55**

[Type of Test Performed](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 22:34:55
User entered 'Nasopharyngeal Swab (Nasopharyngeal Swab)'	(b) (4), (b) (6)	04 Nov 2020 23:49:02

US3312605

Folder: Covid-19 Assessment 04 Nov 2020

Form: COVID Diagnostic Test

Generated On: 26 Nov 2020 10:55:55

[Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 22:34:55
User entered empty.	(b) (4), (b) (6)	04 Nov 2020 23:49:02

**US3312605**

**Folder: Covid-19 Assessment 04 Nov 2020**

**Form: COVID Diagnostic Test**

**Generated On: 26 Nov 2020 10:55:55**

[Was this diagnostic test performed at a lab other than the Study Central Lab?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 22:34:55
User entered 'Yes (Y)'	(b) (4), (b) (6)	04 Nov 2020 23:49:02

US3312605

Folder: Covid-19 Assessment 04 Nov 2020

Form: COVID Diagnostic Test

Generated On: 26 Nov 2020 10:55:55

[Lab/ Institution Test Performed](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 22:34:55
User entered 'Saint Luke's Hospital'	(b) (4), (b) (6)	04 Nov 2020 23:49:02



**US3312605**

**Folder: Covid-19 Assessment 04 Nov 2020**

**Form: COVID Diagnostic Test**

**Generated On: 26 Nov 2020 10:55:55**

[CLIA Certified?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 22:34:55
User entered 'Yes (Y)'	(b) (4), (b) (6)	04 Nov 2020 23:49:02

**US3312605**

**Folder: Covid-19 Assessment 04 Nov 2020**

**Form: COVID Diagnostic Test**

**Generated On: 26 Nov 2020 10:55:55**

[COVID-19 Positive \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered 'I'	System	04 Nov 2020 23:49:02

US3312605

Folder: Covid-19 Assessment 04 Nov 2020

Form: Covid-19 Severity Assessment

Generated On: 26 Nov 2020 10:55:55

Did the subject have Respiratory Rates  $\geq 30$  per Minute?

Audit	User	Time (GMT)
User closed query 'Per CDM: Please enter this data when it becomes available (or is confirmed to be unavailable). This query will remain open in the meantime.' (Site from DM).	(b) (4), (b) (6)	19 Nov 2020 21:06:43
Query 'Per CDM: Please enter this data when it becomes available (or is confirmed to be unavailable). This query will remain open in the meantime.' answered with 'DATA NOT AVAILABLE. NO FURTHER INFORMATION WILL BE SUPPLIED.' (Site from DM).	Karol Moore (b) (4) (b) (4)	17 Nov 2020 21:52:53
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4), (b) (6)	11 Nov 2020 08:43:49
User opened query 'Per CDM: Please enter this data when it becomes available (or is confirmed to be unavailable). This query will remain open in the meantime.' (Site from DM).	(b) (4), (b) (6)	11 Nov 2020 08:42:59
Query 'Data is required. Please complete.' answered with 'medical records pending, data unknown' (Site from System).	(b) (4), (b) (6)	09 Nov 2020 21:52:28
User opened query 'Data is required. Please complete.' (Site from System).	System	09 Nov 2020 21:52:06
User entered empty; reason for change Data Entry Error	(b) (4), (b) (6)	09 Nov 2020 21:52:06
User entered 'No (N)'	(b) (4), (b) (6)	05 Nov 2020 00:07:44

US3312605

Folder: Covid-19 Assessment 04 Nov 2020

Form: Covid-19 Severity Assessment

Generated On: 26 Nov 2020 10:55:55

[Start Date](#)

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	05 Nov 2020 00:07:44

**US3312605**

**Folder: Covid-19 Assessment 04 Nov 2020**

**Form: Covid-19 Severity Assessment**

**Generated On: 26 Nov 2020 10:55:55**

[End Date](#)

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	05 Nov 2020 00:07:44

US3312605

Folder: Covid-19 Assessment 04 Nov 2020

Form: Covid-19 Severity Assessment

Generated On: 26 Nov 2020 10:55:55

[Respiratory Rate](#)

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	05 Nov 2020 00:07:44

US3312605

Folder: Covid-19 Assessment 04 Nov 2020

Form: Covid-19 Severity Assessment

Generated On: 26 Nov 2020 10:55:55

Did the subject have Heart Rate  $\geq$  125 beats per minute

Audit	User	Time (GMT)
User closed query 'Per CDM: Please enter this data when it becomes available (or is confirmed to be unavailable). This query will remain open in the meantime.' (Site from DM).	(b) (4), (b) (6)	19 Nov 2020 21:06:49
Query 'Per CDM: Please enter this data when it becomes available (or is confirmed to be unavailable). This query will remain open in the meantime.' answered with 'DATA NOT AVAILABLE. NO FURTHER INFORMATION WILL BE SUPPLIED.' (Site from DM).	Karol Moore (b) (4) (b) (4)	17 Nov 2020 21:52:56
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4), (b) (6)	11 Nov 2020 08:43:46
User opened query 'Per CDM: Please enter this data when it becomes available (or is confirmed to be unavailable). This query will remain open in the meantime.' (Site from DM).	(b) (4), (b) (6)	11 Nov 2020 08:43:09
Query 'Data is required. Please complete.' answered with 'medical records pending, data unknown' (Site from System).	(b) (4), (b) (6)	09 Nov 2020 21:52:30
User opened query 'Data is required. Please complete.' (Site from System).	System	09 Nov 2020 21:52:06
User entered empty; reason for change Data Entry Error	(b) (4), (b) (6)	09 Nov 2020 21:52:06
User entered 'No (N)'	(b) (4), (b) (6)	05 Nov 2020 00:07:44

**US3312605**

**Folder: Covid-19 Assessment 04 Nov 2020**

**Form: Covid-19 Severity Assessment**

**Generated On: 26 Nov 2020 10:55:55**

[Start Date](#)

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	05 Nov 2020 00:07:44



**US3312605**

**Folder: Covid-19 Assessment 04 Nov 2020**

**Form: Covid-19 Severity Assessment**

**Generated On: 26 Nov 2020 10:55:55**

[End Date](#)

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	05 Nov 2020 00:07:44

US3312605

Folder: Covid-19 Assessment 04 Nov 2020

Form: Covid-19 Severity Assessment

Generated On: 26 Nov 2020 10:55:55

[Heart Rate](#)

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	05 Nov 2020 00:07:44

US3312605

Folder: Covid-19 Assessment 04 Nov 2020

Form: Covid-19 Severity Assessment

Generated On: 26 Nov 2020 10:55:55

Did the subject have Oxygen Saturation of  $\text{SpO}_2 \leq 93\%$  on room air at sea level?

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	05 Nov 2020 00:07:44

US3312605

Folder: Covid-19 Assessment 04 Nov 2020

Form: Covid-19 Severity Assessment

Generated On: 26 Nov 2020 10:55:55

[Start Date](#)

Audit	User	Time (GMT)
User entered '27 Oct 2020'	(b) (4), (b) (6)	05 Nov 2020 00:07:44

US3312605

Folder: Covid-19 Assessment 04 Nov 2020

Form: Covid-19 Severity Assessment

Generated On: 26 Nov 2020 10:55:55

[End Date](#)

Audit	User	Time (GMT)
User entered '28 Oct 2020'	(b) (4), (b) (6)	05 Nov 2020 00:07:44

US3312605

Folder: Covid-19 Assessment 04 Nov 2020

Form: Covid-19 Severity Assessment

Generated On: 26 Nov 2020 10:55:55

[Oxygen Saturation](#)

Audit	User	Time (GMT)
User entered '85'	(b) (4), (b) (6)	05 Nov 2020 00:07:44

US3312605

Folder: Covid-19 Assessment 04 Nov 2020

Form: Covid-19 Severity Assessment

Generated On: 26 Nov 2020 10:55:55

Did the subject have PaO2/FIO2 Ratio < 300 mm Hg?

Audit	User	Time (GMT)
User closed query 'Per CDM: Please enter this data when it becomes available (or is confirmed to be unavailable). This query will remain open in the meantime.' (Site from DM).	(b) (4), (b) (6)	19 Nov 2020 21:06:54
Query 'Per CDM: Please enter this data when it becomes available (or is confirmed to be unavailable). This query will remain open in the meantime.' answered with 'DATA NOT AVAILABLE. NO FURTHER INFORMATION WILL BE SUPPLIED.' (Site from DM).	Karol Moore (b) (4) (b) (4)	17 Nov 2020 21:52:59
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4), (b) (6)	11 Nov 2020 08:43:41
User opened query 'Per CDM: Please enter this data when it becomes available (or is confirmed to be unavailable). This query will remain open in the meantime.' (Site from DM).	(b) (4), (b) (6)	11 Nov 2020 08:43:36
Query 'Data is required. Please complete.' answered with 'medical records pending-data unknown' (Site from System).	(b) (4), (b) (6)	09 Nov 2020 21:51:50
User opened query 'Data is required. Please complete.' (Site from System).	System	09 Nov 2020 21:51:31
User entered empty; reason for change Data Entry Error	(b) (4), (b) (6)	09 Nov 2020 21:51:31
User entered 'No (N)'	(b) (4), (b) (6)	05 Nov 2020 00:07:44

**US3312605**

**Folder: Covid-19 Assessment 04 Nov 2020**

**Form: Covid-19 Severity Assessment**

**Generated On: 26 Nov 2020 10:55:55**

[Start Date](#)

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	05 Nov 2020 00:07:44



**US3312605**

**Folder: Covid-19 Assessment 04 Nov 2020**

**Form: Covid-19 Severity Assessment**

**Generated On: 26 Nov 2020 10:55:55**

[End Date](#)

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	05 Nov 2020 00:07:44

US3312605

Folder: Covid-19 Assessment 04 Nov 2020

Form: Covid-19 Severity Assessment

Generated On: 26 Nov 2020 10:55:55

[PaO2](#)

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	05 Nov 2020 00:07:44

US3312605

Folder: Covid-19 Assessment 04 Nov 2020

Form: Covid-19 Severity Assessment

Generated On: 26 Nov 2020 10:55:55

Did the subject have Respiratory failure?

Audit	User	Time (GMT)
User entered 'No (N)'	(b) (4), (b) (6)	05 Nov 2020 00:07:44

**US3312605**

**Folder: Covid-19 Assessment 04 Nov 2020**

**Form: Covid-19 Severity Assessment**

**Generated On: 26 Nov 2020 10:55:55**

[Start Date](#)

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	05 Nov 2020 00:07:44

US3312605

Folder: Covid-19 Assessment 04 Nov 2020

Form: Covid-19 Severity Assessment

Generated On: 26 Nov 2020 10:55:55

Did the subject have Acute Respiratory Distress Syndrome (ARDS)?

Audit	User	Time (GMT)
User entered 'No (N)'	(b) (4), (b) (6)	05 Nov 2020 00:07:44

US3312605

Folder: Covid-19 Assessment 04 Nov 2020

Form: Covid-19 Severity Assessment

Generated On: 26 Nov 2020 10:55:55

[Start Date](#)

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	05 Nov 2020 00:07:44

US3312605

Folder: Covid-19 Assessment 04 Nov 2020

Form: Covid-19 Severity Assessment

Generated On: 26 Nov 2020 10:55:55

[High-Flow Oxygen?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	(b) (4), (b) (6)	05 Nov 2020 00:07:44

US3312605

Folder: Covid-19 Assessment 04 Nov 2020

Form: Covid-19 Severity Assessment

Generated On: 26 Nov 2020 10:55:55

[Start Date](#)

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	05 Nov 2020 00:07:44



**US3312605**

**Folder: Covid-19 Assessment 04 Nov 2020**

**Form: Covid-19 Severity Assessment**

**Generated On: 26 Nov 2020 10:55:55**

[End Date](#)

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	05 Nov 2020 00:07:44

US3312605

Folder: Covid-19 Assessment 04 Nov 2020

Form: Covid-19 Severity Assessment

Generated On: 26 Nov 2020 10:55:55

[Non-Invasive Ventilation?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	(b) (4), (b) (6)	05 Nov 2020 00:07:44

**US3312605**

**Folder: Covid-19 Assessment 04 Nov 2020**

**Form: Covid-19 Severity Assessment**

**Generated On: 26 Nov 2020 10:55:55**

[Start Date](#)

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	05 Nov 2020 00:07:44

US3312605

Folder: Covid-19 Assessment 04 Nov 2020

Form: Covid-19 Severity Assessment

Generated On: 26 Nov 2020 10:55:55

[End Date](#)

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	05 Nov 2020 00:07:44

US3312605

Folder: Covid-19 Assessment 04 Nov 2020

Form: Covid-19 Severity Assessment

Generated On: 26 Nov 2020 10:55:55

[Mechanical Ventilation?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	(b) (4), (b) (6)	05 Nov 2020 00:07:44

**US3312605**

**Folder: Covid-19 Assessment 04 Nov 2020**

**Form: Covid-19 Severity Assessment**

**Generated On: 26 Nov 2020 10:55:55**

[Start Date](#)

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	05 Nov 2020 00:07:44

US3312605

Folder: Covid-19 Assessment 04 Nov 2020

Form: Covid-19 Severity Assessment

Generated On: 26 Nov 2020 10:55:55

[End Date](#)

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	05 Nov 2020 00:07:44

**US3312605**

**Folder: Covid-19 Assessment 04 Nov 2020**

**Form: Covid-19 Severity Assessment**

**Generated On: 26 Nov 2020 10:55:55**

[ECMO?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	(b) (4), (b) (6)	05 Nov 2020 00:07:44



US3312605

Folder: Covid-19 Assessment 04 Nov 2020

Form: Covid-19 Severity Assessment

Generated On: 26 Nov 2020 10:55:55

[Start Date](#)

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	05 Nov 2020 00:07:44

US3312605

Folder: Covid-19 Assessment 04 Nov 2020

Form: Covid-19 Severity Assessment

Generated On: 26 Nov 2020 10:55:55

[End Date](#)

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	05 Nov 2020 00:07:44

US3312605

Folder: Covid-19 Assessment 04 Nov 2020

Form: Covid-19 Severity Assessment

Generated On: 26 Nov 2020 10:55:55

Systolic Blood Pressure < 90 mmHg, Diastolic Blood Pressure < 60 mmHg

Audit	User	Time (GMT)
User entered 'No (N)'	(b) (4), (b) (6)	05 Nov 2020 00:07:44

**US3312605**

**Folder: Covid-19 Assessment 04 Nov 2020**

**Form: Covid-19 Severity Assessment**

**Generated On: 26 Nov 2020 10:55:55**

[Start Date](#)

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	05 Nov 2020 00:07:44

US3312605

Folder: Covid-19 Assessment 04 Nov 2020

Form: Covid-19 Severity Assessment

Generated On: 26 Nov 2020 10:55:55

[End Date](#)

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	05 Nov 2020 00:07:44

US3312605

Folder: Covid-19 Assessment 04 Nov 2020

Form: Covid-19 Severity Assessment

Generated On: 26 Nov 2020 10:55:55

[Evidence of Shock Requires](#)

[Vasopressors](#)

Audit	User	Time (GMT)
User entered 'No (N)'	(b) (4), (b) (6)	05 Nov 2020 00:07:44

US3312605

Folder: Covid-19 Assessment 04 Nov 2020

Form: Covid-19 Severity Assessment

Generated On: 26 Nov 2020 10:55:55

[Start Date](#)

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	05 Nov 2020 00:07:44

**US3312605**

**Folder: Covid-19 Assessment 04 Nov 2020**

**Form: Covid-19 Severity Assessment**

**Generated On: 26 Nov 2020 10:55:55**

[End Date](#)

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	05 Nov 2020 00:07:44



US3312605

Folder: Covid-19 Assessment 04 Nov 2020

Form: Covid-19 Severity Assessment

Generated On: 26 Nov 2020 10:55:55

[Acute Renal Dysfunction?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	(b) (4), (b) (6)	05 Nov 2020 00:07:44

US3312605

Folder: Covid-19 Assessment 04 Nov 2020

Form: Covid-19 Severity Assessment

Generated On: 26 Nov 2020 10:55:55

[Start Date](#)

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	05 Nov 2020 00:07:44

US3312605

Folder: Covid-19 Assessment 04 Nov 2020

Form: Covid-19 Severity Assessment

Generated On: 26 Nov 2020 10:55:55

[Hepatic Dysfunction?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	(b) (4), (b) (6)	05 Nov 2020 00:07:44

US3312605

Folder: Covid-19 Assessment 04 Nov 2020

Form: Covid-19 Severity Assessment

Generated On: 26 Nov 2020 10:55:55

[Start Date](#)

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	05 Nov 2020 00:07:44

US3312605

Folder: Covid-19 Assessment 04 Nov 2020

Form: Covid-19 Severity Assessment

Generated On: 26 Nov 2020 10:55:55

[Neurologic Dysfunction?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	(b) (4), (b) (6)	05 Nov 2020 00:07:44

**US3312605**

**Folder: Covid-19 Assessment 04 Nov 2020**

**Form: Covid-19 Severity Assessment**

**Generated On: 26 Nov 2020 10:55:55**

[Start Date](#)

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	05 Nov 2020 00:07:44

**US3312605**

**Folder: Covid-19 Assessment 04 Nov 2020**

**Form: Covid-19 Severity Assessment**

**Generated On: 26 Nov 2020 10:55:55**

[Clinical Evidence](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	05 Nov 2020 00:07:44

US3312605

Folder: Covid-19 Assessment 04 Nov 2020

Form: Covid-19 Severity Assessment

Generated On: 26 Nov 2020 10:55:55

[Date of Assessment](#)

Audit	User	Time (GMT)
User entered '27 Oct 2020'	(b) (4), (b) (6)	05 Nov 2020 00:07:44



US3312605

Folder: Covid-19 Assessment 04 Nov 2020

Form: Covid-19 Severity Assessment

Generated On: 26 Nov 2020 10:55:55

[Radiographical Evidence](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	05 Nov 2020 00:07:44

US3312605

Folder: Covid-19 Assessment 04 Nov 2020

Form: Covid-19 Severity Assessment

Generated On: 26 Nov 2020 10:55:55

[Date of Assessment](#)

Audit	User	Time (GMT)
User entered '27 Oct 2020'	(b) (4), (b) (6)	05 Nov 2020 00:07:44

US3312605

Folder: Covid-19 Assessment 04 Nov 2020

Form: Covid-19 Severity Assessment

Generated On: 26 Nov 2020 10:55:55

[Admission to an intensive care unit due to SARS-CoV-2](#)

Audit	User	Time (GMT)
User entered 'No (N)'	(b) (4), (b) (6)	05 Nov 2020 00:07:44

**US3312605**

**Folder: Covid-19 Assessment 04 Nov 2020**

**Form: Covid-19 Severity Assessment**

**Generated On: 26 Nov 2020 10:55:55**

[Start Date](#)

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	05 Nov 2020 00:07:44

US3312605

Folder: Covid-19 Assessment 04 Nov 2020

Form: Covid-19 Severity Assessment

Generated On: 26 Nov 2020 10:55:55

[End Date](#)

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	05 Nov 2020 00:07:44

**US3312605**

**Folder: Adverse Events**

**Form: Adverse Events Summary**

**Generated On: 26 Nov 2020 10:55:55**

[Did the participant experience any adverse events?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 16:40:02
User entered 'Yes (Y)'	(b) (4), (b) (6)	05 Nov 2020 00:16:08

