

US3312046 (Prod: Johnson County Clin-Trials)

Generated By: (b) (6)

Generated On: 26 Nov 2020 10:51:05

All time stamps listed in this document are displayed in GMT

**US3312046**

**Form: Participant Creation**

**Generated On: 26 Nov 2020 10:51:05**

[Participant ID](#)

US3312046

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

US3312046

Folder: Screening

Form: Visit Date

Generated On: 26 Nov 2020 10:51:05

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	12 AUG 2020
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	SCRN

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Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 10:51:05

Date of Birth (MMM yyyy)	(b) (6) 1937
Age	82
Age Units	YEARS
Age (Derived)	82
Sex	Female <input checked="" type="radio"/> Male <input 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 10:51:05

Date of Informed Consent ( <i>dd MMM yyyy</i> )	12 AUG 2020
Month and Year of Informed Consent (derived)	AUG 2020
Year of Informed Consent (derived)	2020
Protocol Version	Amendment 1 <input type="radio"/>
	Amendment 2 <input checked="" type="radio"/>
	Amendment 3 <input type="radio"/>
	Amendment 4 <input type="radio"/>
	Amendment 5 <input type="radio"/>
Was participant enrolled in the study?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
If No, indicate reason for screen fail	Withdrew Consent <input type="radio"/>
	Inclusion/Exclusion <input type="radio"/>
	Cohort Full <input type="radio"/>
	Other <input type="radio"/>
If reason for screen fail is Other, specify	
Was this participant screened previously?	Yes <input type="radio"/>
	No <input checked="" type="radio"/>
If Yes, previous participant number	
Enrollment Trigger	1

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Folder: Screening

Form: Inclusion/Exclusion Criteria Summary

Generated On: 26 Nov 2020 10:51:05

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Did the participant meet all eligibility criteria?

Yes ☒

No ☐

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Folder: Screening

Form: Medical History Summary

Generated On: 26 Nov 2020 10:51:05

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Were any significant conditions reported?

Yes ☒

No ☐

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Folder: Screening

Form: Medical History (1)

Generated On: 26 Nov 2020 10:51:05

Condition	LOWER BACK PAIN
Start date (dd MMM yyyy)	UN UNK 2000
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 2000
Start Year (derived)	2000
Stop Month and Year (derived)	
Stop Year (derived)	



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Folder: Screening

Form: Medical History (2)

Generated On: 26 Nov 2020 10:51:05

Condition	L5 VERTEBRAL FRACTURE
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 2000
Stop date completely unknown	False
Start Month and Year (derived)	JAN 2000
Start Year (derived)	2000
Stop Month and Year (derived)	JAN 2000
Stop Year (derived)	2000

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Folder: Screening

Form: Medical History (3)

Generated On: 26 Nov 2020 10:51:05

Condition	L4-5 VERTEBRAL FUSION
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 2000
Stop date completely unknown	False
Start Month and Year (derived)	JAN 2000
Start Year (derived)	2000
Stop Month and Year (derived)	JAN 2000
Stop Year (derived)	2000

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Folder: Screening

Form: Medical History (4)

Generated On: 26 Nov 2020 10:51:05

Condition	CONGENITAL SYSTOLIC HEART MURMUR
Start date (dd MMM yyyy)	UN (b) (6) 1937
Start date completely unknown	False
Condition ongoing at study entry	Yes <input checked="" type="radio"/> No <input type="radio"/>
If No, please specify the stop date (dd MMM yyyy)	
Stop date completely unknown	False
Start Month and Year (derived)	(b) (6) 1937
Start Year (derived)	1937
Stop Month and Year (derived)	
Stop Year (derived)	

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Folder: Screening

Form: Medical History (5)

Generated On: 26 Nov 2020 10:51:05

Condition	BILATERAL HEARING LOSS
Start date (dd MMM yyyy)	UN UNK 2009
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 2009
Start Year (derived)	2009
Stop Month and Year (derived)	
Stop Year (derived)	

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Folder: Screening

Form: Medical History (6)

Generated On: 26 Nov 2020 10:51:05

Condition	PARTIAL HYSTERECTOMY
Start date (dd MMM yyyy)	UN UNK 1985
Start date completely unknown	False
Condition ongoing at study entry	Yes <input type="radio"/> No <input checked="" type="radio"/>
If No, please specify the stop date (dd MMM yyyy)	UN UNK 1985
Stop date completely unknown	False
Start Month and Year (derived)	JAN 1985
Start Year (derived)	1985
Stop Month and Year (derived)	JAN 1985
Stop Year (derived)	1985

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Folder: Screening

Form: Medical History (7)

Generated On: 26 Nov 2020 10:51:05

Condition	MENORRHAGIA
Start date (dd MMM yyyy)	UN UNK 1985
Start date completely unknown	False
Condition ongoing at study entry	Yes <input type="radio"/> No <input checked="" type="radio"/>
If No, please specify the stop date (dd MMM yyyy)	UN UNK 1985
Stop date completely unknown	False
Start Month and Year (derived)	JAN 1985
Start Year (derived)	1985
Stop Month and Year (derived)	JAN 1985
Stop Year (derived)	1985

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Folder: Screening

Form: Medical History (8)

Generated On: 26 Nov 2020 10:51:05

Condition	POST MENOPAUSAL
Start date (dd MMM yyyy)	UN UNK 2002
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 2002
Start Year (derived)	2002
Stop Month and Year (derived)	_____
Stop Year (derived)	_____

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Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 10:51:05

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment ( <i>dd MMM yyyy</i> )	12 AUG 2020
Time of assessment ( <i>00:00-23:59</i> )	11:05 (24 HR)
Vital Signs Date and Time (derived)	12 AUG 2020 11:05
Height ( <i>xxx.x</i> )	63 in
Weight ( <i>xxx.x</i> )	146 lb
BMI ( <i>xxx.x</i> )	25.91682 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 10:51:05

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

12 AUG 2020

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

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Folder: Screening

Form: Childbearing Potential

Generated On: 26 Nov 2020 10:51:05

Date of assessment ( <i>dd MMM yyyy</i> )	12 AUG 2020
Is the participant of childbearing potential?	Yes <input type="radio"/>
	No <input checked="" type="radio"/>
If No, what is the reason?	Surgically sterile <input checked="" type="radio"/>
	Post-menopausal <input type="radio"/>
	Partner medically sterile <input type="radio"/>
	Not reached age of Menarche <input type="radio"/>
	Other <input type="radio"/>
If Partner medically sterile or Other, specify	
If Surgically sterile, date of surgery ( <i>dd MMM yyyy</i> )	UN UNK 1985
Date of surgery unknown	False
If Post-menopausal, date of last menstruation ( <i>dd MMM yyyy</i> )	
Date of last menstruation unknown	False

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Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 10:51:05

**Occupational Risk**

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

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

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

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

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

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

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

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

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

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

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

**Other** Yes ☒ No ☐

**Specify**

FOSTER RESCUE DOGS AND  
FREQUENTLY VISITS RESCUE  
CENTER

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

**No Risk Identified** False

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

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Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 10:51:05

<b>Resides in Multi-family dwelling</b> (e.g., cohabitation in dwelling with > 5 people, includes grandparents living with children < 18yrs)	False
<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 10:51:05

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	12 AUG 2020
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	VISIT1

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Folder: Visit 1 Day 1

Form: Randomization

Generated On: 26 Nov 2020 10:51:05

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

What was the participant's randomization number? 185756

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

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

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

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

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

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

Liver Disease Yes ☐ No ☒

Human Immunodeficiency Virus (HIV) infection Yes ☐ No ☒

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**Folder: Visit 1 Day 1**

**Form: Vital Signs - Dosing**

**Generated On: 26 Nov 2020 10:51:05**

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 10:51:05

Height	ND - Not Done
Weight	ND - Not Done
Timepoint	Pre-Dose <input checked="" type="radio"/> Post-Dose <input type="radio"/>
Were vital signs assessed?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Date of assessment (dd MMM yyyy)	12 AUG 2020
Time of assessment (00:00-23:59)	11:05 (24 HR)
Vital Signs Date and Time (derived)	12 AUG 2020 11:05
Temperature (xxx.x)	98.1 F
Route of measurement	Oral <input checked="" type="radio"/> Axillary <input type="radio"/> Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	62 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	14 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	125 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	72 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 10:51:05

Height	ND - Not Done
Weight	ND - Not Done
Timepoint	Pre-Dose <input type="radio"/> Post-Dose <input checked="" type="radio"/>
Were vital signs assessed?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Date of assessment (dd MMM yyyy)	12 AUG 2020
Time of assessment (00:00-23:59)	12:53 (24 HR)
Vital Signs Date and Time (derived)	12 AUG 2020 12:53
Temperature (xxx.x)	97.4 F
Route of measurement	Oral <input checked="" type="radio"/> Axillary <input type="radio"/> Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	60 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	134 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	77 mmHg
Diastolic Blood Pressure units	MMHG

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Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 26 Nov 2020 10:51:05

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 10:51:05

Was study treatment given?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
If No, reason not given	Participant declined due to Adverse Event <input type="radio"/>
	Physician withheld dose due to Adverse Event <input type="radio"/>
	Death <input type="radio"/>
	Lost To Follow-Up <input type="radio"/>
	Physician Decision <input type="radio"/>
	Pregnancy <input type="radio"/>
	Protocol Deviation <input type="radio"/>
	Study Terminated by Sponsor <input type="radio"/>
	Withdrawal of Consent by Participant <input type="radio"/>
	Confirmed COVID-19 <input type="radio"/>
	Other <input type="radio"/>
If reason is Physician Decision, Withdrawal of Consent by Participant, Protocol Deviation, or Other, specify	
What was the study treatment?	MRNA-1273 OR PLACEBO
What was the treatment date? (dd MMM yyyy)	12 AUG 2020
What was the treatment time? (00:00-23:59)	12:22 (24 HR)
Treatment Date and Time (derived)	12 AUG 2020 12:22
Which arm was used to give treatment?	Left Arm <input checked="" type="radio"/>
	Right Arm <input type="radio"/>
What was the frequency of the study treatment dosing?	ONCE
What was the route of administration for the study treatment?	INTRAMUSCULAR

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Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 10:51:05

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date ( <i>dd MMM yyyy</i> )	12 AUG 2020
Collection time ( <i>00:00-23:59</i> )	11:37 (24 HR)
Collection date and time (derived)	12 AUG 2020 11:37

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Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 26 Nov 2020 10:51:05

Collection date ( <i>dd MMM yyyy</i> )			12 AUG 2020
Lab Test	Was the sample collected?	Collection time ( <i>00:00 - 23:59</i> )	Collection date and time (derived)
Nasopharyngeal Swab 1	Yes	11:15	12 AUG 2020 11:15
Nasopharyngeal Swab 2	No		

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Folder: Visit 1 Day 1

Form: Continuing

Generated On: 26 Nov 2020 10:51:05

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

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Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/1)

Generated On: 26 Nov 2020 10:51:05

**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

97.4 °F

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

Yes ☐

No ☒

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

PC Time Stamp

12 AUG 2020 12:55

PC Open Date & Time

12 AUG 2020 12:42

PC Close Date & Time

12 AUG 2020 15:12

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Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/2)

Generated On: 26 Nov 2020 10:51:05

**TIMEPOINT**

DAY 1, AFTER VACCINATION  
(AT HOME)

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

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

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

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

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

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

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

Was **TEMPERATURE** taken? Yes ☒ No ☐

Please record your **TEMPERATURE** in °F 97.1 °F

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

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

PC Time Stamp	12 AUG 2020 19:44
PC Open Date & Time	12 AUG 2020 16:07
PC Close Date & Time	13 AUG 2020 11:59



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Folder: Diary Dose 1 (1)

Form: Temperature\_Day(2)

Generated On: 26 Nov 2020 10:51:05

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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

97.1 °F

---

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

Yes ☐

No ☒

---

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

---

PC Time Stamp

13 AUG 2020 21:05

---

PC Open Date & Time

13 AUG 2020 12:00

---

PC Close Date & Time

14 AUG 2020 11:59

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US3312046

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(3)

Generated On: 26 Nov 2020 10:51:05

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**TIMEPOINT**

DAY 3

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

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

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

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

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

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

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

---

Was **TEMPERATURE** taken?

Yes ☒

No ☐

---

Please record your **TEMPERATURE** in °F

97.1 °F

---

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

Yes ☐

No ☒

---

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

---

PC Time Stamp

14 AUG 2020 21:05

---

PC Open Date & Time

14 AUG 2020 12:00

---

PC Close Date & Time

15 AUG 2020 11:59

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US3312046

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(4)

Generated On: 26 Nov 2020 10:51:05

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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

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

15 AUG 2020 19:35

---

PC Open Date & Time

15 AUG 2020 12:00

---

PC Close Date & Time

16 AUG 2020 11:59

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US3312046

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(5)

Generated On: 26 Nov 2020 10:51:05

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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

96.9 °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

16 AUG 2020 20:24

PC Open Date & Time

16 AUG 2020 12:00

PC Close Date & Time

17 AUG 2020 11:59

US3312046

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(6)

Generated On: 26 Nov 2020 10:51:05

---

**TIMEPOINT**

DAY 6

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

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

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

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

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

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

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

---

Was **TEMPERATURE** taken?