**US3312605**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 26 Nov 2020 10:55:55**

[AEID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 16:37:11
Reviewed for Safety.	(b) (4), (b) (6)	05 Nov 2020 20:20:13
User entered 'USA-US300-2020-mRNA-1273-P301000009'	System	05 Nov 2020 20:20:08
User entered 'New'	(b) (4), (b) (6)	05 Nov 2020 20:20:08

US3312605

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 10:55:55

[Adverse event](#)

Audit	User	Time (GMT)
Query 'PV Query: As the veracity of the subject's story is in doubt, please consider updating the event term to "possible COVID-19"?' canceled (Site from Safety).	(b) (4), (b) (6)	19 Nov 2020 21:16:35
User opened query 'PV Query: As the veracity of the subject's story is in doubt, please consider updating the event term to "possible COVID-19"?' (Site from Safety).	(b) (4), (b) (6)	19 Nov 2020 15:43:55
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 16:37:11
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)	05 Nov 2020 00:21:32
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	05 Nov 2020 00:21:32
Data point term sent to Coder	System	05 Nov 2020 00:20:40
User entered 'symptomatic covid 19'	(b) (4), (b) (6)	05 Nov 2020 00:20:12



**US3312605**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 26 Nov 2020 10:55:55**

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 16:37:11
User entered 'Yes (Y)'	(b) (4), (b) (6)	05 Nov 2020 00:20:12

**US3312605**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 26 Nov 2020 10:55:55**

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 16:37:11
User entered 'No (N)'	(b) (4), (b) (6)	05 Nov 2020 00:20:12

**US3312605**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 26 Nov 2020 10:55:55**

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 16:37:11
User entered 'Yes (Y)'	(b) (4), (b) (6)	05 Nov 2020 00:20:12

**US3312605**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 26 Nov 2020 10:55:55**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 16:37:11
User entered '19 Oct 2020'	(b) (4), (b) (6)	05 Nov 2020 00:20:12

**US3312605**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 26 Nov 2020 10:55:55**

[Start time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 16:37:11
User entered empty.	(b) (4), (b) (6)	05 Nov 2020 00:20:12

**US3312605**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 26 Nov 2020 10:55:55**

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	05 Nov 2020 00:20:12

**US3312605**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 26 Nov 2020 10:55:55**

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 16:37:11
User entered 'No (N)'	(b) (4), (b) (6)	05 Nov 2020 00:20:12

**US3312605**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 26 Nov 2020 10:55:55**

**If not Ongoing, end date (*dd MMM yyyy*)**

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 16:37:11
User entered '02 Nov 2020'	(b) (4), (b) (6)	05 Nov 2020 00:20:12



**US3312605**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 26 Nov 2020 10:55:55**

[End time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 16:37:11
User entered empty.	(b) (4), (b) (6)	05 Nov 2020 00:20:12

**US3312605**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 26 Nov 2020 10:55:55**

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	05 Nov 2020 00:20:12

US3312605

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 10:55:55

[Severity](#)

Audit	User	Time (GMT)
User closed query 'PV Query: As event required hospitalization, please confirm severity as grade 3.' (Site from Safety).	(b) (4), (b) (6)	16 Nov 2020 20:19:13
Query 'PV Query: As event required hospitalization, please confirm severity as grade 3.' answered with 'correct per PI' (Site from Safety).	(b) (4), (b) (6)	13 Nov 2020 21:07:08
User opened query 'PV Query: As event required hospitalization, please confirm severity as grade 3.' (Site from Safety).	(b) (4), (b) (6)	10 Nov 2020 22:11:34
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 16:37:11
User entered 'Grade 3/Severe (Grade 3/Severe)'	(b) (4), (b) (6)	05 Nov 2020 00:20:12

**US3312605**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 26 Nov 2020 10:55:55**

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 16:37:11
User entered 'Yes (Y)'	(b) (4), (b) (6)	05 Nov 2020 00:20:12

**US3312605**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 26 Nov 2020 10:55:55**

[Death](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 16:37:11
User entered '0'	(b) (4), (b) (6)	05 Nov 2020 00:20:12

**US3312605**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 26 Nov 2020 10:55:55**

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 16:37:11
User entered '0'	(b) (4), (b) (6)	05 Nov 2020 00:20:12

**US3312605**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 26 Nov 2020 10:55:55**

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 16:37:11
User entered '1'	(b) (4), (b) (6)	05 Nov 2020 00:20:12

**US3312605**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 26 Nov 2020 10:55:55**

[Hospital Admission Date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 16:37:11
User entered '27 Oct 2020'	(b) (4), (b) (6)	05 Nov 2020 00:20:12



**US3312605**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 26 Nov 2020 10:55:55**

[Hospital Discharge Date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 16:37:11
User entered '29 Oct 2020'	(b) (4), (b) (6)	05 Nov 2020 00:20:12

**US3312605**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 26 Nov 2020 10:55:55**

[Admitted to ICU?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 16:37:11
User entered 'No (N)'	(b) (4), (b) (6)	05 Nov 2020 00:20:12

**US3312605**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 26 Nov 2020 10:55:55**

[Number of Days in ICU](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 16:37:11
User entered empty.	(b) (4), (b) (6)	05 Nov 2020 00:20:12

**US3312605**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 26 Nov 2020 10:55:55**

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 16:37:11
User entered '0'	(b) (4), (b) (6)	05 Nov 2020 00:20:12

**US3312605**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 26 Nov 2020 10:55:55**

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 16:37:11
User entered '0'	(b) (4), (b) (6)	05 Nov 2020 00:20:12

**US3312605**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 26 Nov 2020 10:55:55**

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 16:37:11
User entered '0'	(b) (4), (b) (6)	05 Nov 2020 00:20:12

**US3312605**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 26 Nov 2020 10:55:55**

[Relationship to investigational product](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 16:37:11
User entered 'Not Related (NOT RELATED)'	(b) (4), (b) (6)	05 Nov 2020 00:20:12

**US3312605**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 26 Nov 2020 10:55:55**

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 16:37:11
User entered 'Not Related (NOT RELATED)'	(b) (4), (b) (6)	05 Nov 2020 00:20:12



US3312605

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 10:55:55

Action taken with investigational product

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 23:21:47
User closed query 'PV Query: As the last dose of study drug was given on 08 Oct 2020, please update the action taken with study drug from none to not applicable' (Site from Safety).	(b) (4), (b) (6)	13 Nov 2020 13:05:04
Query 'PV Query: As the last dose of study drug was given on 08 Oct 2020, please update the action taken with study drug from none to not applicable' answered with 'updated' (Site from Safety).	(b) (4), (b) (6)	12 Nov 2020 22:07:41
DataPoint Un-verified.	(b) (4), (b) (6)	12 Nov 2020 22:07:32
User entered 'Not Applicable (NOT APPLICABLE)' reason for change: Data Entry Error	(b) (4), (b) (6)	12 Nov 2020 22:07:32
User opened query 'PV Query: As the last dose of study drug was given on 08 Oct 2020, please update the action taken with study drug from none to not applicable' (Site from Safety).	(b) (4), (b) (6)	10 Nov 2020 22:11:23
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 16:37:11
User entered 'None (NONE)'	(b) (4), (b) (6)	05 Nov 2020 00:20:12

**US3312605**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 26 Nov 2020 10:55:55**

[None](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 16:37:11
User entered '0'	(b) (4), (b) (6)	05 Nov 2020 00:20:12

**US3312605**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 26 Nov 2020 10:55:55**

[Concomitant Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 16:37:11
User entered '1'	(b) (4), (b) (6)	05 Nov 2020 00:20:12

**US3312605**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 26 Nov 2020 10:55:55**

[Concomitant Procedure](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 16:37:11
User entered '0'	(b) (4), (b) (6)	05 Nov 2020 00:20:12

**US3312605**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 26 Nov 2020 10:55:55**

[Outcome](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 16:37:11
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)'	(b) (4), (b) (6)	05 Nov 2020 00:20:12

**US3312605**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 26 Nov 2020 10:55:55**

[If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 16:37:11
User entered empty.	(b) (4), (b) (6)	05 Nov 2020 00:20:12

US3312605

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 10:55:55

[Narrative](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	25 Nov 2020 00:05:50
User closed query 'PV Query: Please provide any relevant laboratory and diagnostic test results. Please include units and reference ranges if applicable.' (Site from Safety).	(b) (4), (b) (6)	16 Nov 2020 20:19:22
User closed query 'PV Query: Did the subject have any known exposure or risk factors for COVID-19?' (Site from Safety).	(b) (4), (b) (6)	16 Nov 2020 20:19:20
Query 'PV Query: Please provide any relevant laboratory and diagnostic test results. Please include units and reference ranges if applicable.' answered with 'unavailable' (Site from Safety).	(b) (4), (b) (6)	13 Nov 2020 21:06:56
DataPoint Un-verified.	(b) (4), (b) (6)	13 Nov 2020 21:05:57

US3312605

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 10:55:55

[Narrative](#)

Audit	User	Time (GMT)
User entered 'SUBJECT DEVELOPED COUGH, SORE THROAT, MYALGIAS, HEADACHE, FATIGUE, NAUSEA, EMESIS, ABDOMINAL DISCOMFORT & DIARRHEA 19OCT2020 & STARTED CMs noted SUBJECT PROCURED COVID TEST 20OCT2020. ON 21OCT2020,SYMPTOMS PROGRESSED TO FEVER 101.9, CHILLS, SOA, CHEST PRESSURE. COVID TEST REPORTED + 22OCT2020 & STARTED additional CMs noted on log NAUSEA, EMESIS, ABDOMINAL DISCOMFORT & DIARRHEA RESOLVED; SUBJECT STARTED ALBUTEROL INHALER. 26OCT2020 LOSS OF TASTE AND SMELL. 27OCT2020 WORSENING OF SYMPTOMS: FATIGUE, SHORTNESS OF AIR, COUGH, DIFFICULTY CONCENTRATING. SUBJECT WENT TO HOSPITAL & ADMITTED FOR SATS DOWN TO 85% WHICH IMPROVED WITH IV HYDRATION. DIAGNOSED WITH COVID-19 DISEASE.OTHER TREATMENT IN HOSPITAL ALBUTEROL AND TESSALON PERLES BUT REPORTEDLY NO OXYGEN.DCd TO HOME 29OCT2020 ON ALBUTEROL INHALER & CONTINUED VITAMINS, MELATONIN & FAMOTIDINE. STEADY IMPROVEMENT OF SYMPTOMS ended BY 02NOV2020.SAT 98% AT SITE VISIT 04NOV2020 WITH NORMAL PE.DIDN'T REPORT SYMPTOMS TO SITE AT TIME OF ILLNESS DUE TO SEVERITY OF ILLNESS,STATED HE "FELT TOO BAD TO DO ANYTHING". MED RECs PENDING. Follow up:Subject notified site he wishes to no longer participate in study and gave no reason. cannot confirm his account of Covid-19 illness, as hospital which he reported being admitted has no record of admission,& subject never produced a copy of his initial SARS-COV2 test as he stated that he would quickly do.Of note, in his account of hospitalization,subject stated that he never received oxygen therapy even though he had O2sats as low as 85%.This is inconsistent with standard of care and I	(b) (4), (b) (6)	13 Nov 2020 21:05:57



US3312605

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 10:55:55

[Narrative](#)

Audit	User	Time (GMT)
doubted the veracity of it, but thought it must be an error made by the subject that would be clarified by medical records. has history of noncompliance with diaries and inconsistencies in history reporting to different site staff that have required further clarification for the final account. In retrospect, the accuracy of subject's reporting is seriously in doubt. Please advise best way to close this SAE' reason for change: Data Entry Error		
Query 'PV Query: Did the subject have any known exposure or risk factors for COVID-19?' answered with 'no know exposure or risk factors' (Site from Safety).	(b) (4), (b) (6)	13 Nov 2020 20:37:25
User opened query 'PV Query: Please provide any relevant laboratory and diagnostic test results. Please include units and reference ranges if applicable.' (Site from Safety).	(b) (4), (b) (6)	10 Nov 2020 22:11:58
User opened query 'PV Query: Did the subject have any known exposure or risk factors for COVID-19?' (Site from Safety).	(b) (4), (b) (6)	10 Nov 2020 22:11:47
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 16:37:11

**US3312605**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 26 Nov 2020 10:55:55**

[Narrative](#)

Audit	User	Time (GMT)
User entered 'Subject developed cough, sore throat, myalgias, headache, fatigue, nausea, emesis, abdominal discomfort and diarrhea on 19Oct2020 and started con meds of ibuprofen, APAP, Dayquil and Nyquil. Subject procured a Covid test on 20Oct2020. On 21Oct2020, symptoms progressed to fever of 101.9, chills, shortness of air, chest pressure. Covid test reported positive on 22Oct2020 and started con meds Vitamin D3, Vitamin C, zinc, melatonin, famotidine. On 25Oct2020 nausea, emesis, abdominal discomfort and diarrhea resolved; subject started albuterol inhaler. On 26Oct2020 loss of taste and smell began. On 27Oct2020 worsening of symptoms of fatigue, shortness of air, cough, difficulty concentrating. Subject went to hospital and admitted for low sats down to 85% which improved with iv hydration. Diagnosed with Covid-19 disease. Other treatment in hospital albuterol and tessalon perles but reportedly no oxygen. Subject discharged to home 29Oct2020 on albuterol inhaler and continued vitamins, melatonin and famotidine. Steady improvement of symptoms to resolution by 02Nov2020. O2sat 98% at site visit 04Nov2020 with normal physical exam. Subject did not report symptoms to site at time of illness due to severity of illness, stated he "felt too bad to do anything". Medical Records pending.'	(b) (4), (b) (6)	05 Nov 2020 00:20:12

**US3312605**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 26 Nov 2020 10:55:55**

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered 'I'	System	05 Nov 2020 00:20:12

**US3312605**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 26 Nov 2020 10:55:55**

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered 'I'	System	05 Nov 2020 00:20:12

**US3312605**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 26 Nov 2020 10:55:55**

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '0'	System	05 Nov 2020 00:20:12

**US3312605**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination Summary**

**Generated On: 26 Nov 2020 10:55:55**

[Were any prior/concomitant medications and/or vaccinations taken?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 16:35:51
User entered 'Yes (Y)'	Karol Moore (b) (4) (b) (4)	06 Oct 2020 22:15:10

US3312605

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 10:55:55

[Name of Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 16:35:36
User coded data point as ATC: NERVOUS SYSTEM, ATC: PSYCHOLEPTICS, ATC: ANXIOLYTICS, ATC: OTHER ANXIOLYTICS, PRODUCT: ESCITALOPRAM - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	06 Oct 2020 22:17:24
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	06 Oct 2020 22:17:24
Data point term sent to Coder	System	06 Oct 2020 22:16:13
User entered 'escitalopram'	Karol Moore (b) (4) (b) (4)	06 Oct 2020 22:16:01

**US3312605**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 26 Nov 2020 10:55:55**

[Prophylaxis](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 16:35:36
User entered 'No (N)'	Karol Moore (b) (4) (b) (4)	06 Oct 2020 22:16:01



**US3312605**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 26 Nov 2020 10:55:55**

[Indication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 16:35:36
User entered 'depression and anxiety'	Karol Moore (b) (4) (b) (4)	06 Oct 2020 22:16:01

**US3312605**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 26 Nov 2020 10:55:55**

[Dose per administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 16:35:36
User entered '20'	Karol Moore (b) (4) (b) (4)	06 Oct 2020 22:16:01

US3312605

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 10:55:55

[Dose unit](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 16:35:36
User entered 'mg (mg)'	Karol Moore (b) (4) (b) (4)	06 Oct 2020 22:16:01

US3312605

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 26 Nov 2020 10:55:55**

If dose unit is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 16:35:36
User entered empty.	Karol Moore (b) (4) (b) (4)	06 Oct 2020 22:16:01

US3312605

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 10:55:55

[Frequency](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 16:35:36
User entered 'once daily (QD)'	Karol Moore (b) (4) (b) (4)	06 Oct 2020 22:16:01

US3312605

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 26 Nov 2020 10:55:55**

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 16:35:36
User entered empty.	Karol Moore (b) (4) (b) (4)	06 Oct 2020 22:16:01

**US3312605**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 26 Nov 2020 10:55:55**

[Route of administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 16:35:36
User entered 'Oral (ORAL)'	Karol Moore (b) (4) (b) (4)	06 Oct 2020 22:16:01

US3312605

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 26 Nov 2020 10:55:55**

If route of administration is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 16:35:36
User entered empty.	Karol Moore (b) (4) (b) (4)	06 Oct 2020 22:16:01



**US3312605**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 26 Nov 2020 10:55:55**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 16:35:36
User entered 'un UNK 2016'	Karol Moore (b) (4) (b) (4)	06 Oct 2020 22:16:01

US3312605

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 26 Nov 2020 10:55:55**

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 16:35:36
User entered '0'	Karol Moore (b) (4) (b) (4)	06 Oct 2020 22:16:01

**US3312605**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 26 Nov 2020 10:55:55**

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 16:35:36
User entered 'Yes (Y)'	Karol Moore (b) (4) (b) (4)	06 Oct 2020 22:16:01

US3312605

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 26 Nov 2020 10:55:55**

*If not Ongoing, End date (dd MMM yyyy)*

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 16:35:36
User entered empty.	Karol Moore (b) (4) (b) (4)	06 Oct 2020 22:16:01

US3312605

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 26 Nov 2020 10:55:55**

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 16:35:36
User entered 'No (N)'	Karol Moore (b) (4) (b) (4)	06 Oct 2020 22:16:01

**US3312605**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 26 Nov 2020 10:55:55**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	06 Oct 2020 22:16:01

**US3312605**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 26 Nov 2020 10:55:55**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	06 Oct 2020 22:16:01

**US3312605**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 26 Nov 2020 10:55:55**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	06 Oct 2020 22:16:01



US3312605

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 10:55:55

[Name of Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 16:35:36
User coded data point as ATC: NERVOUS SYSTEM, ATC: PSYCHOANALEPTICS, ATC: PSYCHOSTIMULANTS, AGENTS USED FOR ADHD AND NOOTROPICS, ATC: CENTRALLY ACTING SYMPATHOMIMETICS, PRODUCT: AMFETAMINE;DEXAMFETAMINE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	12 Oct 2020 20:38:21
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	12 Oct 2020 20:38:21
Data point term sent to Coder	System	06 Oct 2020 22:19:16
User entered 'destroamphetamine-amphetamine'	Karol Moore (b) (4) (b) (4)	06 Oct 2020 22:18:26

US3312605

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 10:55:55

[Prophylaxis](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 16:35:36
User entered 'No (N)'	Karol Moore (b) (4) (b) (4)	06 Oct 2020 22:18:26

US3312605

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 10:55:55

[Indication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 16:35:36
User entered 'Attention deficit hyperactivity disorder'	Karol Moore (b) (4) (b) (4)	06 Oct 2020 22:18:26

US3312605

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 10:55:55

[Dose per administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 16:35:36
User entered '10'	Karol Moore (b) (4) (b) (4)	06 Oct 2020 22:18:26

US3312605

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 10:55:55

[Dose unit](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 16:35:36
User entered 'mg (mg)'	Karol Moore (b) (4) (b) (4)	06 Oct 2020 22:18:26

US3312605

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 10:55:55

If dose unit is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 16:35:36
User entered empty.	Karol Moore (b) (4) (b) (4)	06 Oct 2020 22:18:26

**US3312605**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 26 Nov 2020 10:55:55**

[Frequency](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 16:35:36
User entered 'three times daily (TID)'	Karol Moore (b) (4) (b) (4)	06 Oct 2020 22:18:26