Yes ☒

No ☐

---

Please record your **TEMPERATURE** in °F

97.3 °F

---

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

Yes ☐

No ☒

---

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

---

PC Time Stamp

17 AUG 2020 21:53

---

PC Open Date & Time

17 AUG 2020 12:00

---

PC Close Date & Time

18 AUG 2020 11:59

---

US3312046

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(7)

Generated On: 26 Nov 2020 10:51:05

---

**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

97.3 °F

---

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

Yes ☐

No ☒

---

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

---

PC Time Stamp

18 AUG 2020 21:27

---

PC Open Date & Time

18 AUG 2020 12:00

---

PC Close Date & Time

19 AUG 2020 11:59

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US3312046

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 26 Nov 2020 10:51:05

**TIMEPOINT**

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

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

PC Time Stamp

12 AUG 2020 12:56

PC Open Date & Time

12 AUG 2020 12:42

PC Close Date & Time

12 AUG 2020 15:12

US3312046

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 26 Nov 2020 10:51:05

**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

12 AUG 2020 19:44

PC Open Date & Time

12 AUG 2020 16:07

PC Close Date & Time

13 AUG 2020 11:59



US3312046

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 26 Nov 2020 10:51:05

**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

13 AUG 2020 21:06

PC Open Date & Time

13 AUG 2020 12:00

PC Close Date & Time

14 AUG 2020 11:59

US3312046

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 26 Nov 2020 10:51:05

**TIMEPOINT**

DAY 3

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

PC Time Stamp

14 AUG 2020 21:05

PC Open Date & Time

14 AUG 2020 12:00

PC Close Date & Time

15 AUG 2020 11:59

US3312046

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 26 Nov 2020 10:51:05

**TIMEPOINT**

DAY 4

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

PC Time Stamp

15 AUG 2020 19:36

PC Open Date & Time

15 AUG 2020 12:00

PC Close Date & Time

16 AUG 2020 11:59

US3312046

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 26 Nov 2020 10:51:05

**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

16 AUG 2020 20:24

PC Open Date & Time

16 AUG 2020 12:00

PC Close Date & Time

17 AUG 2020 11:59

US3312046

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(6)

Generated On: 26 Nov 2020 10:51:05

**TIMEPOINT**

DAY 6

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

PC Time Stamp

17 AUG 2020 21:54

PC Open Date & Time

17 AUG 2020 12:00

PC Close Date & Time

18 AUG 2020 11:59

US3312046

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 26 Nov 2020 10:51:05

**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

18 AUG 2020 21:28

PC Open Date & Time

18 AUG 2020 12:00

PC Close Date & Time

19 AUG 2020 11:59

US3312046

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 26 Nov 2020 10:51:05

**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 ☐

US3312046

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 26 Nov 2020 10:51:05

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

No ☒

Yes ☐

PC Time stamp	12 AUG 2020 12:57
PC Open Date & Time	12 AUG 2020 12:42
PC Close Date & Time	12 AUG 2020 15:12



US3312046

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 26 Nov 2020 10:51:05

**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 ☐

US3312046

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 26 Nov 2020 10:51:05

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

No ☒

Yes ☐

PC Time stamp	12 AUG 2020 19:45
PC Open Date & Time	12 AUG 2020 16:07
PC Close Date & Time	13 AUG 2020 11:59

US3312046

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 26 Nov 2020 10:51:05

**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 ☒

US3312046

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 26 Nov 2020 10:51:05

Yes <input type="checkbox"/>	
PC Time stamp	13 AUG 2020 21:07
PC Open Date & Time	13 AUG 2020 12:00
PC Close Date & Time	14 AUG 2020 11:59

US3312046

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 26 Nov 2020 10:51:05

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 ☒

US3312046

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 26 Nov 2020 10:51:05

Yes <input type="checkbox"/>	
PC Time stamp	14 AUG 2020 21:06
PC Open Date & Time	14 AUG 2020 12:00
PC Close Date & Time	15 AUG 2020 11:59

US3312046

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 26 Nov 2020 10:51:05

**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 ☒

US3312046

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 26 Nov 2020 10:51:05

Yes <input type="checkbox"/>	
PC Time stamp	15 AUG 2020 19:37
PC Open Date & Time	15 AUG 2020 12:00
PC Close Date & Time	16 AUG 2020 11:59



US3312046

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 26 Nov 2020 10:51:05

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 ☒

US3312046

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 26 Nov 2020 10:51:05

Yes <input type="checkbox"/>	
PC Time stamp	16 AUG 2020 20:25
PC Open Date & Time	16 AUG 2020 12:00
PC Close Date & Time	17 AUG 2020 11:59

US3312046

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 26 Nov 2020 10:51:05

**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 ☒

US3312046

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 26 Nov 2020 10:51:05

Yes <input type="checkbox"/>	
PC Time stamp	17 AUG 2020 21:54
PC Open Date & Time	17 AUG 2020 12:00
PC Close Date & Time	18 AUG 2020 11:59

US3312046

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 26 Nov 2020 10:51:05

**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 ☒

US3312046

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 26 Nov 2020 10:51:05

Yes <input type="checkbox"/>	
PC Time stamp	18 AUG 2020 21:29
PC Open Date & Time	18 AUG 2020 12:00
PC Close Date & Time	19 AUG 2020 11:59

US3312046

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 26 Nov 2020 10:51:05

Was Contact Attempted?

Yes ☒

No ☐

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

19 AUG 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

*If Contact Not Made, please provide Comments*

US3312046

Folder: Safety Call Day 8 (1)

Form: Continuing

Generated On: 26 Nov 2020 10:51:05

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1



US3312046

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 26 Nov 2020 10:51:05

Was Contact Attempted?

Yes ☒

No ☐

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

26 AUG 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

*If Contact Not Made, please provide Comments*

US3312046

Folder: Safety Call Day 15 (1)

Form: Continuing

Generated On: 26 Nov 2020 10:51:05

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3312046

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 26 Nov 2020 10:51:05

Was Contact Attempted?

Yes ☒

No ☐

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

2 SEP 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

*If Contact Not Made, please provide Comments*

US3312046

Folder: Safety Call Day 22 (1)

Form: Continuing

Generated On: 26 Nov 2020 10:51:05

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3312046

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 26 Nov 2020 10:51:05

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

US3312046

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 10:51:05

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)	09 SEP 2020
Time of assessment (00:00-23:59)	13:02 (24 HR)
Vital Signs Date and Time (derived)	09 SEP 2020 13:02
Temperature (xxx.x)	97.8 F
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	61 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	14 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	138 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	86 mmHg
Diastolic Blood Pressure units	MMHG

US3312046

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 10:51:05

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)	09 SEP 2020
Time of assessment (00:00-23:59)	14:21 (24 HR)
Vital Signs Date and Time (derived)	09 SEP 2020 14:21
Temperature (xxx.x)	98.0 F
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	60 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	140 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	83 mmHg
Diastolic Blood Pressure units	MMHG

US3312046

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Generated On: 26 Nov 2020 10:51:05

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

09 SEP 2020

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



US3312046

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 26 Nov 2020 10:51:05

Was study treatment given?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
If No, reason not given	Participant declined due to Adverse Event <input type="radio"/>
	Physician withheld dose due to Adverse Event <input type="radio"/>
	Death <input type="radio"/>
	Lost To Follow-Up <input type="radio"/>
	Physician Decision <input type="radio"/>
	Pregnancy <input type="radio"/>
	Protocol Deviation <input type="radio"/>
	Study Terminated by Sponsor <input type="radio"/>
	Withdrawal of Consent by Participant <input type="radio"/>
	Confirmed COVID-19 <input type="radio"/>
	Other <input type="radio"/>
If reason is Physician Decision, Withdrawal of Consent by Participant, Protocol Deviation, or Other, specify	
What was the study treatment?	MRNA-1273 OR PLACEBO
What was the treatment date? (dd MMM yyyy)	9 SEP 2020
What was the treatment time? (00:00-23:59)	13:50 (24 HR)
Treatment Date and Time (derived)	9 SEP 2020 13:50
Which arm was used to give treatment?	Left Arm <input checked="" type="radio"/>
	Right Arm <input type="radio"/>
What was the frequency of the study treatment dosing?	ONCE
What was the route of administration for the study treatment?	INTRAMUSCULAR

US3312046

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 10:51:05

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date ( <i>dd MMM yyyy</i> )	09 SEP 2020
Collection time ( <i>00:00-23:59</i> )	13:16 (24 HR)
Collection date and time (derived)	09 SEP 2020 13:16

US3312046

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 26 Nov 2020 10:51:05

Collection date (dd MMM yyyy)			09 SEP 2020
Lab Test	Was the sample collected?	Collection time (00:00 - 23:59)	Collection date and time (derived)
Nasopharyngeal Swab 1	Yes	13:10	09 SEP 2020 13:10
Nasopharyngeal Swab 2	No		

US3312046

Folder: Visit 2 Day 29 (1)

Form: Continuing

Generated On: 26 Nov 2020 10:51:05

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3312046

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/1)

Generated On: 26 Nov 2020 10:51:05

**TIMEPOINT**

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

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.0 °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

09 SEP 2020 14:21

PC Open Date & Time

09 SEP 2020 14:10

PC Close Date & Time

09 SEP 2020 16:40

US3312046

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/2)

Generated On: 26 Nov 2020 10:51:05

**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 98.0 °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 09 SEP 2020 19:45

PC Open Date & Time 09 SEP 2020 17:35

PC Close Date & Time 10 SEP 2020 11:59

US3312046

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(2)

Generated On: 26 Nov 2020 10:51:05

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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

96.9 °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

10 SEP 2020 19:02

PC Open Date & Time

10 SEP 2020 12:00

PC Close Date & Time

11 SEP 2020 11:59

US3312046

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(3)

Generated On: 26 Nov 2020 10:51:05

**TIMEPOINT**

DAY 3

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.1 °F

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

Yes ☒

No ☐

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

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

True

To **PREVENT** pain or fever from occurring

False

PC Time Stamp

11 SEP 2020 18:24

PC Open Date & Time

11 SEP 2020 12:00

PC Close Date & Time

12 SEP 2020 11:59



US3312046

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(4)

Generated On: 26 Nov 2020 10:51:05

**TIMEPOINT**

DAY 4

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

96.8 °F

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

Yes ☒

No ☐

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

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

True

To **PREVENT** pain or fever from occurring

False

PC Time Stamp

12 SEP 2020 19:11

PC Open Date & Time

12 SEP 2020 12:00

PC Close Date & Time

13 SEP 2020 11:59

US3312046

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(5)

Generated On: 26 Nov 2020 10:51:05

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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

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

13 SEP 2020 18:42

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PC Open Date & Time

13 SEP 2020 12:00

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PC Close Date & Time

14 SEP 2020 11:59

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US3312046

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(6)

Generated On: 26 Nov 2020 10:51:05

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**TIMEPOINT**

DAY 6

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

96.4 °F

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

Yes ☐

No ☒

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

PC Time Stamp

14 SEP 2020 19:06

PC Open Date & Time

14 SEP 2020 12:00

PC Close Date & Time

15 SEP 2020 11:59

US3312046

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(7)

Generated On: 26 Nov 2020 10:51:05

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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

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 20:34

PC Open Date & Time

15 SEP 2020 12:00

PC Close Date & Time

16 SEP 2020 11:59

US3312046

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/1)

Generated On: 26 Nov 2020 10:51:05

**TIMEPOINT**

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

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

PC Time Stamp

09 SEP 2020 14:22

PC Open Date & Time

09 SEP 2020 14:10

PC Close Date & Time

09 SEP 2020 16:40

US3312046

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/2)

Generated On: 26 Nov 2020 10:51:05

**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 SEP 2020 19:46

PC Open Date & Time

09 SEP 2020 17:35

PC Close Date & Time

10 SEP 2020 11:59

US3312046

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(2)

Generated On: 26 Nov 2020 10:51:05

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

7

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

10 SEP 2020 19:07

PC Open Date & Time

10 SEP 2020 12:00

PC Close Date & Time

11 SEP 2020 11:59

US3312046

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(3)

Generated On: 26 Nov 2020 10:51:05

**TIMEPOINT**

DAY 3

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

None ☐

Please select one response below

Does not interfere with activity ☒

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

Any use of prescription pain  
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☒

No ☐

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

4

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

11 SEP 2020 18:25

PC Open Date & Time

11 SEP 2020 12:00

PC Close Date & Time

12 SEP 2020 11:59



US3312046

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(4)

Generated On: 26 Nov 2020 10:51:05

**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 ☐

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

4

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)**

4

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

12 SEP 2020 19:12

PC Open Date & Time

12 SEP 2020 12:00

PC Close Date & Time

13 SEP 2020 11:59

US3312046

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(5)