US3312605

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 10:55:55

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 16:35:36
User entered empty.	Karol Moore (b) (4) (b) (4)	06 Oct 2020 22:18:26



**US3312605**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 26 Nov 2020 10:55:55**

[Route of administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 16:35:36
User entered 'Oral (ORAL)'	Karol Moore (b) (4) (b) (4)	06 Oct 2020 22:18:26

US3312605

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 26 Nov 2020 10:55:55**

If route of administration is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 16:35:36
User entered empty.	Karol Moore (b) (4) (b) (4)	06 Oct 2020 22:18:26

US3312605

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 10:55:55

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 16:35:36
User entered 'un UNK 2011'	Karol Moore (b) (4) (b) (4)	06 Oct 2020 22:18:26

**US3312605**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 26 Nov 2020 10:55:55**

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 16:35:36
User entered '0'	Karol Moore (b) (4) (b) (4)	06 Oct 2020 22:18:26

**US3312605**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 26 Nov 2020 10:55:55**

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 16:35:36
User entered 'Yes (Y)'	Karol Moore (b) (4) (b) (4)	06 Oct 2020 22:18:26

US3312605

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 10:55:55

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 16:35:36
User entered empty.	Karol Moore (b) (4) (b) (4)	06 Oct 2020 22:18:26

US3312605

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 10:55:55

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 16:35:36
User entered 'No (N)'	Karol Moore (b) (4) (b) (4)	06 Oct 2020 22:18:26

**US3312605**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 26 Nov 2020 10:55:55**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '3'	System	06 Oct 2020 22:18:26



**US3312605**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 26 Nov 2020 10:55:55**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	06 Oct 2020 22:18:26

**US3312605**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 26 Nov 2020 10:55:55**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	06 Oct 2020 22:18:26

US3312605

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 10:55:55

[Name of Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 16:35:36
User coded data point as ATC: DERMATOLOGICALS, ATC: OTHER DERMATOLOGICAL PREPARATIONS, ATC: OTHER DERMATOLOGICAL PREPARATIONS, ATC: OTHER DERMATOLOGICALS, PRODUCT: FINASTERIDE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	06 Oct 2020 23:23:19
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	06 Oct 2020 23:23:19
Data point term sent to Coder	System	06 Oct 2020 22:20:19
User entered 'finasteride'	Karol Moore (b) (4) (b) (4)	06 Oct 2020 22:19:25

US3312605

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 10:55:55

[Prophylaxis](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 16:35:36
User entered 'No (N)'	Karol Moore (b) (4) (b) (4)	06 Oct 2020 22:19:25

US3312605

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 10:55:55

[Indication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 16:35:36
User entered 'excessive hair loss'	Karol Moore (b) (4) (b) (4)	06 Oct 2020 22:19:25

US3312605

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 10:55:55

[Dose per administration](#)

Audit	User	Time (GMT)
User opened query 'Per DM CLR: Please review the dose recorded as this is not the standard dose for this medication. Please correct the dosage or provide explanation for alternate dosage.' (Site from DM). DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 12:24:15
	(b) (4), (b) (6)	10 Nov 2020 16:35:36
User entered '1.25'	Karol Moore (b) (4)	06 Oct 2020 22:19:25
	(b) (4)	

US3312605

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 26 Nov 2020 10:55:55**

[Dose unit](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 16:35:36
User entered 'mg (mg)'	Karol Moore (b) (4) (b) (4)	06 Oct 2020 22:19:25

US3312605

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 26 Nov 2020 10:55:55**

If dose unit is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 16:35:36
User entered empty.	Karol Moore (b) (4) (b) (4)	06 Oct 2020 22:19:25



US3312605

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 10:55:55

[Frequency](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 16:35:36
User entered 'once daily (QD)'	Karol Moore (b) (4) (b) (4)	06 Oct 2020 22:19:25

US3312605

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 26 Nov 2020 10:55:55**

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 16:35:36
User entered empty.	Karol Moore (b) (4) (b) (4)	06 Oct 2020 22:19:25

**US3312605**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 26 Nov 2020 10:55:55**

[Route of administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 16:35:36
User entered 'Oral (ORAL)'	Karol Moore (b) (4) (b) (4)	06 Oct 2020 22:19:25

US3312605

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 26 Nov 2020 10:55:55**

If route of administration is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 16:35:36
User entered empty.	Karol Moore (b) (4) (b) (4)	06 Oct 2020 22:19:25

US3312605

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 10:55:55

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 16:35:36
User entered 'un UNK 2019'	Karol Moore (b) (4) (b) (4)	06 Oct 2020 22:19:25

**US3312605**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 26 Nov 2020 10:55:55**

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 16:35:36
User entered '0'	Karol Moore (b) (4) (b) (4)	06 Oct 2020 22:19:25

**US3312605**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 26 Nov 2020 10:55:55**

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 16:35:36
User entered 'Yes (Y)'	Karol Moore (b) (4) (b) (4)	06 Oct 2020 22:19:25

US3312605

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 10:55:55

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 16:35:36
User entered empty.	Karol Moore (b) (4) (b) (4)	06 Oct 2020 22:19:25



**US3312605**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 26 Nov 2020 10:55:55**

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 16:35:36
User entered 'No (N)'	Karol Moore (b) (4) (b) (4)	06 Oct 2020 22:19:25

**US3312605**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 26 Nov 2020 10:55:55**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	06 Oct 2020 22:19:25

**US3312605**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 26 Nov 2020 10:55:55**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	06 Oct 2020 22:19:25

**US3312605**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 26 Nov 2020 10:55:55**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	06 Oct 2020 22:19:25

US3312605

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 10:55:55

[Name of Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 16:35:36
User coded data point as ATC: GENITO URINARY SYSTEM AND SEX HORMONES, ATC: UROLOGICALS, ATC: UROLOGICALS, ATC: URINARY CONCREMENT SOLVENTS, PRODUCT: POTASSIUM CITRATE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	06 Oct 2020 22:23:19
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	06 Oct 2020 22:23:19
Data point term sent to Coder	System	06 Oct 2020 22:22:22
User entered 'potassium citrate'	Karol Moore (b) (4) (b) (4)	06 Oct 2020 22:22:05

US3312605

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 10:55:55

[Prophylaxis](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 16:35:36
User entered 'No (N)'	Karol Moore (b) (4) (b) (4)	06 Oct 2020 22:22:05

US3312605

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 10:55:55

[Indication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 16:35:36
User entered 'nephrolithiasis'	Karol Moore (b) (4) (b) (4)	06 Oct 2020 22:22:05

US3312605

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 10:55:55

[Dose per administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 16:35:36
User entered '10'	Karol Moore (b) (4) (b) (4)	06 Oct 2020 22:22:05



US3312605

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 10:55:55

[Dose unit](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 16:35:36
User closed query 'Per DM CLR: Please review the unit recorded as this is not the expected unit for this medication. Please update the unit as appropriate or provide explanation for alternate unit. ' (Site from DM).	(b) (4), (b) (6)	07 Nov 2020 18:29:02
Query 'Per DM CLR: Please review the unit recorded as this is not the expected unit for this medication. Please update the unit as appropriate or provide explanation for alternate unit. ' answered with 'updated' (Site from DM).	Karol Moore (b) (4) (b) (4)	06 Nov 2020 15:24:47
User entered 'Other (OTHER)' reason for change: Data Entry Error	Karol Moore (b) (4) (b) (4)	06 Nov 2020 15:24:43
User opened query 'Per DM CLR: Please review the unit recorded as this is not the expected unit for this medication. Please update the unit as appropriate or provide explanation for alternate unit. ' (Site from DM).	(b) (4), (b) (6)	06 Nov 2020 10:24:04
User entered 'ug (ug)'	Karol Moore (b) (4) (b) (4)	06 Oct 2020 22:22:05

US3312605

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 10:55:55

If dose unit is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 16:35:36
User entered 'milliequivalents' reason for change:	Karol Moore (b) (4)	06 Nov 2020 15:24:43
Data Entry Error	(b) (4)	
Un-reviewed for Data Management.	(b) (4), (b) (6)	06 Nov 2020 10:23:58
Reviewed for Data Management.	(b) (4), (b) (6)	06 Nov 2020 10:23:55
User entered empty.	Karol Moore (b) (4)	06 Oct 2020 22:22:05
	(b) (4)	

**US3312605**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 26 Nov 2020 10:55:55**

[Frequency](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 16:35:36
User entered 'three times daily (TID)'	Karol Moore (b) (4) (b) (4)	06 Oct 2020 22:22:05

US3312605

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 26 Nov 2020 10:55:55**

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 16:35:36
User entered empty.	Karol Moore (b) (4) (b) (4)	06 Oct 2020 22:22:05

**US3312605**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 26 Nov 2020 10:55:55**

[Route of administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 16:35:36
User entered 'Oral (ORAL)'	Karol Moore (b) (4) (b) (4)	06 Oct 2020 22:22:05

US3312605

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 26 Nov 2020 10:55:55**

If route of administration is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 16:35:36
User entered empty.	Karol Moore (b) (4) (b) (4)	06 Oct 2020 22:22:05

**US3312605**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 26 Nov 2020 10:55:55**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 16:35:36
User entered 'un UNK 2016'	Karol Moore (b) (4) (b) (4)	06 Oct 2020 22:22:05

**US3312605**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 26 Nov 2020 10:55:55**

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 16:35:36
User entered '0'	Karol Moore (b) (4) (b) (4)	06 Oct 2020 22:22:05



**US3312605**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 26 Nov 2020 10:55:55**

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 16:35:36
User entered 'Yes (Y)'	Karol Moore (b) (4) (b) (4)	06 Oct 2020 22:22:05

US3312605

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 26 Nov 2020 10:55:55**

*If not Ongoing, End date (dd MMM yyyy)*

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 16:35:36
User entered empty.	Karol Moore (b) (4) (b) (4)	06 Oct 2020 22:22:05

US3312605

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 26 Nov 2020 10:55:55**

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 16:35:36
User entered 'No (N)'	Karol Moore (b) (4) (b) (4)	06 Oct 2020 22:22:05

**US3312605**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 26 Nov 2020 10:55:55**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '3'	System	06 Oct 2020 22:22:05

US3312605

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 26 Nov 2020 10:55:55**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	06 Oct 2020 22:22:05

**US3312605**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 26 Nov 2020 10:55:55**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	06 Oct 2020 22:22:05

US3312605

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 10:55:55

[Name of Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 16:35:36
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)	06 Oct 2020 22:25:21
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	06 Oct 2020 22:25:21
Data point term sent to Coder	System	06 Oct 2020 22:24:25
User entered 'cetirizine'	Karol Moore (b) (4) (b) (4)	06 Oct 2020 22:23:42

**US3312605**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 26 Nov 2020 10:55:55**

[Prophylaxis](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 16:35:36
User entered 'No (N)'	Karol Moore (b) (4) (b) (4)	06 Oct 2020 22:23:42



**US3312605**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 26 Nov 2020 10:55:55**

[Indication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 16:35:36
User entered 'seasonal allergies'	Karol Moore (b) (4) (b) (4)	06 Oct 2020 22:23:42

**US3312605**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 26 Nov 2020 10:55:55**

[Dose per administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 16:35:36
User entered '10'	Karol Moore (b) (4) (b) (4)	06 Oct 2020 22:23:42

US3312605

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 10:55:55

[Dose unit](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 16:35:36
User entered 'mg (mg)'	Karol Moore (b) (4) (b) (4)	06 Oct 2020 22:23:42

US3312605

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 26 Nov 2020 10:55:55**

If dose unit is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 16:35:36
User entered empty.	Karol Moore (b) (4) (b) (4)	06 Oct 2020 22:23:42

US3312605

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 10:55:55

[Frequency](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 16:35:36
User entered 'once daily (QD)'	Karol Moore (b) (4) (b) (4)	06 Oct 2020 22:23:42

US3312605

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 10:55:55

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 16:35:36
User entered empty.	Karol Moore (b) (4) (b) (4)	06 Oct 2020 22:23:42

**US3312605**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 26 Nov 2020 10:55:55**

[Route of administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 16:35:36
User entered 'Oral (ORAL)'	Karol Moore (b) (4) (b) (4)	06 Oct 2020 22:23:42

US3312605

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 26 Nov 2020 10:55:55**

If route of administration is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 16:35:36
User entered empty.	Karol Moore (b) (4) (b) (4)	06 Oct 2020 22:23:42



US3312605

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 10:55:55

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 16:35:36
User entered 'un UNK 2010'	Karol Moore (b) (4) (b) (4)	06 Oct 2020 22:23:42

**US3312605**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 26 Nov 2020 10:55:55**

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 16:35:36
User entered '0'	Karol Moore (b) (4) (b) (4)	06 Oct 2020 22:23:42

**US3312605**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 26 Nov 2020 10:55:55**

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 16:35:36
User entered 'Yes (Y)'	Karol Moore (b) (4) (b) (4)	06 Oct 2020 22:23:42

US3312605

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 26 Nov 2020 10:55:55**

*If not Ongoing, End date (dd MMM yyyy)*

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 16:35:36
User entered empty.	Karol Moore (b) (4) (b) (4)	06 Oct 2020 22:23:42

US3312605

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 26 Nov 2020 10:55:55**

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 16:35:36
User entered 'No (N)'	Karol Moore (b) (4) (b) (4)	06 Oct 2020 22:23:42

**US3312605**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 26 Nov 2020 10:55:55**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	06 Oct 2020 22:23:42

**US3312605**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 26 Nov 2020 10:55:55**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	06 Oct 2020 22:23:42

**US3312605**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 26 Nov 2020 10:55:55**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	06 Oct 2020 22:23:42



US3312605

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 10:55:55

[Name of Medication](#)

Audit	User	Time (GMT)
User opened query 'Per DM CLR: Please review the start/stop date of this medication as it overlaps with Con Med ACETAMINOPHEN, # 8 / (19OCT-30OCT2020). Please consider updating dates if necessary or review if this is a duplicate. Update Con Med eCRF as appropriate.' (Site from DM).	(b) (4), (b) (6)	24 Nov 2020 12:26:13
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 16:35:36
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)	06 Oct 2020 22:25:21
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	(b) (4)	
Data point term sent to Coder	System	06 Oct 2020 22:24:25
User entered 'acetaminophen'	Karol Moore (b) (4)	06 Oct 2020 22:24:12
	(b) (4)	

US3312605

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 10:55:55

[Prophylaxis](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 16:35:36
User entered 'No (N)'	Karol Moore (b) (4) (b) (4)	06 Oct 2020 22:24:12

**US3312605**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 26 Nov 2020 10:55:55**

[Indication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 16:35:36
User entered 'mild occasional headaches'	Karol Moore (b) (4) (b) (4)	06 Oct 2020 22:24:12

**US3312605**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 26 Nov 2020 10:55:55**

[Dose per administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 16:35:36
User entered '500'	Karol Moore (b) (4) (b) (4)	06 Oct 2020 22:24:12

US3312605

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 10:55:55

[Dose unit](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 16:35:36
User entered 'mg (mg)'	Karol Moore (b) (4) (b) (4)	06 Oct 2020 22:24:12

**US3312605**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 26 Nov 2020 10:55:55**

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 16:35:36
User entered empty.	Karol Moore (b) (4) (b) (4)	06 Oct 2020 22:24:12

**US3312605**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 26 Nov 2020 10:55:55**

[Frequency](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 16:35:36
User entered 'as needed (PRN)'	Karol Moore (b) (4) (b) (4)	06 Oct 2020 22:24:12

US3312605

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 26 Nov 2020 10:55:55**

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 16:35:36
User entered empty.	Karol Moore (b) (4) (b) (4)	06 Oct 2020 22:24:12



**US3312605**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 26 Nov 2020 10:55:55**

[Route of administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 16:35:36
User entered 'Oral (ORAL)'	Karol Moore (b) (4) (b) (4)	06 Oct 2020 22:24:12

US3312605

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 26 Nov 2020 10:55:55**

If route of administration is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 16:35:36
User entered empty.	Karol Moore (b) (4) (b) (4)	06 Oct 2020 22:24:12

**US3312605**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 26 Nov 2020 10:55:55**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 16:35:36
User entered 'un UNK 2010'	Karol Moore (b) (4) (b) (4)	06 Oct 2020 22:24:12

**US3312605**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 26 Nov 2020 10:55:55**

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 16:35:36
User entered '0'	Karol Moore (b) (4) (b) (4)	06 Oct 2020 22:24:12

**US3312605**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 26 Nov 2020 10:55:55**

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 16:35:36
User entered 'Yes (Y)'	Karol Moore (b) (4) (b) (4)	06 Oct 2020 22:24:12

US3312605

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 26 Nov 2020 10:55:55**

*If not Ongoing, End date (dd MMM yyyy)*

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 16:35:36
User entered empty.	Karol Moore (b) (4) (b) (4)	06 Oct 2020 22:24:12

**US3312605**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 26 Nov 2020 10:55:55**

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 16:35:36
User entered 'No (N)'	Karol Moore (b) (4) (b) (4)	06 Oct 2020 22:24:12

**US3312605**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 26 Nov 2020 10:55:55**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	06 Oct 2020 22:24:12



**US3312605**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 26 Nov 2020 10:55:55**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	06 Oct 2020 22:24:12

**US3312605**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 26 Nov 2020 10:55:55**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	06 Oct 2020 22:24:12

US3312605

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 26 Nov 2020 10:55:55

[Name of Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 16:35:36
User coded data point as ATC: MUSCULO-SKELETAL SYSTEM, ATC: ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, ATC: ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, NON-STEROIDS, ATC: PROPIONIC ACID DERIVATIVES, PRODUCT: IBUPROFEN - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	05 Nov 2020 16:00:47
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	05 Nov 2020 16:00:47
Data point term sent to Coder	System	05 Nov 2020 15:59:57
User entered 'ibuprofen'	Karol Moore (b) (4) (b) (4)	05 Nov 2020 15:59:54

**US3312605**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 26 Nov 2020 10:55:55**

[Prophylaxis](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 16:35:36
User entered 'No (N)'	Karol Moore (b) (4) (b) (4)	05 Nov 2020 15:59:54

**US3312605**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 26 Nov 2020 10:55:55**

[Indication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 16:35:36
User entered 'symptomatic covid-19'	Karol Moore (b) (4) (b) (4)	05 Nov 2020 15:59:54

**US3312605**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 26 Nov 2020 10:55:55**

[Dose per administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 16:35:36
User entered '400'	Karol Moore (b) (4) (b) (4)	05 Nov 2020 15:59:54

US3312605

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 26 Nov 2020 10:55:55

[Dose unit](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 16:35:36
User entered 'mg (mg)'	Karol Moore (b) (4) (b) (4)	05 Nov 2020 15:59:54

US3312605

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 26 Nov 2020 10:55:55**

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 16:35:36
User entered empty.	Karol Moore (b) (4) (b) (4)	05 Nov 2020 15:59:54



**US3312605**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 26 Nov 2020 10:55:55**

[Frequency](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 16:35:36
User entered 'as needed (PRN)'	Karol Moore (b) (4) (b) (4)	05 Nov 2020 15:59:54

US3312605

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 26 Nov 2020 10:55:55**

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 16:35:36
User entered empty.	Karol Moore (b) (4) (b) (4)	05 Nov 2020 15:59:54

**US3312605**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 26 Nov 2020 10:55:55**

[Route of administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 16:35:36
User entered 'Oral (ORAL)'	Karol Moore (b) (4) (b) (4)	05 Nov 2020 15:59:54