Generated On: 26 Nov 2020 10:51:05

**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

13 SEP 2020 18:42

PC Open Date & Time

13 SEP 2020 12:00

PC Close Date & Time

14 SEP 2020 11:59

US3312046

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(6)

Generated On: 26 Nov 2020 10:51:05

**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

14 SEP 2020 19:06

PC Open Date & Time

14 SEP 2020 12:00

PC Close Date & Time

15 SEP 2020 11:59

US3312046

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(7)

Generated On: 26 Nov 2020 10:51:05

**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

15 SEP 2020 20:34

PC Open Date & Time

15 SEP 2020 12:00

PC Close Date & Time

16 SEP 2020 11:59

US3312046

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 26 Nov 2020 10:51:05

**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 ☐

US3312046

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 26 Nov 2020 10:51:05

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

No ☒

Yes ☐

PC Time stamp	09 SEP 2020 14:22
PC Open Date & Time	09 SEP 2020 14:10
PC Close Date & Time	09 SEP 2020 16:40

US3312046

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 26 Nov 2020 10:51:05

**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 ☐

US3312046

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 26 Nov 2020 10:51:05

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

No ☒

Yes ☐

PC Time stamp	09 SEP 2020 19:46
PC Open Date & Time	09 SEP 2020 17:35
PC Close Date & Time	10 SEP 2020 11:59



US3312046

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 26 Nov 2020 10:51:05

**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 ☒

**US3312046**

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

**Form: General\_Day(2)**

**Generated On: 26 Nov 2020 10:51:05**

Yes <input type="checkbox"/>	
PC Time stamp	10 SEP 2020 19:08
PC Open Date & Time	10 SEP 2020 12:00
PC Close Date & Time	11 SEP 2020 11:59

US3312046

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 26 Nov 2020 10:51:05

**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 ☒

US3312046

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 26 Nov 2020 10:51:05

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

US3312046

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 26 Nov 2020 10:51:05

**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 ☒

US3312046

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 26 Nov 2020 10:51:05

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

US3312046

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 26 Nov 2020 10:51:05

**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 ☒

US3312046

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 26 Nov 2020 10:51:05

Yes <input type="checkbox"/>	
PC Time stamp	13 SEP 2020 18:43
PC Open Date & Time	13 SEP 2020 12:00
PC Close Date & Time	14 SEP 2020 11:59



US3312046

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 26 Nov 2020 10:51:05

**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 ☒

US3312046

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 26 Nov 2020 10:51:05

Yes <input type="checkbox"/>	
PC Time stamp	14 SEP 2020 19:07
PC Open Date & Time	14 SEP 2020 12:00
PC Close Date & Time	15 SEP 2020 11:59

US3312046

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 26 Nov 2020 10:51:05

**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 ☒

US3312046

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 26 Nov 2020 10:51:05

Yes <input type="checkbox"/>	
PC Time stamp	15 SEP 2020 20:35
PC Open Date & Time	15 SEP 2020 12:00
PC Close Date & Time	16 SEP 2020 11:59

US3312046

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 26 Nov 2020 10:51:05

Was Contact Attempted?

Yes ☒

No ☐

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

16 SEP 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

*If Contact Not Made, please provide Comments*

US3312046

Folder: Safety Call Day 36 (1)

Form: Continuing

Generated On: 26 Nov 2020 10:51:05

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3312046

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 26 Nov 2020 10:51:05

Was Contact Attempted?

Yes ☒

No ☐

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

23 SEP 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

*If Contact Not Made, please provide Comments*

US3312046

Folder: Safety Call Day 43 (1)

Form: Continuing

Generated On: 26 Nov 2020 10:51:05

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1



US3312046

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 26 Nov 2020 10:51:05

Was Contact Attempted?

Yes ☒

No ☐

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

30 SEP 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

*If Contact Not Made, please provide Comments*

US3312046

Folder: Safety Call Day 50 (1)

Form: Continuing

Generated On: 26 Nov 2020 10:51:05

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3312046

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 26 Nov 2020 10:51:05

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

Visit date (dd MMM yyyy)	
--------------------------	--

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

Folder OID	VISIT3
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US3312046

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 10:51:05

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

US3312046

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Generated On: 26 Nov 2020 10:51:05

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.*

US3312046

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 10:51:05

Was the sample collected?

Yes ☐

No ☒

Collection date (*dd MMM yyyy*)

Collection time (*00:00-23:59*)

Collection date and time (derived)

US3312046

Folder: Visit 3 Day 57 (1)

Form: Continuing

Generated On: 26 Nov 2020 10:51:05

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3312046

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:51:05

**TIMEPOINT**

DAY 71

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

23 OCT 2020 18:04:37

Patient Cloud Open Date & Time

19 OCT 2020 00:01

Patient Cloud Close Date & Time

23 OCT 2020 23:59



US3312046

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:51:05

**TIMEPOINT**

DAY 78

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

26 OCT 2020 13:10:15

Patient Cloud Open Date & Time

26 OCT 2020 00:01

Patient Cloud Close Date & Time

30 OCT 2020 23:59

US3312046

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:51:05

**TIMEPOINT**

DAY 92

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

09 NOV 2020 06:35:47

Patient Cloud Open Date & Time

09 NOV 2020 00:01

Patient Cloud Close Date & Time

13 NOV 2020 23:59

US3312046

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:51:05

**TIMEPOINT**

DAY 99

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

18 NOV 2020 16:52:06

Patient Cloud Open Date & Time

16 NOV 2020 00:01

Patient Cloud Close Date & Time

20 NOV 2020 23:59

US3312046

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:51:05

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

**US3312046**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:51:05**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm 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>	09 OCT 2020 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	13 OCT 2020 23:59

US3312046

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:51:05

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

**US3312046**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:51:05**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

16 OCT 2020 00:01

[Patient Cloud Close Date & Time](#)

20 OCT 2020 23:59

US3312046

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:51:05

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"/>



**US3312046**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:51:05**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
<a href="#">Patient Cloud Open Date &amp; Time</a>	23 OCT 2020 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	27 OCT 2020 23:59

US3312046

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:51:05

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="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"/>

**US3312046**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:51:05**

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

[Patient Cloud Close Date & Time](#)

03 NOV 2020 23:59

US3312046

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:51:05

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="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"/>

**US3312046**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:51:05**

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

06 NOV 2020 00:01

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[Patient Cloud Close Date & Time](#)

10 NOV 2020 23:59

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US3312046

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:51:05

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

**US3312046**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:51:05**

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

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[Patient Cloud Close Date & Time](#)

17 NOV 2020 23:59

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US3312046

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:51:05

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"/>



**US3312046**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:51:05**

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

US3312046

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:51:05

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"/>

**US3312046**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:51:05**

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

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[Patient Cloud Close Date & Time](#)

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01 DEC 2020 23:59

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US3312046

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:51:05

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"/>

**US3312046**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:51:05**

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

[Patient Cloud Close Date & Time](#)

08 DEC 2020 23:59

US3312046

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:51:05

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

**US3312046**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:51:05**

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

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[Patient Cloud Close Date & Time](#)

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15 DEC 2020 23:59

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US3312046

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:51:05

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



**US3312046**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:51:05**

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

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[Patient Cloud Close Date & Time](#)

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22 DEC 2020 23:59

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US3312046

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:51:05

**TIMEPOINT**

DAY 138

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

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

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

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

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

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

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

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

**US3312046**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:51:05**

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

[Patient Cloud Close Date & Time](#)

29 DEC 2020 23:59

US3312046

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:51:05

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"/>

**US3312046**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:51:05**

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

[Patient Cloud Close Date & Time](#)

05 JAN 2021 23:59

US3312046

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:51:05

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"/>

**US3312046**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:51:05**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm 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 JAN 2021 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	12 JAN 2021 23:59

US3312046

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:51:05

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



**US3312046**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:51:05**

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

US3312046

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:51:05

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"/>

**US3312046**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:51:05**

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

22 JAN 2021 00:01

[Patient Cloud Close Date & Time](#)

26 JAN 2021 23:59

US3312046

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:51:05

**TIMEPOINT**

DAY 173

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

**US3312046**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:51:05**

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

[Patient Cloud Close Date & Time](#)

02 FEB 2021 23:59

US3312046

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:51:05

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"/>

**US3312046**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:51:05**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm 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 2021 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	09 FEB 2021 23:59

US3312046

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:51:05

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



**US3312046**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:51:05**

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

US3312046

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:51:05

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"/>

**US3312046**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:51:05**

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

[Patient Cloud Close Date & Time](#)

23 FEB 2021 23:59

US3312046

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:51:05

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"/>

**US3312046**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:51:05**

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

[Patient Cloud Close Date & Time](#)

02 MAR 2021 23:59

US3312046

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:51:05

TIMEPOINT

DAY 208

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

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

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

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

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

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

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

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

**US3312046**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:51:05**

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

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[Patient Cloud Close Date & Time](#)

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09 MAR 2021 23:59

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US3312046

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:51:05

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"/>



**US3312046**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:51:05**

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

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[Patient Cloud Close Date & Time](#)

16 MAR 2021 23:59

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US3312046

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:51:05

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"/>

**US3312046**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:51:05**

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

[Patient Cloud Close Date & Time](#)

23 MAR 2021 23:59

US3312046

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:51:05

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

**US3312046**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:51:05**

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

[Patient Cloud Close Date & Time](#)

30 MAR 2021 23:59

US3312046

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:51:05

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"/>

**US3312046**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:51:05**

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

[Patient Cloud Close Date & Time](#)

06 APR 2021 23:59

US3312046

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:51:05

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"/>



**US3312046**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:51:05**

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

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[Patient Cloud Open Date & Time](#)

09 APR 2021 00:01

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[Patient Cloud Close Date & Time](#)

13 APR 2021 23:59

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US3312046

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:51:05

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="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"/>

**US3312046**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:51:05**

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

[Patient Cloud Close Date & Time](#)

20 APR 2021 23:59

US3312046

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:51:05

**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 ☐

**US3312046**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:51:05**

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

[Patient Cloud Close Date & Time](#)

27 APR 2021 23:59

US3312046

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:51:05

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"/>

**US3312046**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:51:05**

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

[Patient Cloud Close Date & Time](#)

04 MAY 2021 23:59

US3312046

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:51:05

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



**US3312046**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:51:05**

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

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[Patient Cloud Close Date & Time](#)

11 MAY 2021 23:59

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US3312046

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:51:05

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"/>

**US3312046**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:51:05**

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

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[Patient Cloud Close Date & Time](#)

18 MAY 2021 23:59

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US3312046

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:51:05

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"/>

**US3312046**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:51:05**

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

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[Patient Cloud Close Date & Time](#)

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25 MAY 2021 23:59

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US3312046

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:51:05

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

**US3312046**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:51:05**

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

[Patient Cloud Close Date & Time](#)

01 JUN 2021 23:59

US3312046

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:51:05

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"/>



**US3312046**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:51:05**

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

[Patient Cloud Close Date & Time](#)

08 JUN 2021 23:59

US3312046

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:51:05

**TIMEPOINT**

DAY 306

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

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

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

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

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

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

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

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

**US3312046**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:51:05**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

11 JUN 2021 00:01

[Patient Cloud Close Date & Time](#)

15 JUN 2021 23:59

US3312046

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:51:05

**TIMEPOINT**

DAY 313

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

**US3312046**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:51:05**

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

18 JUN 2021 00:01

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[Patient Cloud Close Date & Time](#)

22 JUN 2021 23:59

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US3312046

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:51:05

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

**US3312046**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:51:05**

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

US3312046

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:51:05

TIMEPOINT

DAY 327

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

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

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

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

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

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



**US3312046**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:51:05**

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

[Patient Cloud Close Date & Time](#)

06 JUL 2021 23:59

US3312046

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:51:05

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

**US3312046**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:51:05**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm 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>	09 JUL 2021 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	13 JUL 2021 23:59

US3312046

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:51:05

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

**US3312046**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:51:05**

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

[Patient Cloud Close Date & Time](#)

20 JUL 2021 23:59

US3312046

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:51:05

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"/>

**US3312046**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:51:05**

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

[Patient Cloud Close Date & Time](#)

27 JUL 2021 23:59

US3312046

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:51:05

**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 ☐



**US3312046**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:51:05**

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

[Patient Cloud Close Date & Time](#)

03 AUG 2021 23:59

US3312046

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:51:05

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"/>

**US3312046**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:51:05**

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

[Patient Cloud Close Date & Time](#)

10 AUG 2021 23:59

US3312046

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:51:05

**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 ☐

**US3312046**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:51:05**

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

[Patient Cloud Close Date & Time](#)

17 AUG 2021 23:59

US3312046

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:51:05

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

**US3312046**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:51:05**

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

[Patient Cloud Close Date & Time](#)

24 AUG 2021 23:59

US3312046

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:51:05

**TIMEPOINT**

DAY 383

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

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

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

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

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

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

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

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



**US3312046**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:51:05**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm 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>	27 AUG 2021 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	31 AUG 2021 23:59