US3312605

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 26 Nov 2020 10:55:55**

If route of administration is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 16:35:36
User entered empty.	Karol Moore (b) (4) (b) (4)	05 Nov 2020 15:59:54

US3312605

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 26 Nov 2020 10:55:55

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 16:35:36
User entered '19 Oct 2020'	Karol Moore (b) (4) (b) (4)	05 Nov 2020 15:59:54

**US3312605**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 26 Nov 2020 10:55:55**

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 16:35:36
User entered '0'	Karol Moore (b) (4) (b) (4)	05 Nov 2020 15:59:54

**US3312605**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 26 Nov 2020 10:55:55**

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 16:35:36
User entered 'No (N)'	Karol Moore (b) (4) (b) (4)	05 Nov 2020 15:59:54

**US3312605**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 26 Nov 2020 10:55:55**

**If not Ongoing, End date (*dd MMM yyyy*)**

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 16:35:36
User entered '19 Oct 2020'	Karol Moore (b) (4) (b) (4)	05 Nov 2020 15:59:54



**US3312605**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 26 Nov 2020 10:55:55**

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 16:35:36
User entered 'No (N)'	Karol Moore (b) (4) (b) (4)	05 Nov 2020 15:59:54

**US3312605**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 26 Nov 2020 10:55:55**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	05 Nov 2020 15:59:54

**US3312605**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 26 Nov 2020 10:55:55**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	05 Nov 2020 15:59:54

**US3312605**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 26 Nov 2020 10:55:55**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	05 Nov 2020 15:59:54

US3312605

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 26 Nov 2020 10:55:55

[Name of Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 16:35:36
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)	05 Nov 2020 16:01:19
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	05 Nov 2020 16:01:19
Data point term sent to Coder	System	05 Nov 2020 16:01:00
User entered 'acetaminophen'	Karol Moore (b) (4) (b) (4)	05 Nov 2020 16:00:34

US3312605

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 26 Nov 2020 10:55:55

[Prophylaxis](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 16:35:36
User entered 'No (N)'	Karol Moore (b) (4) (b) (4)	05 Nov 2020 16:00:34

**US3312605**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (8)**

**Generated On: 26 Nov 2020 10:55:55**

[Indication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 16:35:36
User entered 'symptomatic covid-19'	Karol Moore (b) (4) (b) (4)	05 Nov 2020 16:00:34

**US3312605**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (8)**

**Generated On: 26 Nov 2020 10:55:55**

[Dose per administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 16:35:36
User entered '500'	Karol Moore (b) (4) (b) (4)	05 Nov 2020 16:00:34



US3312605

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 26 Nov 2020 10:55:55

[Dose unit](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 16:35:36
User entered 'mg (mg)'	Karol Moore (b) (4) (b) (4)	05 Nov 2020 16:00:34

US3312605

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 26 Nov 2020 10:55:55

If dose unit is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 16:35:36
User entered empty.	Karol Moore (b) (4) (b) (4)	05 Nov 2020 16:00:34

US3312605

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 26 Nov 2020 10:55:55

[Frequency](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 16:35:36
User entered 'as needed (PRN)'	Karol Moore (b) (4) (b) (4)	05 Nov 2020 16:00:34

US3312605

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 26 Nov 2020 10:55:55

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 16:35:36
User entered empty.	Karol Moore (b) (4) (b) (4)	05 Nov 2020 16:00:34

**US3312605**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (8)**

**Generated On: 26 Nov 2020 10:55:55**

[Route of administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 16:35:36
User entered 'Oral (ORAL)'	Karol Moore (b) (4) (b) (4)	05 Nov 2020 16:00:34

US3312605

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (8)**

**Generated On: 26 Nov 2020 10:55:55**

If route of administration is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 16:35:36
User entered empty.	Karol Moore (b) (4) (b) (4)	05 Nov 2020 16:00:34

**US3312605**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (8)**

**Generated On: 26 Nov 2020 10:55:55**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 16:35:36
User entered '19 Oct 2020'	Karol Moore (b) (4) (b) (4)	05 Nov 2020 16:00:34

**US3312605**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (8)**

**Generated On: 26 Nov 2020 10:55:55**

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 16:35:36
User entered '0'	Karol Moore (b) (4) (b) (4)	05 Nov 2020 16:00:34



**US3312605**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (8)**

**Generated On: 26 Nov 2020 10:55:55**

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 16:35:36
User entered 'No (N)'	Karol Moore (b) (4) (b) (4)	05 Nov 2020 16:00:34

US3312605

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 26 Nov 2020 10:55:55

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 16:35:36
User entered '30 Oct 2020'	Karol Moore (b) (4) (b) (4)	05 Nov 2020 16:00:34

US3312605

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (8)**

**Generated On: 26 Nov 2020 10:55:55**

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 16:35:36
User entered 'No (N)'	Karol Moore (b) (4) (b) (4)	05 Nov 2020 16:00:34

**US3312605**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (8)**

**Generated On: 26 Nov 2020 10:55:55**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	05 Nov 2020 16:00:34

**US3312605**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (8)**

**Generated On: 26 Nov 2020 10:55:55**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	05 Nov 2020 16:00:34

**US3312605**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (8)**

**Generated On: 26 Nov 2020 10:55:55**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	05 Nov 2020 16:00:34

US3312605

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 26 Nov 2020 10:55:55

[Name of Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 16:35:36
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)	05 Nov 2020 16:30:21
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	05 Nov 2020 16:30:21
Data point term sent to Coder	System	05 Nov 2020 16:02:00
User entered 'vitamin c'	Karol Moore (b) (4) (b) (4)	05 Nov 2020 16:01:06

US3312605

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 26 Nov 2020 10:55:55

[Prophylaxis](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 16:35:36
User entered 'No (N)'	Karol Moore (b) (4) (b) (4)	05 Nov 2020 16:01:06



US3312605

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 26 Nov 2020 10:55:55

[Indication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 16:35:36
User entered 'symptomatic covid-19'	Karol Moore (b) (4) (b) (4)	05 Nov 2020 16:01:06

**US3312605**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (9)**

**Generated On: 26 Nov 2020 10:55:55**

[Dose per administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 16:35:36
User entered '500'	Karol Moore (b) (4) (b) (4)	05 Nov 2020 16:01:06

US3312605

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 26 Nov 2020 10:55:55

[Dose unit](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 16:35:36
User entered 'mg (mg)'	Karol Moore (b) (4) (b) (4)	05 Nov 2020 16:01:06

US3312605

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 26 Nov 2020 10:55:55

If dose unit is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 16:35:36
User entered empty.	Karol Moore (b) (4) (b) (4)	05 Nov 2020 16:01:06

US3312605

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 26 Nov 2020 10:55:55

[Frequency](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 16:35:36
User entered 'twice daily (BID)'	Karol Moore (b) (4) (b) (4)	05 Nov 2020 16:01:06

US3312605

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 26 Nov 2020 10:55:55

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 16:35:36
User entered empty.	Karol Moore (b) (4) (b) (4)	05 Nov 2020 16:01:06

US3312605

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 26 Nov 2020 10:55:55

[Route of administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 16:35:36
User entered 'Oral (ORAL)'	Karol Moore (b) (4) (b) (4)	05 Nov 2020 16:01:06

US3312605

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (9)**

**Generated On: 26 Nov 2020 10:55:55**

If route of administration is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 16:35:36
User entered empty.	Karol Moore (b) (4) (b) (4)	05 Nov 2020 16:01:06



**US3312605**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (9)**

**Generated On: 26 Nov 2020 10:55:55**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 16:35:36
User entered '22 Oct 2020'	Karol Moore (b) (4) (b) (4)	05 Nov 2020 16:01:06

**US3312605**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (9)**

**Generated On: 26 Nov 2020 10:55:55**

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 16:35:36
User entered '0'	Karol Moore (b) (4) (b) (4)	05 Nov 2020 16:01:06

**US3312605**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (9)**

**Generated On: 26 Nov 2020 10:55:55**

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 16:35:36
User entered 'Yes (Y)'	Karol Moore (b) (4) (b) (4)	05 Nov 2020 16:01:06

US3312605

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 26 Nov 2020 10:55:55

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 16:35:36
User entered empty.	Karol Moore (b) (4) (b) (4)	05 Nov 2020 16:01:06

**US3312605**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (9)**

**Generated On: 26 Nov 2020 10:55:55**

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 16:35:36
User entered 'No (N)'	Karol Moore (b) (4) (b) (4)	05 Nov 2020 16:01:06

**US3312605**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (9)**

**Generated On: 26 Nov 2020 10:55:55**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '2'	System	05 Nov 2020 16:01:06

**US3312605**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (9)**

**Generated On: 26 Nov 2020 10:55:55**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	05 Nov 2020 16:01:06

**US3312605**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (9)**

**Generated On: 26 Nov 2020 10:55:55**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	05 Nov 2020 16:01:06



US3312605

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 26 Nov 2020 10:55:55

[Name of Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 16:35:36
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: MINERAL SUPPLEMENTS, ATC: OTHER MINERAL SUPPLEMENTS, ATC: ZINC, PRODUCT: ZINC - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	05 Nov 2020 16:30:20
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	05 Nov 2020 16:30:20
Data point term sent to Coder	System	05 Nov 2020 16:02:01
User entered 'zinc'	Karol Moore (b) (4) (b) (4)	05 Nov 2020 16:01:31

US3312605

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 26 Nov 2020 10:55:55

[Prophylaxis](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 16:35:36
User entered 'No (N)'	Karol Moore (b) (4) (b) (4)	05 Nov 2020 16:01:31

**US3312605**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (10)**

**Generated On: 26 Nov 2020 10:55:55**

[Indication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 16:35:36
User entered 'symptomatic covid-19'	Karol Moore (b) (4) (b) (4)	05 Nov 2020 16:01:31

**US3312605**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (10)**

**Generated On: 26 Nov 2020 10:55:55**

[Dose per administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 16:35:36
User entered '75'	Karol Moore (b) (4) (b) (4)	05 Nov 2020 16:01:31

US3312605

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 26 Nov 2020 10:55:55

[Dose unit](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 16:35:36
User entered 'mg (mg)'	Karol Moore (b) (4) (b) (4)	05 Nov 2020 16:01:31

US3312605

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 26 Nov 2020 10:55:55

If dose unit is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 16:35:36
User entered empty.	Karol Moore (b) (4) (b) (4)	05 Nov 2020 16:01:31

US3312605

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 26 Nov 2020 10:55:55

[Frequency](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 16:35:36
User entered 'once daily (QD)'	Karol Moore (b) (4) (b) (4)	05 Nov 2020 16:01:31

US3312605

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (10)**

**Generated On: 26 Nov 2020 10:55:55**

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 16:35:36
User entered empty.	Karol Moore (b) (4) (b) (4)	05 Nov 2020 16:01:31



**US3312605**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (10)**

**Generated On: 26 Nov 2020 10:55:55**

[Route of administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 16:35:36
User entered 'Oral (ORAL)'	Karol Moore (b) (4) (b) (4)	05 Nov 2020 16:01:31

US3312605

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 26 Nov 2020 10:55:55

If route of administration is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 16:35:36
User entered empty.	Karol Moore (b) (4) (b) (4)	05 Nov 2020 16:01:31

**US3312605**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (10)**

**Generated On: 26 Nov 2020 10:55:55**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 16:35:36
User entered '22 Oct 2020'	Karol Moore (b) (4) (b) (4)	05 Nov 2020 16:01:31

**US3312605**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (10)**

**Generated On: 26 Nov 2020 10:55:55**

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 16:35:36
User entered '0'	Karol Moore (b) (4) (b) (4)	05 Nov 2020 16:01:31

**US3312605**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (10)**

**Generated On: 26 Nov 2020 10:55:55**

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 16:35:36
User entered 'Yes (Y)'	Karol Moore (b) (4) (b) (4)	05 Nov 2020 16:01:31

US3312605

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (10)**

**Generated On: 26 Nov 2020 10:55:55**

*If not Ongoing, End date (dd MMM yyyy)*

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 16:35:36
User entered empty.	Karol Moore (b) (4) (b) (4)	05 Nov 2020 16:01:31

**US3312605**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (10)**

**Generated On: 26 Nov 2020 10:55:55**

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 16:35:36
User entered 'No (N)'	Karol Moore (b) (4) (b) (4)	05 Nov 2020 16:01:31

**US3312605**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (10)**

**Generated On: 26 Nov 2020 10:55:55**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	05 Nov 2020 16:01:31



**US3312605**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (10)**

**Generated On: 26 Nov 2020 10:55:55**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	05 Nov 2020 16:01:31

**US3312605**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (10)**

**Generated On: 26 Nov 2020 10:55:55**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	05 Nov 2020 16:01:31

US3312605

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 26 Nov 2020 10:55:55

[Name of Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 16:35:36
User coded data point as ATC: NERVOUS SYSTEM, ATC: PSYCHOLEPTICS, ATC: HYPNOTICS AND SEDATIVES, ATC: MELATONIN RECEPTOR AGONISTS, PRODUCT: MELATONIN - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	05 Nov 2020 16:37:21
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	05 Nov 2020 16:37:21
Data point term sent to Coder	System	05 Nov 2020 16:02:01
User entered 'melatonin'	Karol Moore (b) (4) (b) (4)	05 Nov 2020 16:02:01

US3312605

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 26 Nov 2020 10:55:55

[Prophylaxis](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 16:35:36
User entered 'No (N)'	Karol Moore (b) (4) (b) (4)	05 Nov 2020 16:02:01

**US3312605**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (11)**

**Generated On: 26 Nov 2020 10:55:55**

[Indication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 16:35:36
User entered 'symptomatic covid-19'	Karol Moore (b) (4) (b) (4)	05 Nov 2020 16:02:01

US3312605

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (11)**

**Generated On: 26 Nov 2020 10:55:55**

[Dose per administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 16:35:36
User entered '1'	Karol Moore (b) (4) (b) (4)	05 Nov 2020 16:02:01

US3312605

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 26 Nov 2020 10:55:55

[Dose unit](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 16:35:36
User entered 'mg (mg)'	Karol Moore (b) (4) (b) (4)	05 Nov 2020 16:02:01

US3312605

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 26 Nov 2020 10:55:55

If dose unit is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 16:35:36
User entered empty.	Karol Moore (b) (4) (b) (4)	05 Nov 2020 16:02:01



US3312605

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 26 Nov 2020 10:55:55

[Frequency](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 16:35:36
User entered 'once daily (QD)'	Karol Moore (b) (4) (b) (4)	05 Nov 2020 16:02:01

US3312605

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (11)**

**Generated On: 26 Nov 2020 10:55:55**

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 16:35:36
User entered empty.	Karol Moore (b) (4) (b) (4)	05 Nov 2020 16:02:01

**US3312605**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (11)**

**Generated On: 26 Nov 2020 10:55:55**

[Route of administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 16:35:36
User entered 'Oral (ORAL)'	Karol Moore (b) (4) (b) (4)	05 Nov 2020 16:02:01

US3312605

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (11)**

**Generated On: 26 Nov 2020 10:55:55**

If route of administration is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 16:35:36
User entered empty.	Karol Moore (b) (4) (b) (4)	05 Nov 2020 16:02:01

**US3312605**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (11)**

**Generated On: 26 Nov 2020 10:55:55**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 16:35:36
User entered '22 Oct 2020'	Karol Moore (b) (4) (b) (4)	05 Nov 2020 16:02:01

**US3312605**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (11)**

**Generated On: 26 Nov 2020 10:55:55**

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 16:35:36
User entered '0'	Karol Moore (b) (4) (b) (4)	05 Nov 2020 16:02:01

**US3312605**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (11)**

**Generated On: 26 Nov 2020 10:55:55**

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 16:35:36
User entered 'Yes (Y)'	Karol Moore (b) (4) (b) (4)	05 Nov 2020 16:02:01

**US3312605**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (11)**

**Generated On: 26 Nov 2020 10:55:55**

**If not Ongoing, End date (*dd MMM yyyy*)**

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 16:35:36
User entered empty.	Karol Moore (b) (4) (b) (4)	05 Nov 2020 16:02:01



**US3312605**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (11)**

**Generated On: 26 Nov 2020 10:55:55**

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 16:35:36
User entered 'No (N)'	Karol Moore (b) (4) (b) (4)	05 Nov 2020 16:02:01

**US3312605**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (11)**

**Generated On: 26 Nov 2020 10:55:55**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	05 Nov 2020 16:02:01

**US3312605**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (11)**

**Generated On: 26 Nov 2020 10:55:55**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	05 Nov 2020 16:02:01

**US3312605**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (11)**

**Generated On: 26 Nov 2020 10:55:55**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	05 Nov 2020 16:02:01

US3312605

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 26 Nov 2020 10:55:55

[Name of Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 16:35:36
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: H2-RECEPTOR ANTAGONISTS, PRODUCT: FAMOTIDINE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	05 Nov 2020 16:17:20
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	05 Nov 2020 16:17:20
Data point term sent to Coder	System	05 Nov 2020 16:03:01
User entered 'famotidine'	Karol Moore (b) (4) (b) (4)	05 Nov 2020 16:02:33

US3312605

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 26 Nov 2020 10:55:55

[Prophylaxis](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 16:35:36
User entered 'No (N)'	Karol Moore (b) (4) (b) (4)	05 Nov 2020 16:02:33

US3312605

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 26 Nov 2020 10:55:55

[Indication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 16:35:36
User entered 'symptomatic covid-19'	Karol Moore (b) (4) (b) (4)	05 Nov 2020 16:02:33

US3312605

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 26 Nov 2020 10:55:55

[Dose per administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 16:35:36
User entered '20'	Karol Moore (b) (4) (b) (4)	05 Nov 2020 16:02:33



US3312605

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (12)**

**Generated On: 26 Nov 2020 10:55:55**

[Dose unit](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 16:35:36
User entered 'mg (mg)'	Karol Moore (b) (4) (b) (4)	05 Nov 2020 16:02:33

US3312605

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 26 Nov 2020 10:55:55

If dose unit is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 16:35:36
User entered empty.	Karol Moore (b) (4) (b) (4)	05 Nov 2020 16:02:33

US3312605

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 26 Nov 2020 10:55:55

[Frequency](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 16:35:36
User entered 'once daily (QD)'	Karol Moore (b) (4) (b) (4)	05 Nov 2020 16:02:33

US3312605

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 26 Nov 2020 10:55:55

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 16:35:36
User entered empty.	Karol Moore (b) (4) (b) (4)	05 Nov 2020 16:02:33

**US3312605**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (12)**

**Generated On: 26 Nov 2020 10:55:55**

[Route of administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 16:35:36
User entered 'Oral (ORAL)'	Karol Moore (b) (4) (b) (4)	05 Nov 2020 16:02:33

US3312605

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (12)**

**Generated On: 26 Nov 2020 10:55:55**

If route of administration is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 16:35:36
User entered empty.	Karol Moore (b) (4) (b) (4)	05 Nov 2020 16:02:33

**US3312605**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (12)**

**Generated On: 26 Nov 2020 10:55:55**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 16:35:36
User entered '22 Oct 2020'	Karol Moore (b) (4) (b) (4)	05 Nov 2020 16:02:33

**US3312605**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (12)**

**Generated On: 26 Nov 2020 10:55:55**

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 16:35:36
User entered '0'	Karol Moore (b) (4) (b) (4)	05 Nov 2020 16:02:33



**US3312605**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (12)**

**Generated On: 26 Nov 2020 10:55:55**

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 16:35:36
User entered 'Yes (Y)'	Karol Moore (b) (4) (b) (4)	05 Nov 2020 16:02:33