US3312046

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:51:05

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

**US3312046**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:51:05**

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

[Patient Cloud Close Date & Time](#)

07 SEP 2021 23:59

US3312046

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:51:05

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 ☐

**US3312046**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:51:05**

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

10 SEP 2021 00:01

[Patient Cloud Close Date & Time](#)

14 SEP 2021 23:59

US3312046

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:51:05

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"/>

**US3312046**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:51:05**

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

[Patient Cloud Close Date & Time](#)

21 SEP 2021 23:59

US3312046

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:51:05

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



**US3312046**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:51:05**

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

US3312046

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:51:05

**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 ☐  
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 ☐

**US3312046**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:51:05**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm 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 2021 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	05 OCT 2021 23:59

US3312046

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:51:05

**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 ☐

**US3312046**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:51:05**

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

[Patient Cloud Close Date & Time](#)

12 OCT 2021 23:59

US3312046

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:51:05

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"/>

**US3312046**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:51:05**

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

US3312046

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:51:05

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"/>



**US3312046**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:51:05**

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

22 OCT 2021 00:01

[Patient Cloud Close Date & Time](#)

26 OCT 2021 23:59

US3312046

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:51:05

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

**US3312046**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:51:05**

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

[Patient Cloud Close Date & Time](#)

02 NOV 2021 23:59

US3312046

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:51:05

TIMEPOINT	DAY 453
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$ )	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>

**US3312046**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:51:05**

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

[Patient Cloud Close Date & Time](#)

09 NOV 2021 23:59

US3312046

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:51:05

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"/>

**US3312046**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:51:05**

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

[Patient Cloud Close Date & Time](#)

16 NOV 2021 23:59

US3312046

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:51:05

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



**US3312046**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:51:05**

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

[Patient Cloud Close Date & Time](#)

23 NOV 2021 23:59

US3312046

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:51:05

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="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"/>

**US3312046**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:51:05**

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

[Patient Cloud Close Date & Time](#)

30 NOV 2021 23:59

US3312046

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:51:05

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="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"/>

**US3312046**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:51:05**

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

[Patient Cloud Close Date & Time](#)

07 DEC 2021 23:59

US3312046

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:51:05

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"/>

**US3312046**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:51:05**

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

US3312046

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:51:05

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



**US3312046**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:51:05**

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

US3312046

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:51:05

**TIMEPOINT**

DAY 502

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

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

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

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

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

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

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

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

**US3312046**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:51:05**

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

US3312046

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:51:05

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 <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"/>

**US3312046**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:51:05**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm 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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31 DEC 2021 00:01

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[Patient Cloud Close Date & Time](#)

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04 JAN 2022 23:59

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US3312046

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:51:05

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

**US3312046**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:51:05**

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

[Patient Cloud Close Date & Time](#)

11 JAN 2022 23:59

US3312046

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:51:05

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 ☐



**US3312046**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:51:05**

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

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[Patient Cloud Close Date & Time](#)

18 JAN 2022 23:59

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US3312046

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:51:05

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

**US3312046**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:51:05**

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

US3312046

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:51:05

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 ☐

**US3312046**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:51:05**

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

[Patient Cloud Close Date & Time](#)

01 FEB 2022 23:59

US3312046

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:51:05

**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 ☐

**US3312046**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:51:05**

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

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[Patient Cloud Open Date & Time](#)

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04 FEB 2022 00:01

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[Patient Cloud Close Date & Time](#)

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08 FEB 2022 23:59

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US3312046

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:51:05

**TIMEPOINT**

DAY 551

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

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

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

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

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

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

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

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



**US3312046**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:51:05**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

11 FEB 2022 00:01

[Patient Cloud Close Date & Time](#)

15 FEB 2022 23:59

US3312046

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:51:05

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 ☐

**US3312046**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:51:05**

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

18 FEB 2022 00:01

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[Patient Cloud Close Date & Time](#)

22 FEB 2022 23:59

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US3312046

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:51:05

**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 ☐

**US3312046**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:51:05**

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

[Patient Cloud Close Date & Time](#)

01 MAR 2022 23:59

US3312046

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:51:05

**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 ☐

**US3312046**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:51:05**

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

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[Patient Cloud Open Date & Time](#)

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04 MAR 2022 00:01

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[Patient Cloud Close Date & Time](#)

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08 MAR 2022 23:59

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US3312046

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:51:05

**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 ☐



**US3312046**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:51:05**

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

US3312046

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:51:05

TIMEPOINT	DAY 586
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$ )	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>

**US3312046**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:51:05**

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

[Patient Cloud Close Date & Time](#)

22 MAR 2022 23:59

US3312046

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:51:05

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 ☐

**US3312046**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:51:05**

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

US3312046

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:51:05

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"/>

**US3312046**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:51:05**

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

US3312046

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:51:05

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"/>



**US3312046**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:51:05**

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

[Patient Cloud Close Date & Time](#)

12 APR 2022 23:59

US3312046

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:51:05

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

**US3312046**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:51:05**

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

15 APR 2022 00:01

[Patient Cloud Close Date & Time](#)

19 APR 2022 23:59

US3312046

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:51:05

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"/>

**US3312046**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:51:05**

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

22 APR 2022 00:01

[Patient Cloud Close Date & Time](#)

26 APR 2022 23:59

US3312046

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:51:05

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="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"/>

**US3312046**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:51:05**

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

[Patient Cloud Close Date & Time](#)

03 MAY 2022 23:59

US3312046

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:51:05

TIMEPOINT

DAY 635

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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



**US3312046**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:51:05**

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

[Patient Cloud Close Date & Time](#)

10 MAY 2022 23:59

US3312046

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:51:05

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

**US3312046**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:51:05**

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

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[Patient Cloud Open Date & Time](#)

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13 MAY 2022 00:01

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[Patient Cloud Close Date & Time](#)

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17 MAY 2022 23:59

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US3312046

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:51:05

**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 ☐  
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 ☐

**US3312046**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:51:05**

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

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[Patient Cloud Open Date & Time](#)

20 MAY 2022 00:01

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[Patient Cloud Close Date & Time](#)

24 MAY 2022 23:59

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US3312046

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:51:05

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

**US3312046**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:51:05**

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

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[Patient Cloud Close Date & Time](#)

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31 MAY 2022 23:59

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US3312046

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:51:05

**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 ☐



**US3312046**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:51:05**

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

[Patient Cloud Close Date & Time](#)

07 JUN 2022 23:59

US3312046

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:51:05

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

**US3312046**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:51:05**

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

10 JUN 2022 00:01

[Patient Cloud Close Date & Time](#)