US3312605

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (12)**

**Generated On: 26 Nov 2020 10:55:55**

*If not Ongoing, End date (dd MMM yyyy)*

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 16:35:36
User entered empty.	Karol Moore (b) (4) (b) (4)	05 Nov 2020 16:02:33

**US3312605**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (12)**

**Generated On: 26 Nov 2020 10:55:55**

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 16:35:36
User entered 'No (N)'	Karol Moore (b) (4) (b) (4)	05 Nov 2020 16:02:33

**US3312605**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (12)**

**Generated On: 26 Nov 2020 10:55:55**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	05 Nov 2020 16:02:33

US3312605

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (12)**

**Generated On: 26 Nov 2020 10:55:55**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	05 Nov 2020 16:02:33

**US3312605**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (12)**

**Generated On: 26 Nov 2020 10:55:55**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	05 Nov 2020 16:02:33

US3312605

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 26 Nov 2020 10:55:55

[Name of Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 16:35:36
User coded data point as ATC: RESPIRATORY SYSTEM, ATC: COUGH AND COLD PREPARATIONS, ATC: COUGH SUPPRESSANTS, EXCL. COMBINATIONS WITH EXPECTORANTS, ATC: OTHER COUGH SUPPRESSANTS, PRODUCT: BENZONATATE, PRODUCTSYNONYM: TESSALON PERLE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	05 Nov 2020 16:30:22
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	05 Nov 2020 16:30:22
Data point term sent to Coder	System	05 Nov 2020 16:04:04
User entered 'tessalon perles benzonatate'	Karol Moore (b) (4) (b) (4)	05 Nov 2020 16:03:20

US3312605

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 26 Nov 2020 10:55:55

[Prophylaxis](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 16:35:36
User entered 'No (N)'	Karol Moore (b) (4) (b) (4)	05 Nov 2020 16:03:20



**US3312605**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (13)**

**Generated On: 26 Nov 2020 10:55:55**

[Indication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 16:35:36
User entered 'symptomatic covid-19'	Karol Moore (b) (4) (b) (4)	05 Nov 2020 16:03:20

US3312605

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (13)**

**Generated On: 26 Nov 2020 10:55:55**

[Dose per administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 16:35:36
User entered '100'	Karol Moore (b) (4) (b) (4)	05 Nov 2020 16:03:20

US3312605

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 26 Nov 2020 10:55:55

[Dose unit](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 16:35:36
User entered 'mg (mg)'	Karol Moore (b) (4) (b) (4)	05 Nov 2020 16:03:20

US3312605

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 26 Nov 2020 10:55:55

If dose unit is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 16:35:36
User entered empty.	Karol Moore (b) (4) (b) (4)	05 Nov 2020 16:03:20

**US3312605**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (13)**

**Generated On: 26 Nov 2020 10:55:55**

[Frequency](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 16:35:36
User entered 'as needed (PRN)'	Karol Moore (b) (4) (b) (4)	05 Nov 2020 16:03:20

US3312605

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 26 Nov 2020 10:55:55

If frequency is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 16:35:36
User entered empty.	Karol Moore (b) (4) (b) (4)	05 Nov 2020 16:03:20

**US3312605**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (13)**

**Generated On: 26 Nov 2020 10:55:55**

[Route of administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 16:35:36
User entered 'Oral (ORAL)'	Karol Moore (b) (4) (b) (4)	05 Nov 2020 16:03:20

**US3312605**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (13)**

**Generated On: 26 Nov 2020 10:55:55**

If route of administration is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 16:35:36
User entered empty.	Karol Moore (b) (4) (b) (4)	05 Nov 2020 16:03:20



**US3312605**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (13)**

**Generated On: 26 Nov 2020 10:55:55**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 16:35:36
User entered '27 Oct 2020'	Karol Moore (b) (4) (b) (4)	05 Nov 2020 16:03:20

**US3312605**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (13)**

**Generated On: 26 Nov 2020 10:55:55**

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 16:35:36
User entered '0'	Karol Moore (b) (4) (b) (4)	05 Nov 2020 16:03:20

**US3312605**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (13)**

**Generated On: 26 Nov 2020 10:55:55**

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 16:35:36
User entered 'No (N)'	Karol Moore (b) (4) (b) (4)	05 Nov 2020 16:03:20

**US3312605**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (13)**

**Generated On: 26 Nov 2020 10:55:55**

**If not Ongoing, End date (*dd MMM yyyy*)**

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 16:35:36
User entered '29 Oct 2020'	Karol Moore (b) (4) (b) (4)	05 Nov 2020 16:03:20

**US3312605**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (13)**

**Generated On: 26 Nov 2020 10:55:55**

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 16:35:36
User entered 'No (N)'	Karol Moore (b) (4) (b) (4)	05 Nov 2020 16:03:20

**US3312605**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (13)**

**Generated On: 26 Nov 2020 10:55:55**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	05 Nov 2020 16:03:20

**US3312605**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (13)**

**Generated On: 26 Nov 2020 10:55:55**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	05 Nov 2020 16:03:20

**US3312605**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (13)**

**Generated On: 26 Nov 2020 10:55:55**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	05 Nov 2020 16:03:20



US3312605

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 26 Nov 2020 10:55:55

[Name of Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 16:35:36
User coded data point as ATC: RESPIRATORY SYSTEM, ATC: DRUGS FOR OBSTRUCTIVE AIRWAY DISEASES, ATC: ADRENERGICS, INHALANTS, ATC: SELECTIVE BETA-2-ADRENORECEPTOR AGONISTS, PRODUCT: SALBUTAMOL, PRODUCTSYNONYM: ALBUTEROL [SALBUTAMOL] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	05 Nov 2020 16:12:22
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	05 Nov 2020 16:12:22
Data point term sent to Coder	System	05 Nov 2020 16:04:04
User entered 'albuterol nebulizer'	Karol Moore (b) (4) (b) (4)	05 Nov 2020 16:03:59

**US3312605**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (14)**

**Generated On: 26 Nov 2020 10:55:55**

[Prophylaxis](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 16:35:36
User entered 'No (N)'	Karol Moore (b) (4) (b) (4)	05 Nov 2020 16:03:59

**US3312605**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (14)**

**Generated On: 26 Nov 2020 10:55:55**

[Indication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 16:35:36
User entered 'symptomatic covid-19'	Karol Moore (b) (4) (b) (4)	05 Nov 2020 16:03:59

US3312605

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 26 Nov 2020 10:55:55

[Dose per administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 16:35:36
User entered '2.5'	Karol Moore (b) (4) (b) (4)	05 Nov 2020 16:03:59

US3312605

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 26 Nov 2020 10:55:55

[Dose unit](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 16:35:36
User entered 'mg (mg)'	Karol Moore (b) (4) (b) (4)	05 Nov 2020 16:03:59

US3312605

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 26 Nov 2020 10:55:55

If dose unit is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 16:35:36
User entered empty.	Karol Moore (b) (4) (b) (4)	05 Nov 2020 16:03:59

**US3312605**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (14)**

**Generated On: 26 Nov 2020 10:55:55**

[Frequency](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 16:35:36
User entered 'four times daily (QID)'	Karol Moore (b) (4) (b) (4)	05 Nov 2020 16:03:59

US3312605

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 26 Nov 2020 10:55:55

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 16:35:36
User entered empty.	Karol Moore (b) (4) (b) (4)	05 Nov 2020 16:03:59



**US3312605**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (14)**

**Generated On: 26 Nov 2020 10:55:55**

[Route of administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 16:35:36
User entered 'Respiratory (Inhalation) (RESPIRATORY (INHALATION))'	Karol Moore (b) (4) (b) (4)	05 Nov 2020 16:03:59

US3312605

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (14)**

**Generated On: 26 Nov 2020 10:55:55**

If route of administration is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 16:35:36
User entered empty.	Karol Moore (b) (4) (b) (4)	05 Nov 2020 16:03:59

**US3312605**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (14)**

**Generated On: 26 Nov 2020 10:55:55**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 16:35:36
User entered '27 Oct 2020'	Karol Moore (b) (4) (b) (4)	05 Nov 2020 16:03:59

**US3312605**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (14)**

**Generated On: 26 Nov 2020 10:55:55**

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 16:35:36
User entered '0'	Karol Moore (b) (4) (b) (4)	05 Nov 2020 16:03:59

**US3312605**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (14)**

**Generated On: 26 Nov 2020 10:55:55**

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 16:35:36
User entered 'No (N)'	Karol Moore (b) (4) (b) (4)	05 Nov 2020 16:03:59

US3312605

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 26 Nov 2020 10:55:55

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 16:35:36
User entered '29 Oct 2020'	Karol Moore (b) (4) (b) (4)	05 Nov 2020 16:03:59

**US3312605**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (14)**

**Generated On: 26 Nov 2020 10:55:55**

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 16:35:36
User entered 'No (N)'	Karol Moore (b) (4) (b) (4)	05 Nov 2020 16:03:59

**US3312605**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (14)**

**Generated On: 26 Nov 2020 10:55:55**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '4'	System	05 Nov 2020 16:03:59



**US3312605**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (14)**

**Generated On: 26 Nov 2020 10:55:55**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	05 Nov 2020 16:03:59

**US3312605**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (14)**

**Generated On: 26 Nov 2020 10:55:55**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	05 Nov 2020 16:03:59

US3312605

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 26 Nov 2020 10:55:55

[Name of Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 16:35:36
User coded data point as ATC: RESPIRATORY SYSTEM, ATC: DRUGS FOR OBSTRUCTIVE AIRWAY DISEASES, ATC: ADRENERGICS, INHALANTS, ATC: SELECTIVE BETA-2-ADRENORECEPTOR AGONISTS, PRODUCT: SALBUTAMOL, PRODUCTSYNONYM: ALBUTEROL [SALBUTAMOL] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	05 Nov 2020 16:12:21
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	05 Nov 2020 16:12:21
Data point term sent to Coder	System	05 Nov 2020 16:05:05
User entered 'albuterol inhaler'	Karol Moore (b) (4) (b) (4)	05 Nov 2020 16:04:27

**US3312605**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (15)**

**Generated On: 26 Nov 2020 10:55:55**

[Prophylaxis](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 16:35:36
User entered 'No (N)'	Karol Moore (b) (4) (b) (4)	05 Nov 2020 16:04:27

**US3312605**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (15)**

**Generated On: 26 Nov 2020 10:55:55**

[Indication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 16:35:36
User entered 'symptomatic covid-19'	Karol Moore (b) (4) (b) (4)	05 Nov 2020 16:04:27

US3312605

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 26 Nov 2020 10:55:55

[Dose per administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 16:35:36
User entered '200'	Karol Moore (b) (4) (b) (4)	05 Nov 2020 16:04:27

**US3312605**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (15)**

**Generated On: 26 Nov 2020 10:55:55**

[Dose unit](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 16:35:36
User entered 'ug (ug)'	Karol Moore (b) (4) (b) (4)	05 Nov 2020 16:04:27

US3312605

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 26 Nov 2020 10:55:55

If dose unit is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 16:35:36
User entered empty.	Karol Moore (b) (4) (b) (4)	05 Nov 2020 16:04:27



**US3312605**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (15)**

**Generated On: 26 Nov 2020 10:55:55**

[Frequency](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 16:35:36
User entered 'as needed (PRN)'	Karol Moore (b) (4) (b) (4)	05 Nov 2020 16:04:27

US3312605

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 26 Nov 2020 10:55:55

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 16:35:36
User entered empty.	Karol Moore (b) (4) (b) (4)	05 Nov 2020 16:04:27

**US3312605**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (15)**

**Generated On: 26 Nov 2020 10:55:55**

[Route of administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 16:35:36
User entered 'Respiratory (Inhalation) (RESPIRATORY (INHALATION))'	Karol Moore (b) (4) (b) (4)	05 Nov 2020 16:04:27

US3312605

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (15)**

**Generated On: 26 Nov 2020 10:55:55**

If route of administration is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 16:35:36
User entered empty.	Karol Moore (b) (4) (b) (4)	05 Nov 2020 16:04:27

**US3312605**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (15)**

**Generated On: 26 Nov 2020 10:55:55**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 16:35:36
User entered '25 Oct 2020'	Karol Moore (b) (4) (b) (4)	05 Nov 2020 16:04:27

**US3312605**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (15)**

**Generated On: 26 Nov 2020 10:55:55**

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 16:35:36
User entered '0'	Karol Moore (b) (4) (b) (4)	05 Nov 2020 16:04:27

**US3312605**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (15)**

**Generated On: 26 Nov 2020 10:55:55**

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 16:35:36
User entered 'Yes (Y)'	Karol Moore (b) (4) (b) (4)	05 Nov 2020 16:04:27

US3312605

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 26 Nov 2020 10:55:55

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 16:35:36
User entered empty.	Karol Moore (b) (4) (b) (4)	05 Nov 2020 16:04:27



**US3312605**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (15)**

**Generated On: 26 Nov 2020 10:55:55**

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 16:35:36
User entered 'No (N)'	Karol Moore (b) (4) (b) (4)	05 Nov 2020 16:04:27

**US3312605**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (15)**

**Generated On: 26 Nov 2020 10:55:55**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	05 Nov 2020 16:04:27

**US3312605**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (15)**

**Generated On: 26 Nov 2020 10:55:55**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	05 Nov 2020 16:04:27

**US3312605**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (15)**

**Generated On: 26 Nov 2020 10:55:55**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	05 Nov 2020 16:04:27

US3312605

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 26 Nov 2020 10:55:55

[Name of Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 16:35:36
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: OTHER ANALGESICS AND ANTIPYRETICS, ATC: ANILIDES, PRODUCT: DEXTROMETHORPHAN HYDROBROMIDE;PARACETAMOL;PHENYLEPHRINE HYDROCHLORIDE, PRODUCTSYNONYM: DAYQUIL COLD & FLU - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	06 Nov 2020 17:39:18
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	06 Nov 2020 17:39:18
Data point term sent to Coder	System	05 Nov 2020 16:06:05
User entered 'dayquil cold & flu (acetaminophen 325mg/phenylephrine hcl 5mg/dextromethorphan hbr 10mg)'	Karol Moore (b) (4) (b) (4)	05 Nov 2020 16:05:35

US3312605

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 26 Nov 2020 10:55:55

[Prophylaxis](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 16:35:36
User entered 'No (N)'	Karol Moore (b) (4) (b) (4)	05 Nov 2020 16:05:35

**US3312605**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (16)**

**Generated On: 26 Nov 2020 10:55:55**

[Indication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 16:35:36
User entered 'symptomatic covid-19'	Karol Moore (b) (4) (b) (4)	05 Nov 2020 16:05:35

US3312605

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 26 Nov 2020 10:55:55

[Dose per administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 16:35:36
User entered '2'	Karol Moore (b) (4) (b) (4)	05 Nov 2020 16:05:35



US3312605

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 26 Nov 2020 10:55:55

[Dose unit](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 16:35:36
User entered 'tablet (TABLET)'	Karol Moore (b) (4) (b) (4)	05 Nov 2020 16:05:35

US3312605

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 26 Nov 2020 10:55:55

If dose unit is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 16:35:36
User entered empty.	Karol Moore (b) (4) (b) (4)	05 Nov 2020 16:05:35

**US3312605**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (16)**

**Generated On: 26 Nov 2020 10:55:55**

[Frequency](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 16:35:36
User entered 'as needed (PRN)'	Karol Moore (b) (4) (b) (4)	05 Nov 2020 16:05:35

US3312605

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 26 Nov 2020 10:55:55

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 16:35:36
User entered empty.	Karol Moore (b) (4) (b) (4)	05 Nov 2020 16:05:35

**US3312605**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (16)**

**Generated On: 26 Nov 2020 10:55:55**

[Route of administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 16:35:36
User entered 'Oral (ORAL)'	Karol Moore (b) (4) (b) (4)	05 Nov 2020 16:05:35

US3312605

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (16)**

**Generated On: 26 Nov 2020 10:55:55**

If route of administration is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 16:35:36
User entered empty.	Karol Moore (b) (4) (b) (4)	05 Nov 2020 16:05:35

US3312605

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 26 Nov 2020 10:55:55

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 16:35:36
User entered '19 Oct 2020'	Karol Moore (b) (4) (b) (4)	05 Nov 2020 16:05:35

**US3312605**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (16)**

**Generated On: 26 Nov 2020 10:55:55**

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 16:35:36
User entered '0'	Karol Moore (b) (4) (b) (4)	05 Nov 2020 16:05:35



US3312605

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 26 Nov 2020 10:55:55

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 16:35:36
User entered 'No (N)'	Karol Moore (b) (4) (b) (4)	05 Nov 2020 16:05:35

US3312605

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 26 Nov 2020 10:55:55

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 16:35:36
User entered '30 Oct 2020'	Karol Moore (b) (4) (b) (4)	05 Nov 2020 16:05:35

US3312605

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 26 Nov 2020 10:55:55

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 16:35:36
User closed query 'Data is required. Please complete.' (Site from System).	System	05 Nov 2020 16:06:46
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	05 Nov 2020 16:06:46
User entered 'No (N)' reason for change: Data Entry Error	Karol Moore (b) (4)	05 Nov 2020 16:06:46
User opened query 'Data is required. Please complete.' (Site from System).	System	05 Nov 2020 16:05:35
User entered empty.	Karol Moore (b) (4)	05 Nov 2020 16:05:35

**US3312605**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (16)**

**Generated On: 26 Nov 2020 10:55:55**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	05 Nov 2020 16:05:35

**US3312605**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (16)**

**Generated On: 26 Nov 2020 10:55:55**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	05 Nov 2020 16:05:35

**US3312605**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (16)**

**Generated On: 26 Nov 2020 10:55:55**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	05 Nov 2020 16:05:35

US3312605

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 26 Nov 2020 10:55:55

[Name of Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 16:35:36
User coded data point as ATC: RESPIRATORY SYSTEM, ATC: COUGH AND COLD PREPARATIONS, ATC: OTHER COLD PREPARATIONS, PRODUCT: DEXTROMETHORPHAN HYDROBROMIDE;DOXYLAMINE SUCCINATE;PARACETAMOL, PRODUCTSYNONYM: NYQUIL COLD & FLU - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	06 Nov 2020 20:13:24
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	06 Nov 2020 20:13:24
Data point term sent to Coder	System	05 Nov 2020 16:07:06
User entered 'nyquil cold & flu (acetaminophen 325mg/dextromethorphan 15 mg/ doxylamine succinate 6.25mg)'	Karol Moore (b) (4) (b) (4)	05 Nov 2020 16:06:40

**US3312605**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (17)**

**Generated On: 26 Nov 2020 10:55:55**

[Prophylaxis](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 16:35:36
User entered 'No (N)'	Karol Moore (b) (4) (b) (4)	05 Nov 2020 16:06:40



**US3312605**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (17)**

**Generated On: 26 Nov 2020 10:55:55**

[Indication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 16:35:36
User entered 'symptomatic covid-19'	Karol Moore (b) (4) (b) (4)	05 Nov 2020 16:06:40

US3312605

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 26 Nov 2020 10:55:55

[Dose per administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 16:35:36
User entered '2'	Karol Moore (b) (4) (b) (4)	05 Nov 2020 16:06:40

**US3312605**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (17)**

**Generated On: 26 Nov 2020 10:55:55**

[Dose unit](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 16:35:36
User entered 'tablet (TABLET)'	Karol Moore (b) (4) (b) (4)	05 Nov 2020 16:06:40

**US3312605**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (17)**

**Generated On: 26 Nov 2020 10:55:55**

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 16:35:36
User entered empty.	Karol Moore (b) (4) (b) (4)	05 Nov 2020 16:06:40

**US3312605**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (17)**

**Generated On: 26 Nov 2020 10:55:55**

[Frequency](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 16:35:36
User entered 'as needed (PRN)'	Karol Moore (b) (4) (b) (4)	05 Nov 2020 16:06:40

US3312605

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 26 Nov 2020 10:55:55

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 16:35:36
User entered empty.	Karol Moore (b) (4) (b) (4)	05 Nov 2020 16:06:40

**US3312605**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (17)**

**Generated On: 26 Nov 2020 10:55:55**

[Route of administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 16:35:36
User entered 'Oral (ORAL)'	Karol Moore (b) (4) (b) (4)	05 Nov 2020 16:06:40

US3312605

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (17)**

**Generated On: 26 Nov 2020 10:55:55**

If route of administration is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 16:35:36
User entered empty.	Karol Moore (b) (4) (b) (4)	05 Nov 2020 16:06:40



**US3312605**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (17)**

**Generated On: 26 Nov 2020 10:55:55**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 16:35:36
User entered '19 Oct 2020'	Karol Moore (b) (4) (b) (4)	05 Nov 2020 16:06:40

US3312605

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 26 Nov 2020 10:55:55

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 16:35:36
User entered '0'	Karol Moore (b) (4) (b) (4)	05 Nov 2020 16:06:40

**US3312605**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (17)**

**Generated On: 26 Nov 2020 10:55:55**

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 16:35:36
User entered 'No (N)'	Karol Moore (b) (4) (b) (4)	05 Nov 2020 16:06:40

US3312605

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 26 Nov 2020 10:55:55

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 16:35:36
User entered '30 Oct 2020'	Karol Moore (b) (4) (b) (4)	05 Nov 2020 16:06:40

**US3312605**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (17)**

**Generated On: 26 Nov 2020 10:55:55**

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 16:35:36
User entered 'No (N)'	Karol Moore (b) (4) (b) (4)	05 Nov 2020 16:06:40

**US3312605**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (17)**

**Generated On: 26 Nov 2020 10:55:55**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	05 Nov 2020 16:06:40

**US3312605**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (17)**

**Generated On: 26 Nov 2020 10:55:55**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	05 Nov 2020 16:06:40

**US3312605**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (17)**

**Generated On: 26 Nov 2020 10:55:55**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	05 Nov 2020 16:06:40



US3312605

Folder: COVID-19 Impact (1)

Form: COVID-19 Impact (1)

Generated On: 26 Nov 2020 10:55:55

[Visit](#)

Audit	User	Time (GMT)
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4), (b) (6)	23 Nov 2020 08:28:12
Query 'Data is required. Please complete.' answered with 'na. day 43 safety call was missed' (Site from System).	Karol Moore (b) (4)	10 Nov 2020 14:01:03
User opened query 'Data is required. Please complete.' (Site from System).	(b) (4)	10 Nov 2020 14:00:26
User entered empty.	System	10 Nov 2020 14:00:26
	Karol Moore (b) (4)	10 Nov 2020 14:00:26
	(b) (4)	

**US3312605**

**Folder: COVID-19 Impact (1)**

**Form: COVID-19 Impact (1)**

**Generated On: 26 Nov 2020 10:55:55**

[Visit Date](#)

Audit	User	Time (GMT)
User entered '0'	Karol Moore (b) (4) (b) (4)	10 Nov 2020 14:00:26

US3312605

Folder: COVID-19 Impact (1)

Form: COVID-19 Impact (1)

Generated On: 26 Nov 2020 10:55:55

[Demographics](#)

Audit	User	Time (GMT)
User entered '0'	Karol Moore (b) (4) (b) (4)	10 Nov 2020 14:00:26

US3312605

Folder: COVID-19 Impact (1)

Form: COVID-19 Impact (1)

Generated On: 26 Nov 2020 10:55:55

[Enrollment](#)

Audit	User	Time (GMT)
User entered '0'	Karol Moore (b) (4) (b) (4)	10 Nov 2020 14:00:26

US3312605

Folder: COVID-19 Impact (1)

Form: COVID-19 Impact (1)

Generated On: 26 Nov 2020 10:55:55

[Inclusion/Exclusion Criteria Summary](#)

Audit	User	Time (GMT)
User entered '0'	Karol Moore (b) (4) (b) (4)	10 Nov 2020 14:00:26

US3312605

Folder: COVID-19 Impact (1)

Form: COVID-19 Impact (1)

Generated On: 26 Nov 2020 10:55:55

[Inclusion/Exclusion Criteria](#)

Audit	User	Time (GMT)
User entered '0'	Karol Moore (b) (4) (b) (4)	10 Nov 2020 14:00:26

US3312605

Folder: COVID-19 Impact (1)

Form: COVID-19 Impact (1)

Generated On: 26 Nov 2020 10:55:55

[Medical History Summary](#)

Audit	User	Time (GMT)
User entered '0'	Karol Moore (b) (4) (b) (4)	10 Nov 2020 14:00:26

US3312605

Folder: COVID-19 Impact (1)

Form: COVID-19 Impact (1)

Generated On: 26 Nov 2020 10:55:55

[Medical History](#)

Audit	User	Time (GMT)
User entered '0'	Karol Moore (b) (4) (b) (4)	10 Nov 2020 14:00:26



**US3312605**

**Folder: COVID-19 Impact (1)**

**Form: COVID-19 Impact (1)**

**Generated On: 26 Nov 2020 10:55:55**

[Vital Signs](#)

Audit	User	Time (GMT)
User entered '0'	Karol Moore (b) (4) (b) (4)	10 Nov 2020 14:00:26

US3312605

Folder: COVID-19 Impact (1)

Form: COVID-19 Impact (1)

Generated On: 26 Nov 2020 10:55:55

[Vital Signs - Dosing](#)

Audit	User	Time (GMT)
User entered '0'	Karol Moore (b) (4) (b) (4)	10 Nov 2020 14:00:26

US3312605

Folder: COVID-19 Impact (1)

Form: COVID-19 Impact (1)

Generated On: 26 Nov 2020 10:55:55

[Physical Examination](#)

Audit	User	Time (GMT)
User entered '0'	Karol Moore (b) (4) (b) (4)	10 Nov 2020 14:00:26

US3312605

Folder: COVID-19 Impact (1)

Form: COVID-19 Impact (1)

Generated On: 26 Nov 2020 10:55:55

[Central Laboratory - Nasopharyngeal Swab](#)

Audit	User	Time (GMT)
User entered '0'	Karol Moore (b) (4) (b) (4)	10 Nov 2020 14:00:26

US3312605

Folder: COVID-19 Impact (1)

Form: COVID-19 Impact (1)

Generated On: 26 Nov 2020 10:55:55

[Childbearing Potential](#)

Audit	User	Time (GMT)
User entered '0'	Karol Moore (b) (4) (b) (4)	10 Nov 2020 14:00:26

US3312605

Folder: COVID-19 Impact (1)

Form: COVID-19 Impact (1)

Generated On: 26 Nov 2020 10:55:55

[Pregnancy Test](#)

Audit	User	Time (GMT)
User entered '0'	Karol Moore (b) (4) (b) (4)	10 Nov 2020 14:00:26

US3312605

Folder: COVID-19 Impact (1)

Form: COVID-19 Impact (1)

Generated On: 26 Nov 2020 10:55:55

[Randomization](#)

Audit	User	Time (GMT)
User entered '0'	Karol Moore (b) (4) (b) (4)	10 Nov 2020 14:00:26

US3312605

Folder: COVID-19 Impact (1)

Form: COVID-19 Impact (1)

Generated On: 26 Nov 2020 10:55:55

[Exposure](#)

Audit	User	Time (GMT)
User entered '0'	Karol Moore (b) (4) (b) (4)	10 Nov 2020 14:00:26



US3312605

Folder: COVID-19 Impact (1)

Form: COVID-19 Impact (1)

Generated On: 26 Nov 2020 10:55:55

[Immunogenicity Assessment](#)

Audit	User	Time (GMT)
User entered '0'	Karol Moore (b) (4) (b) (4)	10 Nov 2020 14:00:26

US3312605

Folder: COVID-19 Impact (1)

Form: COVID-19 Impact (1)

Generated On: 26 Nov 2020 10:55:55

[Saliva Collection](#)

Audit	User	Time (GMT)
User entered '0'	Karol Moore (b) (4) (b) (4)	10 Nov 2020 14:00:26

US3312605

Folder: COVID-19 Impact (1)

Form: COVID-19 Impact (1)

Generated On: 26 Nov 2020 10:55:55

[COVID Diagnostic Test](#)

Audit	User	Time (GMT)
User entered '0'	Karol Moore (b) (4) (b) (4)	10 Nov 2020 14:00:26

US3312605

Folder: COVID-19 Impact (1)

Form: COVID-19 Impact (1)

Generated On: 26 Nov 2020 10:55:55

[Symptom Log](#)

Audit	User	Time (GMT)
User entered '0'	Karol Moore (b) (4) (b) (4)	10 Nov 2020 14:00:26

US3312605

Folder: COVID-19 Impact (1)

Form: COVID-19 Impact (1)

Generated On: 26 Nov 2020 10:55:55

[Blood Sample Collection for Immunologic Assessment of SARS-CoV-2 Infection](#)

Audit	User	Time (GMT)
User entered '0'	Karol Moore (b) (4) (b) (4)	10 Nov 2020 14:00:26

US3312605

Folder: COVID-19 Impact (1)

Form: COVID-19 Impact (1)

Generated On: 26 Nov 2020 10:55:55

[COVID-19 Severity Assessment](#)

Audit	User	Time (GMT)
User entered '0'	Karol Moore (b) (4) (b) (4)	10 Nov 2020 14:00:26

US3312605

Folder: COVID-19 Impact (1)

Form: COVID-19 Impact (1)

Generated On: 26 Nov 2020 10:55:55

[COVID-19 Contact](#)

Audit	User	Time (GMT)
User entered '0'	Karol Moore (b) (4) (b) (4)	10 Nov 2020 14:00:26

US3312605

Folder: COVID-19 Impact (1)

Form: COVID-19 Impact (1)

Generated On: 26 Nov 2020 10:55:55

[Risk of Exposure](#)

Audit	User	Time (GMT)
User entered '0'	Karol Moore (b) (4) (b) (4)	10 Nov 2020 14:00:26



**US3312605**

**Folder: COVID-19 Impact (1)**

**Form: COVID-19 Impact (1)**

**Generated On: 26 Nov 2020 10:55:55**

[Safety Call](#)

Audit	User	Time (GMT)
User entered 'I'	Karol Moore (b) (4) (b) (4)	10 Nov 2020 14:00:26

US3312605

Folder: COVID-19 Impact (1)

Form: COVID-19 Impact (1)

Generated On: 26 Nov 2020 10:55:55

[Dosing Discontinuation](#)

Audit	User	Time (GMT)
User entered '0'	Karol Moore (b) (4) (b) (4)	10 Nov 2020 14:00:26

US3312605

Folder: COVID-19 Impact (1)

Form: COVID-19 Impact (1)

Generated On: 26 Nov 2020 10:55:55

[End of Study / Study Discontinuation](#)

Audit	User	Time (GMT)
User entered '0'	Karol Moore (b) (4) (b) (4)	10 Nov 2020 14:00:26

**US3312605**

**Folder: COVID-19 Impact (1)**

**Form: COVID-19 Impact (1)**

**Generated On: 26 Nov 2020 10:55:55**

[All](#)

Audit	User	Time (GMT)
User entered '0'	Karol Moore (b) (4) (b) (4)	10 Nov 2020 14:00:26

US3312605

Folder: COVID-19 Impact (1)

Form: COVID-19 Impact (1)

Generated On: 26 Nov 2020 10:55:55

[Date of missed or out of window visit or assessment](#)

Audit	User	Time (GMT)
User entered '22 Oct 2020'	Karol Moore (b) (4) (b) (4)	10 Nov 2020 14:00:26

US3312605

Folder: COVID-19 Impact (1)

Form: COVID-19 Impact (1)

Generated On: 26 Nov 2020 10:55:55

[Inclusion criteria not met/Exclusion criteria met](#)

Audit	User	Time (GMT)
User entered '0'	Karol Moore (b) (4) (b) (4)	10 Nov 2020 14:00:26

US3312605

Folder: COVID-19 Impact (1)

Form: COVID-19 Impact (1)

Generated On: 26 Nov 2020 10:55:55

Study Treatment not given

Audit	User	Time (GMT)
User entered '0'	Karol Moore (b) (4) (b) (4)	10 Nov 2020 14:00:26

US3312605

Folder: COVID-19 Impact (1)

Form: COVID-19 Impact (1)

Generated On: 26 Nov 2020 10:55:55

[Missed Visit](#)

Audit	User	Time (GMT)
User entered '0'	Karol Moore (b) (4) (b) (4)	10 Nov 2020 14:00:26



US3312605

Folder: COVID-19 Impact (1)

Form: COVID-19 Impact (1)

Generated On: 26 Nov 2020 10:55:55

[Missed Assessment](#)

Audit	User	Time (GMT)
User entered 'I'	Karol Moore (b) (4) (b) (4)	10 Nov 2020 14:00:26

US3312605

Folder: COVID-19 Impact (1)

Form: COVID-19 Impact (1)

Generated On: 26 Nov 2020 10:55:55

[Visit performed out of window](#)

Audit	User	Time (GMT)
User entered '0'	Karol Moore (b) (4) (b) (4)	10 Nov 2020 14:00:26

US3312605

Folder: COVID-19 Impact (1)

Form: COVID-19 Impact (1)

Generated On: 26 Nov 2020 10:55:55

[Assessment performed out of window](#)

Audit	User	Time (GMT)
User entered '0'	Karol Moore (b) (4) (b) (4)	10 Nov 2020 14:00:26

US3312605

Folder: COVID-19 Impact (1)

Form: COVID-19 Impact (1)

Generated On: 26 Nov 2020 10:55:55

[Scheduled clinical visit performed as home visit](#)

Audit	User	Time (GMT)
User entered '0'	Karol Moore (b) (4) (b) (4)	10 Nov 2020 14:00:26

**US3312605**

**Folder: COVID-19 Impact (1)**

**Form: COVID-19 Impact (1)**

**Generated On: 26 Nov 2020 10:55:55**

[Other](#)

Audit	User	Time (GMT)
User entered '0'	Karol Moore (b) (4) (b) (4)	10 Nov 2020 14:00:26

US3312605

Folder: COVID-19 Impact (1)

Form: COVID-19 Impact (1)

Generated On: 26 Nov 2020 10:55:55

[Other, specify](#)

Audit	User	Time (GMT)
User entered empty.	Karol Moore (b) (4) (b) (4)	10 Nov 2020 14:00:26

**US3312605**

**Folder: COVID-19 Impact (1)**

**Form: COVID-19 Impact (1)**

**Generated On: 26 Nov 2020 10:55:55**

[Clinical site closed](#)

Audit	User	Time (GMT)
User entered '0'	Karol Moore (b) (4) (b) (4)	10 Nov 2020 14:00:26

US3312605

Folder: COVID-19 Impact (1)

Form: COVID-19 Impact (1)

Generated On: 26 Nov 2020 10:55:55

[Travel restrictions](#)

Audit	User	Time (GMT)
User entered '0'	Karol Moore (b) (4) (b) (4)	10 Nov 2020 14:00:26



US3312605

Folder: COVID-19 Impact (1)

Form: COVID-19 Impact (1)

Generated On: 26 Nov 2020 10:55:55

[Quarantine due to COVID-19](#)

Audit	User	Time (GMT)
User entered '0'	Karol Moore (b) (4) (b) (4)	10 Nov 2020 14:00:26

US3312605

Folder: COVID-19 Impact (1)

Form: COVID-19 Impact (1)

Generated On: 26 Nov 2020 10:55:55

[Possible exposure to COVID-19](#)

Audit	User	Time (GMT)
User entered '0'	Karol Moore (b) (4) (b) (4)	10 Nov 2020 14:00:26

US3312605

Folder: COVID-19 Impact (1)

Form: COVID-19 Impact (1)

Generated On: 26 Nov 2020 10:55:55

[Exposure to COVID-19](#)

Audit	User	Time (GMT)
User entered '0'	Karol Moore (b) (4) (b) (4)	10 Nov 2020 14:00:26

US3312605

Folder: COVID-19 Impact (1)

Form: COVID-19 Impact (1)

Generated On: 26 Nov 2020 10:55:55

[Presumption / confirmed COVID-19](#)

Audit	User	Time (GMT)
User entered 'I'	Karol Moore (b) (4) (b) (4)	10 Nov 2020 14:00:26

US3312605

Folder: COVID-19 Impact (1)

Form: COVID-19 Impact (1)

Generated On: 26 Nov 2020 10:55:55

[Symptoms of COVID-19](#)

Audit	User	Time (GMT)
User entered '0'	Karol Moore (b) (4) (b) (4)	10 Nov 2020 14:00:26

US3312605

Folder: COVID-19 Impact (1)

Form: COVID-19 Impact (1)

Generated On: 26 Nov 2020 10:55:55

[Sponsor hold due to COVID-19](#)

Audit	User	Time (GMT)
User entered '0'	Karol Moore (b) (4) (b) (4)	10 Nov 2020 14:00:26

US3312605

Folder: COVID-19 Impact (1)

Form: COVID-19 Impact (1)

Generated On: 26 Nov 2020 10:55:55

[Participant decision](#)

Audit	User	Time (GMT)
User entered '0'	Karol Moore (b) (4) (b) (4)	10 Nov 2020 14:00:26

US3312605

Folder: COVID-19 Impact (1)

Form: COVID-19 Impact (2)

Generated On: 26 Nov 2020 10:55:55

[Visit](#)

Audit	User	Time (GMT)
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4), (b) (6)	23 Nov 2020 08:50:42
Query 'Data is required. Please complete.' answered with 'NA. MISSED DAY 50 SAFETY CALL' (Site from System).	Karol Moore (b) (4)	10 Nov 2020 14:01:55
User opened query 'Data is required. Please complete.' (Site from System).	(b) (4)	10 Nov 2020 14:01:35
User entered empty.	System	10 Nov 2020 14:01:35
	Karol Moore (b) (4)	10 Nov 2020 14:01:35
	(b) (4)	



**US3312605**

**Folder: COVID-19 Impact (1)**

**Form: COVID-19 Impact (2)**

**Generated On: 26 Nov 2020 10:55:55**

[Visit Date](#)

Audit	User	Time (GMT)
User entered '0'	Karol Moore (b) (4) (b) (4)	10 Nov 2020 14:01:35

US3312605

Folder: COVID-19 Impact (1)

Form: COVID-19 Impact (2)

Generated On: 26 Nov 2020 10:55:55

[Demographics](#)

Audit	User	Time (GMT)
User entered '0'	Karol Moore (b) (4) (b) (4)	10 Nov 2020 14:01:35

US3312605

Folder: COVID-19 Impact (1)

Form: COVID-19 Impact (2)

Generated On: 26 Nov 2020 10:55:55

[Enrollment](#)

Audit	User	Time (GMT)
User entered '0'	Karol Moore (b) (4) (b) (4)	10 Nov 2020 14:01:35

US3312605

Folder: COVID-19 Impact (1)

Form: COVID-19 Impact (2)

Generated On: 26 Nov 2020 10:55:55

[Inclusion/Exclusion Criteria Summary](#)

Audit	User	Time (GMT)
User entered '0'	Karol Moore (b) (4) (b) (4)	10 Nov 2020 14:01:35

US3312605

Folder: COVID-19 Impact (1)

Form: COVID-19 Impact (2)

Generated On: 26 Nov 2020 10:55:55

[Inclusion/Exclusion Criteria](#)

Audit	User	Time (GMT)
User entered '0'	Karol Moore (b) (4) (b) (4)	10 Nov 2020 14:01:35

US3312605

Folder: COVID-19 Impact (1)

Form: COVID-19 Impact (2)

Generated On: 26 Nov 2020 10:55:55

[Medical History Summary](#)

Audit	User	Time (GMT)
User entered '0'	Karol Moore (b) (4) (b) (4)	10 Nov 2020 14:01:35

US3312605

Folder: COVID-19 Impact (1)

Form: COVID-19 Impact (2)

Generated On: 26 Nov 2020 10:55:55

[Medical History](#)

Audit	User	Time (GMT)
User entered '0'	Karol Moore (b) (4) (b) (4)	10 Nov 2020 14:01:35

**US3312605**

**Folder: COVID-19 Impact (1)**

**Form: COVID-19 Impact (2)**

**Generated On: 26 Nov 2020 10:55:55**

[Vital Signs](#)

Audit	User	Time (GMT)
User entered '0'	Karol Moore (b) (4) (b) (4)	10 Nov 2020 14:01:35



US3312605

Folder: COVID-19 Impact (1)

Form: COVID-19 Impact (2)

Generated On: 26 Nov 2020 10:55:55

[Vital Signs - Dosing](#)

Audit	User	Time (GMT)
User entered '0'	Karol Moore (b) (4) (b) (4)	10 Nov 2020 14:01:35

US3312605

Folder: COVID-19 Impact (1)

Form: COVID-19 Impact (2)

Generated On: 26 Nov 2020 10:55:55

[Physical Examination](#)

Audit	User	Time (GMT)
User entered '0'	Karol Moore (b) (4) (b) (4)	10 Nov 2020 14:01:35

US3312605

Folder: COVID-19 Impact (1)

Form: COVID-19 Impact (2)

Generated On: 26 Nov 2020 10:55:55

[Central Laboratory - Nasopharyngeal Swab](#)

Audit	User	Time (GMT)
User entered '0'	Karol Moore (b) (4) (b) (4)	10 Nov 2020 14:01:35

US3312605

Folder: COVID-19 Impact (1)

Form: COVID-19 Impact (2)

Generated On: 26 Nov 2020 10:55:55

[Childbearing Potential](#)

Audit	User	Time (GMT)
User entered '0'	Karol Moore (b) (4) (b) (4)	10 Nov 2020 14:01:35

US3312605

Folder: COVID-19 Impact (1)

Form: COVID-19 Impact (2)

Generated On: 26 Nov 2020 10:55:55

[Pregnancy Test](#)

Audit	User	Time (GMT)
User entered '0'	Karol Moore (b) (4) (b) (4)	10 Nov 2020 14:01:35

US3312605

Folder: COVID-19 Impact (1)

Form: COVID-19 Impact (2)

Generated On: 26 Nov 2020 10:55:55

[Randomization](#)

Audit	User	Time (GMT)
User entered '0'	Karol Moore (b) (4) (b) (4)	10 Nov 2020 14:01:35

US3312605

Folder: COVID-19 Impact (1)

Form: COVID-19 Impact (2)

Generated On: 26 Nov 2020 10:55:55

[Exposure](#)

Audit	User	Time (GMT)
User entered '0'	Karol Moore (b) (4) (b) (4)	10 Nov 2020 14:01:35

US3312605

Folder: COVID-19 Impact (1)

Form: COVID-19 Impact (2)

Generated On: 26 Nov 2020 10:55:55

[Immunogenicity Assessment](#)

Audit	User	Time (GMT)
User entered '0'	Karol Moore (b) (4) (b) (4)	10 Nov 2020 14:01:35



US3312605

Folder: COVID-19 Impact (1)

Form: COVID-19 Impact (2)

Generated On: 26 Nov 2020 10:55:55

[Saliva Collection](#)

Audit	User	Time (GMT)
User entered '0'	Karol Moore (b) (4) (b) (4)	10 Nov 2020 14:01:35

US3312605

Folder: COVID-19 Impact (1)

Form: COVID-19 Impact (2)

Generated On: 26 Nov 2020 10:55:55

[COVID Diagnostic Test](#)

Audit	User	Time (GMT)
User entered '0'	Karol Moore (b) (4) (b) (4)	10 Nov 2020 14:01:35

US3312605

Folder: COVID-19 Impact (1)

Form: COVID-19 Impact (2)

Generated On: 26 Nov 2020 10:55:55

[Symptom Log](#)

Audit	User	Time (GMT)
User entered '0'	Karol Moore (b) (4) (b) (4)	10 Nov 2020 14:01:35

US3312605

Folder: COVID-19 Impact (1)

Form: COVID-19 Impact (2)

Generated On: 26 Nov 2020 10:55:55

[Blood Sample Collection for Immunologic Assessment of SARS-CoV-2 Infection](#)

Audit	User	Time (GMT)
User entered '0'	Karol Moore (b) (4) (b) (4)	10 Nov 2020 14:01:35

US3312605

Folder: COVID-19 Impact (1)

Form: COVID-19 Impact (2)

Generated On: 26 Nov 2020 10:55:55

[COVID-19 Severity Assessment](#)

Audit	User	Time (GMT)
User entered '0'	Karol Moore (b) (4) (b) (4)	10 Nov 2020 14:01:35

US3312605

Folder: COVID-19 Impact (1)

Form: COVID-19 Impact (2)

Generated On: 26 Nov 2020 10:55:55

[COVID-19 Contact](#)

Audit	User	Time (GMT)
User entered '0'	Karol Moore (b) (4) (b) (4)	10 Nov 2020 14:01:35

US3312605

Folder: COVID-19 Impact (1)

Form: COVID-19 Impact (2)

Generated On: 26 Nov 2020 10:55:55

[Risk of Exposure](#)

Audit	User	Time (GMT)
User entered '0'	Karol Moore (b) (4) (b) (4)	10 Nov 2020 14:01:35

**US3312605**

**Folder: COVID-19 Impact (1)**

**Form: COVID-19 Impact (2)**

**Generated On: 26 Nov 2020 10:55:55**

[Safety Call](#)

Audit	User	Time (GMT)
User entered 'I'	Karol Moore (b) (4) (b) (4)	10 Nov 2020 14:01:35



US3312605

Folder: COVID-19 Impact (1)

Form: COVID-19 Impact (2)

Generated On: 26 Nov 2020 10:55:55

[Dosing Discontinuation](#)

Audit	User	Time (GMT)
User entered '0'	Karol Moore (b) (4) (b) (4)	10 Nov 2020 14:01:35

US3312605

Folder: COVID-19 Impact (1)

Form: COVID-19 Impact (2)

Generated On: 26 Nov 2020 10:55:55

[End of Study / Study Discontinuation](#)

Audit	User	Time (GMT)
User entered '0'	Karol Moore (b) (4) (b) (4)	10 Nov 2020 14:01:35

US3312605

Folder: COVID-19 Impact (1)

Form: COVID-19 Impact (2)

Generated On: 26 Nov 2020 10:55:55

[All](#)

Audit	User	Time (GMT)
User entered '0'	Karol Moore (b) (4) (b) (4)	10 Nov 2020 14:01:35

US3312605

Folder: COVID-19 Impact (1)

Form: COVID-19 Impact (2)

Generated On: 26 Nov 2020 10:55:55

[Date of missed or out of window visit or assessment](#)

Audit	User	Time (GMT)
User entered '29 Oct 2020'	Karol Moore (b) (4) (b) (4)	10 Nov 2020 14:01:35

US3312605

Folder: COVID-19 Impact (1)

Form: COVID-19 Impact (2)

Generated On: 26 Nov 2020 10:55:55

[Inclusion criteria not met/Exclusion criteria met](#)

Audit	User	Time (GMT)
User entered '0'	Karol Moore (b) (4) (b) (4)	10 Nov 2020 14:01:35

US3312605

Folder: COVID-19 Impact (1)

Form: COVID-19 Impact (2)

Generated On: 26 Nov 2020 10:55:55

Study Treatment not given

Audit	User	Time (GMT)
User entered '0'	Karol Moore (b) (4) (b) (4)	10 Nov 2020 14:01:35

US3312605

Folder: COVID-19 Impact (1)

Form: COVID-19 Impact (2)

Generated On: 26 Nov 2020 10:55:55

[Missed Visit](#)

Audit	User	Time (GMT)
User entered '0'	Karol Moore (b) (4) (b) (4)	10 Nov 2020 14:01:35

US3312605

Folder: COVID-19 Impact (1)

Form: COVID-19 Impact (2)

Generated On: 26 Nov 2020 10:55:55

[Missed Assessment](#)

Audit	User	Time (GMT)
User entered 'I'	Karol Moore (b) (4) (b) (4)	10 Nov 2020 14:01:35



US3312605

Folder: COVID-19 Impact (1)

Form: COVID-19 Impact (2)

Generated On: 26 Nov 2020 10:55:55

[Visit performed out of window](#)

Audit	User	Time (GMT)
User entered '0'	Karol Moore (b) (4) (b) (4)	10 Nov 2020 14:01:35

US3312605

Folder: COVID-19 Impact (1)

Form: COVID-19 Impact (2)

Generated On: 26 Nov 2020 10:55:55

[Assessment performed out of window](#)

Audit	User	Time (GMT)
User entered '0'	Karol Moore (b) (4) (b) (4)	10 Nov 2020 14:01:35

**US3312605**

**Folder: COVID-19 Impact (1)**

**Form: COVID-19 Impact (2)**

**Generated On: 26 Nov 2020 10:55:55**

[Scheduled clinical visit performed as home visit](#)

Audit	User	Time (GMT)
User entered '0'	Karol Moore (b) (4) (b) (4)	10 Nov 2020 14:01:35

**US3312605**

**Folder: COVID-19 Impact (1)**

**Form: COVID-19 Impact (2)**

**Generated On: 26 Nov 2020 10:55:55**

[Other](#)

Audit	User	Time (GMT)
User entered '0'	Karol Moore (b) (4) (b) (4)	10 Nov 2020 14:01:35

US3312605

Folder: COVID-19 Impact (1)

Form: COVID-19 Impact (2)

Generated On: 26 Nov 2020 10:55:55

[Other, specify](#)

Audit	User	Time (GMT)
User entered empty.	Karol Moore (b) (4) (b) (4)	10 Nov 2020 14:01:35

**US3312605**

**Folder: COVID-19 Impact (1)**

**Form: COVID-19 Impact (2)**

**Generated On: 26 Nov 2020 10:55:55**

[Clinical site closed](#)

Audit	User	Time (GMT)
User entered '0'	Karol Moore (b) (4) (b) (4)	10 Nov 2020 14:01:35

US3312605

Folder: COVID-19 Impact (1)

Form: COVID-19 Impact (2)

Generated On: 26 Nov 2020 10:55:55

[Travel restrictions](#)

Audit	User	Time (GMT)
User entered '0'	Karol Moore (b) (4) (b) (4)	10 Nov 2020 14:01:35

US3312605

Folder: COVID-19 Impact (1)

Form: COVID-19 Impact (2)

Generated On: 26 Nov 2020 10:55:55

[Quarantine due to COVID-19](#)

Audit	User	Time (GMT)
User entered '0'	Karol Moore (b) (4) (b) (4)	10 Nov 2020 14:01:35



US3312605

Folder: COVID-19 Impact (1)

Form: COVID-19 Impact (2)

Generated On: 26 Nov 2020 10:55:55

[Possible exposure to COVID-19](#)

Audit	User	Time (GMT)
User entered '0'	Karol Moore (b) (4) (b) (4)	10 Nov 2020 14:01:35

US3312605

Folder: COVID-19 Impact (1)

Form: COVID-19 Impact (2)

Generated On: 26 Nov 2020 10:55:55

[Exposure to COVID-19](#)

Audit	User	Time (GMT)
User entered '0'	Karol Moore (b) (4) (b) (4)	10 Nov 2020 14:01:35

US3312605

Folder: COVID-19 Impact (1)

Form: COVID-19 Impact (2)

Generated On: 26 Nov 2020 10:55:55

[Presumption / confirmed COVID-19](#)

Audit	User	Time (GMT)
User entered 'I'	Karol Moore (b) (4) (b) (4)	10 Nov 2020 14:01:35

US3312605

Folder: COVID-19 Impact (1)

Form: COVID-19 Impact (2)

Generated On: 26 Nov 2020 10:55:55

[Symptoms of COVID-19](#)

Audit	User	Time (GMT)
User entered '0'	Karol Moore (b) (4) (b) (4)	10 Nov 2020 14:01:35

US3312605

Folder: COVID-19 Impact (1)

Form: COVID-19 Impact (2)

Generated On: 26 Nov 2020 10:55:55

[Sponsor hold due to COVID-19](#)

Audit	User	Time (GMT)
User entered '0'	Karol Moore (b) (4) (b) (4)	10 Nov 2020 14:01:35

US3312605

Folder: COVID-19 Impact (1)

Form: COVID-19 Impact (2)

Generated On: 26 Nov 2020 10:55:55

[Participant decision](#)

Audit	User	Time (GMT)
User entered '0'	Karol Moore (b) (4) (b) (4)	10 Nov 2020 14:01:35

**US3312605**

**Folder: SAE USA-US300-2020-MRNA-1273-P301000009**

**Form: Safety Report Form**

**Generated On: 26 Nov 2020 10:55:55**

[SAEID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 16:40:20
Reviewed for Safety.	(b) (4), (b) (6)	05 Nov 2020 20:20:30
User entered 'USA-US300-2020-MRNA-1273-P301000009'	System	05 Nov 2020 20:20:08

**US3312605**

**Folder: SAE USA-US300-2020-MRNA-1273-P301000009**

**Form: Safety Report Form**

**Generated On: 26 Nov 2020 10:55:55**

**Serious**

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 16:40:20
Reviewed for Safety.	(b) (4), (b) (6)	05 Nov 2020 20:20:30
User entered 'Yes (Y)'	System	05 Nov 2020 20:20:08



**US3312605**

**Folder: SAE USA-US300-2020-MRNA-1273-P301000009**

**Form: Safety Report Form**

**Generated On: 26 Nov 2020 10:55:55**

[Death](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 16:40:20
Reviewed for Safety.	(b) (4), (b) (6)	05 Nov 2020 20:20:30
User entered 'No (N)'	System	05 Nov 2020 20:20:08

**US3312605**

**Folder: SAE USA-US300-2020-MRNA-1273-P301000009**

**Form: Safety Report Form**

**Generated On: 26 Nov 2020 10:55:55**

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 16:40:20
Reviewed for Safety.	(b) (4), (b) (6)	05 Nov 2020 20:20:30
User entered 'No (N)'	System	05 Nov 2020 20:20:08

**US3312605**

**Folder: SAE USA-US300-2020-MRNA-1273-P301000009**

**Form: Safety Report Form**

**Generated On: 26 Nov 2020 10:55:55**

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 16:40:20
Reviewed for Safety.	(b) (4), (b) (6)	05 Nov 2020 20:20:30
User entered 'Yes (Y)'	System	05 Nov 2020 20:20:08

**US3312605**

**Folder: SAE USA-US300-2020-MRNA-1273-P301000009**

**Form: Safety Report Form**

**Generated On: 26 Nov 2020 10:55:55**

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 16:40:20
Reviewed for Safety.	(b) (4), (b) (6)	05 Nov 2020 20:20:30
User entered 'No (N)'	System	05 Nov 2020 20:20:08

**US3312605**

**Folder: SAE USA-US300-2020-MRNA-1273-P301000009**

**Form: Safety Report Form**

**Generated On: 26 Nov 2020 10:55:55**

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 16:40:20
Reviewed for Safety.	(b) (4), (b) (6)	05 Nov 2020 20:20:30
User entered 'No (N)'	System	05 Nov 2020 20:20:08

**US3312605**

**Folder: SAE USA-US300-2020-MRNA-1273-P301000009**

**Form: Safety Report Form**

**Generated On: 26 Nov 2020 10:55:55**

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 16:40:20
Reviewed for Safety.	(b) (4), (b) (6)	05 Nov 2020 20:20:30
User entered 'No (N)'	System	05 Nov 2020 20:20:08

**US3312605**

**Folder: SAE USA-US300-2020-MRNA-1273-P301000009**

**Form: Safety Report Form**

**Generated On: 26 Nov 2020 10:55:55**

[Investigator's First Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 16:40:20
Reviewed for Safety.	(b) (4), (b) (6)	05 Nov 2020 20:20:30
User entered 'Carlos'	System	05 Nov 2020 20:20:08

**US3312605**

**Folder: SAE USA-US300-2020-MRNA-1273-P301000009**

**Form: Safety Report Form**

**Generated On: 26 Nov 2020 10:55:55**

[Investigator's Last Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 16:40:20
Reviewed for Safety.	(b) (4), (b) (6)	05 Nov 2020 20:20:30
User entered 'Fierro'	System	05 Nov 2020 20:20:08



**US3312605**

**Folder: SAE USA-US300-2020-MRNA-1273-P301000009**

**Form: Safety Report Form**

**Generated On: 26 Nov 2020 10:55:55**

[Site Address: Street](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 16:40:20
Reviewed for Safety.	(b) (4), (b) (6)	05 Nov 2020 20:20:30
User entered '16300 College Blvd'	System	05 Nov 2020 20:20:08

**US3312605**

**Folder: SAE USA-US300-2020-MRNA-1273-P301000009**

**Form: Safety Report Form**

**Generated On: 26 Nov 2020 10:55:55**

[Site Address: City](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 16:40:20
Reviewed for Safety.	(b) (4), (b) (6)	05 Nov 2020 20:20:30
User entered 'Shawnee'	System	05 Nov 2020 20:20:08

**US3312605**

**Folder: SAE USA-US300-2020-MRNA-1273-P301000009**

**Form: Safety Report Form**

**Generated On: 26 Nov 2020 10:55:55**

[Site Address: State](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 16:40:20
Reviewed for Safety.	(b) (4), (b) (6)	05 Nov 2020 20:20:30
User entered 'KS'	System	05 Nov 2020 20:20:08

**US3312605**

**Folder: SAE USA-US300-2020-MRNA-1273-P301000009**

**Form: Safety Report Form**

**Generated On: 26 Nov 2020 10:55:55**

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 16:40:20
Reviewed for Safety.	(b) (4), (b) (6)	05 Nov 2020 20:20:30
User entered '66219'	System	05 Nov 2020 20:20:08

**US3312605**

**Folder: SAE USA-US300-2020-MRNA-1273-P301000009**

**Form: Safety Report Form**

**Generated On: 26 Nov 2020 10:55:55**

[Investigator Country](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	13 Nov 2020 13:05:13
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 16:40:20
User entered 'US'	System	05 Nov 2020 20:20:39

**US3312605**

**Folder: SAE USA-US300-2020-MRNA-1273-P301000009**

**Form: Safety Report Form**

**Generated On: 26 Nov 2020 10:55:55**

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '3'	System	16 Nov 2020 20:28:58
User entered '2'	System	13 Nov 2020 13:05:23
User entered '1'	System	05 Nov 2020 20:20:39

**US3312605**

**Folder: SAE USA-US300-2020-MRNA-1273-P301000009**

**Form: Safety Report Form**

**Generated On: 26 Nov 2020 10:55:55**

[SAEID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 16:40:20
Reviewed for Safety.	(b) (4), (b) (6)	05 Nov 2020 20:20:30
User entered 'USA-US300-2020-MRNA-1273-P301000009'	System	05 Nov 2020 20:20:08

**US3312605**

**Folder: SAE USA-US300-2020-MRNA-1273-P301000009**

**Form: Safety Report Form**

**Generated On: 26 Nov 2020 10:55:55**

**Serious**

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 16:40:20
Reviewed for Safety.	(b) (4), (b) (6)	05 Nov 2020 20:20:30
User entered 'Yes (Y)'	System	05 Nov 2020 20:20:08



**US3312605**

**Folder: SAE USA-US300-2020-MRNA-1273-P301000009**

**Form: Safety Report Form**

**Generated On: 26 Nov 2020 10:55:55**

[Death](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 16:40:20
Reviewed for Safety.	(b) (4), (b) (6)	05 Nov 2020 20:20:30
User entered 'No (N)'	System	05 Nov 2020 20:20:08

**US3312605**

**Folder: SAE USA-US300-2020-MRNA-1273-P301000009**

**Form: Safety Report Form**

**Generated On: 26 Nov 2020 10:55:55**

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 16:40:20
Reviewed for Safety.	(b) (4), (b) (6)	05 Nov 2020 20:20:30
User entered 'No (N)'	System	05 Nov 2020 20:20:08

**US3312605**

**Folder: SAE USA-US300-2020-MRNA-1273-P301000009**

**Form: Safety Report Form**

**Generated On: 26 Nov 2020 10:55:55**

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 16:40:20
Reviewed for Safety.	(b) (4), (b) (6)	05 Nov 2020 20:20:30
User entered 'Yes (Y)'	System	05 Nov 2020 20:20:08

**US3312605**

**Folder: SAE USA-US300-2020-MRNA-1273-P301000009**

**Form: Safety Report Form**

**Generated On: 26 Nov 2020 10:55:55**

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 16:40:20
Reviewed for Safety.	(b) (4), (b) (6)	05 Nov 2020 20:20:30
User entered 'No (N)'	System	05 Nov 2020 20:20:08

**US3312605**

**Folder: SAE USA-US300-2020-MRNA-1273-P301000009**

**Form: Safety Report Form**

**Generated On: 26 Nov 2020 10:55:55**

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 16:40:20
Reviewed for Safety.	(b) (4), (b) (6)	05 Nov 2020 20:20:30
User entered 'No (N)'	System	05 Nov 2020 20:20:08

**US3312605**

**Folder: SAE USA-US300-2020-MRNA-1273-P301000009**

**Form: Safety Report Form**

**Generated On: 26 Nov 2020 10:55:55**

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 16:40:20
Reviewed for Safety.	(b) (4), (b) (6)	05 Nov 2020 20:20:30
User entered 'No (N)'	System	05 Nov 2020 20:20:08

**US3312605**

**Folder: SAE USA-US300-2020-MRNA-1273-P301000009**

**Form: Safety Report Form**

**Generated On: 26 Nov 2020 10:55:55**

[Investigator's First Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 16:40:20
Reviewed for Safety.	(b) (4), (b) (6)	05 Nov 2020 20:20:30
User entered 'Carlos'	System	05 Nov 2020 20:20:08

**US3312605**

**Folder: SAE USA-US300-2020-MRNA-1273-P301000009**

**Form: Safety Report Form**

**Generated On: 26 Nov 2020 10:55:55**

[Investigator's Last Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 16:40:20
Reviewed for Safety.	(b) (4), (b) (6)	05 Nov 2020 20:20:30
User entered 'Fierro'	System	05 Nov 2020 20:20:08



**US3312605**

**Folder: SAE USA-US300-2020-MRNA-1273-P301000009**

**Form: Safety Report Form**

**Generated On: 26 Nov 2020 10:55:55**

[Site Address: Street](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 16:40:20
Reviewed for Safety.	(b) (4), (b) (6)	05 Nov 2020 20:20:30
User entered '16300 College Blvd'	System	05 Nov 2020 20:20:08

**US3312605**

**Folder: SAE USA-US300-2020-MRNA-1273-P301000009**

**Form: Safety Report Form**

**Generated On: 26 Nov 2020 10:55:55**

[Site Address: City](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 16:40:20
Reviewed for Safety.	(b) (4), (b) (6)	05 Nov 2020 20:20:30
User entered 'Shawnee'	System	05 Nov 2020 20:20:08

**US3312605**

**Folder: SAE USA-US300-2020-MRNA-1273-P301000009**

**Form: Safety Report Form**

**Generated On: 26 Nov 2020 10:55:55**

[Site Address: State](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 16:40:20
Reviewed for Safety.	(b) (4), (b) (6)	05 Nov 2020 20:20:30
User entered 'KS'	System	05 Nov 2020 20:20:08

**US3312605**

**Folder: SAE USA-US300-2020-MRNA-1273-P301000009**

**Form: Safety Report Form**

**Generated On: 26 Nov 2020 10:55:55**

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 16:40:20
Reviewed for Safety.	(b) (4), (b) (6)	05 Nov 2020 20:20:30
User entered '66219'	System	05 Nov 2020 20:20:08

**US3312605**

**Folder: SAE USA-US300-2020-MRNA-1273-P301000009**

**Form: Safety Report Form**

**Generated On: 26 Nov 2020 10:55:55**

[Investigator Country](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	13 Nov 2020 13:05:13
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 16:40:20
User entered 'US'	System	05 Nov 2020 20:20:39

**US3312605**

**Folder: SAE USA-US300-2020-MRNA-1273-P301000009**

**Form: Safety Report Form**

**Generated On: 26 Nov 2020 10:55:55**

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '3'	System	16 Nov 2020 20:28:58
User entered '2'	System	13 Nov 2020 13:05:23
User entered '1'	System	05 Nov 2020 20:20:39

**US3312605**

**Folder: SAE USA-US300-2020-MRNA-1273-P301000009**

**Form: Safety Report Form (1)**

**Generated On: 26 Nov 2020 10:55:55**

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 16:40:20
User entered '05/Nov/2020 20:20'	System	05 Nov 2020 20:20:39

US3312605

Folder: SAE USA-US300-2020-MRNA-1273-P301000009

Form: Safety Report Form (1)

Generated On: 26 Nov 2020 10:55:55

**Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.**

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	13 Nov 2020 13:05:13
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 16:40:20
User entered 'I'	(b) (4), (b) (6)	05 Nov 2020 20:20:39



**US3312605**

**Folder: SAE USA-US300-2020-MRNA-1273-P301000009**

**Form: Safety Report Form**

**Generated On: 26 Nov 2020 10:55:55**

[SAEID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 16:40:20
Reviewed for Safety.	(b) (4), (b) (6)	05 Nov 2020 20:20:30
User entered 'USA-US300-2020-MRNA-1273-P301000009'	System	05 Nov 2020 20:20:08

**US3312605**

**Folder: SAE USA-US300-2020-MRNA-1273-P301000009**

**Form: Safety Report Form**

**Generated On: 26 Nov 2020 10:55:55**

**Serious**

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 16:40:20
Reviewed for Safety.	(b) (4), (b) (6)	05 Nov 2020 20:20:30
User entered 'Yes (Y)'	System	05 Nov 2020 20:20:08

**US3312605**

**Folder: SAE USA-US300-2020-MRNA-1273-P301000009**

**Form: Safety Report Form**

**Generated On: 26 Nov 2020 10:55:55**

[Death](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 16:40:20
Reviewed for Safety.	(b) (4), (b) (6)	05 Nov 2020 20:20:30
User entered 'No (N)'	System	05 Nov 2020 20:20:08

**US3312605**

**Folder: SAE USA-US300-2020-MRNA-1273-P301000009**

**Form: Safety Report Form**

**Generated On: 26 Nov 2020 10:55:55**

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 16:40:20
Reviewed for Safety.	(b) (4), (b) (6)	05 Nov 2020 20:20:30
User entered 'No (N)'	System	05 Nov 2020 20:20:08

**US3312605**

**Folder: SAE USA-US300-2020-MRNA-1273-P301000009**

**Form: Safety Report Form**

**Generated On: 26 Nov 2020 10:55:55**

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 16:40:20
Reviewed for Safety.	(b) (4), (b) (6)	05 Nov 2020 20:20:30
User entered 'Yes (Y)'	System	05 Nov 2020 20:20:08

**US3312605**

**Folder: SAE USA-US300-2020-MRNA-1273-P301000009**

**Form: Safety Report Form**

**Generated On: 26 Nov 2020 10:55:55**

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 16:40:20
Reviewed for Safety.	(b) (4), (b) (6)	05 Nov 2020 20:20:30
User entered 'No (N)'	System	05 Nov 2020 20:20:08

**US3312605**

**Folder: SAE USA-US300-2020-MRNA-1273-P301000009**

**Form: Safety Report Form**

**Generated On: 26 Nov 2020 10:55:55**

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 16:40:20
Reviewed for Safety.	(b) (4), (b) (6)	05 Nov 2020 20:20:30
User entered 'No (N)'	System	05 Nov 2020 20:20:08

**US3312605**

**Folder: SAE USA-US300-2020-MRNA-1273-P301000009**

**Form: Safety Report Form**

**Generated On: 26 Nov 2020 10:55:55**

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 16:40:20
Reviewed for Safety.	(b) (4), (b) (6)	05 Nov 2020 20:20:30
User entered 'No (N)'	System	05 Nov 2020 20:20:08



**US3312605**

**Folder: SAE USA-US300-2020-MRNA-1273-P301000009**

**Form: Safety Report Form**

**Generated On: 26 Nov 2020 10:55:55**

[Investigator's First Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 16:40:20
Reviewed for Safety.	(b) (4), (b) (6)	05 Nov 2020 20:20:30
User entered 'Carlos'	System	05 Nov 2020 20:20:08

**US3312605**

**Folder: SAE USA-US300-2020-MRNA-1273-P301000009**

**Form: Safety Report Form**

**Generated On: 26 Nov 2020 10:55:55**

[Investigator's Last Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 16:40:20
Reviewed for Safety.	(b) (4), (b) (6)	05 Nov 2020 20:20:30
User entered 'Fierro'	System	05 Nov 2020 20:20:08

**US3312605**

**Folder: SAE USA-US300-2020-MRNA-1273-P301000009**

**Form: Safety Report Form**

**Generated On: 26 Nov 2020 10:55:55**

[Site Address: Street](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 16:40:20
Reviewed for Safety.	(b) (4), (b) (6)	05 Nov 2020 20:20:30
User entered '16300 College Blvd'	System	05 Nov 2020 20:20:08

**US3312605**

**Folder: SAE USA-US300-2020-MRNA-1273-P301000009**

**Form: Safety Report Form**

**Generated On: 26 Nov 2020 10:55:55**

[Site Address: City](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 16:40:20
Reviewed for Safety.	(b) (4), (b) (6)	05 Nov 2020 20:20:30
User entered 'Shawnee'	System	05 Nov 2020 20:20:08

**US3312605**

**Folder: SAE USA-US300-2020-MRNA-1273-P301000009**

**Form: Safety Report Form**

**Generated On: 26 Nov 2020 10:55:55**

[Site Address: State](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 16:40:20
Reviewed for Safety.	(b) (4), (b) (6)	05 Nov 2020 20:20:30
User entered 'KS'	System	05 Nov 2020 20:20:08

**US3312605**

**Folder: SAE USA-US300-2020-MRNA-1273-P301000009**

**Form: Safety Report Form**

**Generated On: 26 Nov 2020 10:55:55**

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 16:40:20
Reviewed for Safety.	(b) (4), (b) (6)	05 Nov 2020 20:20:30
User entered '66219'	System	05 Nov 2020 20:20:08

**US3312605**

**Folder: SAE USA-US300-2020-MRNA-1273-P301000009**

**Form: Safety Report Form**

**Generated On: 26 Nov 2020 10:55:55**

[Investigator Country](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	13 Nov 2020 13:05:13
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 16:40:20
User entered 'US'	System	05 Nov 2020 20:20:39

**US3312605**

**Folder: SAE USA-US300-2020-MRNA-1273-P301000009**

**Form: Safety Report Form**

**Generated On: 26 Nov 2020 10:55:55**

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '3'	System	16 Nov 2020 20:28:58
User entered '2'	System	13 Nov 2020 13:05:23
User entered '1'	System	05 Nov 2020 20:20:39



**US3312605**

**Folder: SAE USA-US300-2020-MRNA-1273-P301000009**

**Form: Safety Report Form (2)**

**Generated On: 26 Nov 2020 10:55:55**

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 23:21:19
User entered '13/Nov/2020 08:05'	System	13 Nov 2020 13:05:23

US3312605

Folder: SAE USA-US300-2020-MRNA-1273-P301000009

Form: Safety Report Form (2)

Generated On: 26 Nov 2020 10:55:55

**Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.**

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 23:21:21
Reviewed for Safety.	(b) (4), (b) (6)	16 Nov 2020 20:28:47
User entered 'I'	(b) (4), (b) (6)	13 Nov 2020 13:05:23

**US3312605**

**Folder: SAE USA-US300-2020-MRNA-1273-P301000009**

**Form: Safety Report Form**

**Generated On: 26 Nov 2020 10:55:55**

[SAEID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 16:40:20
Reviewed for Safety.	(b) (4), (b) (6)	05 Nov 2020 20:20:30
User entered 'USA-US300-2020-MRNA-1273-P301000009'	System	05 Nov 2020 20:20:08

**US3312605**

**Folder: SAE USA-US300-2020-MRNA-1273-P301000009**

**Form: Safety Report Form**

**Generated On: 26 Nov 2020 10:55:55**

**Serious**

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 16:40:20
Reviewed for Safety.	(b) (4), (b) (6)	05 Nov 2020 20:20:30
User entered 'Yes (Y)'	System	05 Nov 2020 20:20:08

**US3312605**

**Folder: SAE USA-US300-2020-MRNA-1273-P301000009**

**Form: Safety Report Form**

**Generated On: 26 Nov 2020 10:55:55**

[Death](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 16:40:20
Reviewed for Safety.	(b) (4), (b) (6)	05 Nov 2020 20:20:30
User entered 'No (N)'	System	05 Nov 2020 20:20:08

**US3312605**

**Folder: SAE USA-US300-2020-MRNA-1273-P301000009**

**Form: Safety Report Form**

**Generated On: 26 Nov 2020 10:55:55**

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 16:40:20
Reviewed for Safety.	(b) (4), (b) (6)	05 Nov 2020 20:20:30
User entered 'No (N)'	System	05 Nov 2020 20:20:08

**US3312605**

**Folder: SAE USA-US300-2020-MRNA-1273-P301000009**

**Form: Safety Report Form**

**Generated On: 26 Nov 2020 10:55:55**

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 16:40:20
Reviewed for Safety.	(b) (4), (b) (6)	05 Nov 2020 20:20:30
User entered 'Yes (Y)'	System	05 Nov 2020 20:20:08

**US3312605**

**Folder: SAE USA-US300-2020-MRNA-1273-P301000009**

**Form: Safety Report Form**

**Generated On: 26 Nov 2020 10:55:55**

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 16:40:20
Reviewed for Safety.	(b) (4), (b) (6)	05 Nov 2020 20:20:30
User entered 'No (N)'	System	05 Nov 2020 20:20:08



**US3312605**

**Folder: SAE USA-US300-2020-MRNA-1273-P301000009**

**Form: Safety Report Form**

**Generated On: 26 Nov 2020 10:55:55**

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 16:40:20
Reviewed for Safety.	(b) (4), (b) (6)	05 Nov 2020 20:20:30
User entered 'No (N)'	System	05 Nov 2020 20:20:08

**US3312605**

**Folder: SAE USA-US300-2020-MRNA-1273-P301000009**

**Form: Safety Report Form**

**Generated On: 26 Nov 2020 10:55:55**

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 16:40:20
Reviewed for Safety.	(b) (4), (b) (6)	05 Nov 2020 20:20:30
User entered 'No (N)'	System	05 Nov 2020 20:20:08

**US3312605**

**Folder: SAE USA-US300-2020-MRNA-1273-P301000009**

**Form: Safety Report Form**

**Generated On: 26 Nov 2020 10:55:55**

[Investigator's First Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 16:40:20
Reviewed for Safety.	(b) (4), (b) (6)	05 Nov 2020 20:20:30
User entered 'Carlos'	System	05 Nov 2020 20:20:08

**US3312605**

**Folder: SAE USA-US300-2020-MRNA-1273-P301000009**

**Form: Safety Report Form**

**Generated On: 26 Nov 2020 10:55:55**

[Investigator's Last Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 16:40:20
Reviewed for Safety.	(b) (4), (b) (6)	05 Nov 2020 20:20:30
User entered 'Fierro'	System	05 Nov 2020 20:20:08

**US3312605**

**Folder: SAE USA-US300-2020-MRNA-1273-P301000009**

**Form: Safety Report Form**

**Generated On: 26 Nov 2020 10:55:55**

[Site Address: Street](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 16:40:20
Reviewed for Safety.	(b) (4), (b) (6)	05 Nov 2020 20:20:30
User entered '16300 College Blvd'	System	05 Nov 2020 20:20:08

**US3312605**

**Folder: SAE USA-US300-2020-MRNA-1273-P301000009**

**Form: Safety Report Form**

**Generated On: 26 Nov 2020 10:55:55**

[Site Address: City](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 16:40:20
Reviewed for Safety.	(b) (4), (b) (6)	05 Nov 2020 20:20:30
User entered 'Shawnee'	System	05 Nov 2020 20:20:08

**US3312605**

**Folder: SAE USA-US300-2020-MRNA-1273-P301000009**

**Form: Safety Report Form**

**Generated On: 26 Nov 2020 10:55:55**

[Site Address: State](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 16:40:20
Reviewed for Safety.	(b) (4), (b) (6)	05 Nov 2020 20:20:30
User entered 'KS'	System	05 Nov 2020 20:20:08

**US3312605**

**Folder: SAE USA-US300-2020-MRNA-1273-P301000009**

**Form: Safety Report Form**

**Generated On: 26 Nov 2020 10:55:55**

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 16:40:20
Reviewed for Safety.	(b) (4), (b) (6)	05 Nov 2020 20:20:30
User entered '66219'	System	05 Nov 2020 20:20:08



US3312605

Folder: SAE USA-US300-2020-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 26 Nov 2020 10:55:55

[Investigator Country](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	13 Nov 2020 13:05:13
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 16:40:20
User entered 'US'	System	05 Nov 2020 20:20:39

**US3312605**

**Folder: SAE USA-US300-2020-MRNA-1273-P301000009**

**Form: Safety Report Form**

**Generated On: 26 Nov 2020 10:55:55**

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '3'	System	16 Nov 2020 20:28:58
User entered '2'	System	13 Nov 2020 13:05:23
User entered '1'	System	05 Nov 2020 20:20:39

**US3312605**

**Folder: SAE USA-US300-2020-MRNA-1273-P301000009**

**Form: Safety Report Form (3)**

**Generated On: 26 Nov 2020 10:55:55**

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 23:21:27
User entered '16/Nov/2020 20:28'	System	16 Nov 2020 20:28:58

US3312605

Folder: SAE USA-US300-2020-MRNA-1273-P301000009

Form: Safety Report Form (3)

Generated On: 26 Nov 2020 10:55:55

**Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.**

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 23:21:29
User entered 'I'	(b) (4), (b) (6)	16 Nov 2020 20:28:58