14 JUN 2022 23:59

US3312046

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:51:05

TIMEPOINT

DAY 677

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

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

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

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

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

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

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

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

**US3312046**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:51:05**

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

[Patient Cloud Close Date & Time](#)

21 JUN 2022 23:59

US3312046

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:51:05

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"/>

**US3312046**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:51:05**

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

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[Patient Cloud Open Date & Time](#)

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24 JUN 2022 00:01

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[Patient Cloud Close Date & Time](#)

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28 JUN 2022 23:59

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US3312046

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:51:05

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"/>



**US3312046**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:51:05**

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

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[Patient Cloud Close Date & Time](#)

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05 JUL 2022 23:59

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US3312046

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:51:05

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"/>

**US3312046**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:51:05**

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

US3312046

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:51:05

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"/>

**US3312046**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:51:05**

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

US3312046

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:51:05

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

**US3312046**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:51:05**

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

22 JUL 2022 00:01

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26 JUL 2022 23:59

US3312046

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:51:05

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



**US3312046**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:51:05**

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

[Patient Cloud Close Date & Time](#)

02 AUG 2022 23:59

US3312046

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:51:05

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"/>

**US3312046**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:51:05**

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

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09 AUG 2022 23:59

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US3312046

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:51:05

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"/>

**US3312046**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:51:05**

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

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16 AUG 2022 23:59

US3312046

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:51:05

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

**US3312046**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:51:05**

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

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23 AUG 2022 23:59

US3312046

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:51:05

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"/>



**US3312046**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:51:05**

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

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30 AUG 2022 23:59

US3312046

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:51:05

**TIMEPOINT**

DAY 754

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

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

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

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

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

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

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

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

**US3312046**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:51:05**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm 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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02 SEP 2022 00:01

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06 SEP 2022 23:59

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US3312046

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:51:05

**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 ☐  
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 ☐

**US3312046**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:51:05**

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

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[Patient Cloud Open Date & Time](#)

09 SEP 2022 00:01

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13 SEP 2022 23:59

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US3312046

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:51:05

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"/>

**US3312046**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:51:05**

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

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16 SEP 2022 00:01

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20 SEP 2022 23:59

US3312046

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:51:05

**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 ☐



**US3312046**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:51:05**

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

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27 SEP 2022 23:59

US3312046

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:51:05

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"/>

**US3312046**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:51:05**

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

[Patient Cloud Close Date & Time](#)

04 OCT 2022 23:59

US3312046

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:51:05

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

**US3312046**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:51:05**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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>	07 OCT 2022 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	11 OCT 2022 23:59

US3312046

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:51:05

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

**US3312046**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:51:05**

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

[Patient Cloud Close Date & Time](#)

18 OCT 2022 23:59

US3312046

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 26 Nov 2020 10:51:05

Was Contact Attempted?

Yes ☒

No ☐

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

4 NOV 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

*If Contact Not Made, please provide Comments*



US3312046

Folder: Safety Call Day 85 (1)

Form: Continuing

Generated On: 26 Nov 2020 10:51:05

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

**US3312046**

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

**Form: Safety Call**

**Generated On: 26 Nov 2020 10:51:05**

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*

**US3312046**

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

**Form: Continuing**

**Generated On: 26 Nov 2020 10:51:05**

Is the participant continuing to the next visit?

Yes ☐

No ☐

Continuing Flag

US3312046

Folder: Covid-19 Assessment 13 Oct 2020

Form: COVID-19 Contact

Generated On: 26 Nov 2020 10:51:05

Date of Contact	13 OCT 2020
Time of Contact	16:10
Date and Time of Contact (derived)	13 OCT 2020 16:10
Type of Contact	Clinic Visit - Scheduled <input type="checkbox"/>
	Clinical Visit - Unscheduled <input type="checkbox"/>
	Safety Call <input checked="" type="radio"/>
	Convalescent Tele-visit <input type="checkbox"/>
Has the subject reported symptoms of SARS-COV-2?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>

US3312046

Folder: Covid-19 Assessment 13 Oct 2020

Form: Symptom Log (1)

Generated On: 26 Nov 2020 10:51:05

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"/>

US3312046

Folder: Covid-19 Assessment 13 Oct 2020

Form: Symptom Log (1)

Generated On: 26 Nov 2020 10:51:05

	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	07 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 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 type="radio"/>
v6.020 DTW (1102)	341 of 2431	

US3312046

Folder: Covid-19 Assessment 13 Oct 2020

Form: Symptom Log (1)

Generated On: 26 Nov 2020 10:51:05

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

US3312046

Folder: Covid-19 Assessment 13 Oct 2020

Form: Symptom Log (1)

Generated On: 26 Nov 2020 10:51:05

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



US3312046

Folder: Covid-19 Assessment 13 Oct 2020

Form: Symptom Log (2)

Generated On: 26 Nov 2020 10:51:05

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"/>

US3312046

Folder: Covid-19 Assessment 13 Oct 2020

Form: Symptom Log (2)

Generated On: 26 Nov 2020 10:51:05

	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	08 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 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 type="radio"/>
v6.020 DTW (1102)	345 of 2431	

US3312046

Folder: Covid-19 Assessment 13 Oct 2020

Form: Symptom Log (2)

Generated On: 26 Nov 2020 10:51:05

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

US3312046

Folder: Covid-19 Assessment 13 Oct 2020

Form: Symptom Log (2)

Generated On: 26 Nov 2020 10:51:05

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

US3312046

Folder: Covid-19 Assessment 13 Oct 2020

Form: Symptom Log (3)

Generated On: 26 Nov 2020 10:51:05

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"/>

US3312046

Folder: Covid-19 Assessment 13 Oct 2020

Form: Symptom Log (3)

Generated On: 26 Nov 2020 10:51:05

	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	09 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 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 type="radio"/>
v6.020 DTW (1102)	349 of 2431	

US3312046

Folder: Covid-19 Assessment 13 Oct 2020

Form: Symptom Log (3)

Generated On: 26 Nov 2020 10:51:05

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

US3312046

Folder: Covid-19 Assessment 13 Oct 2020

Form: Symptom Log (3)

Generated On: 26 Nov 2020 10:51:05

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



US3312046

Folder: Covid-19 Assessment 13 Oct 2020

Form: Symptom Log (4)

Generated On: 26 Nov 2020 10:51:05

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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Folder: Covid-19 Assessment 13 Oct 2020

Form: Symptom Log (4)

Generated On: 26 Nov 2020 10:51:05

	Day 34	<input type="checkbox"/>
	Day 35	<input type="checkbox"/>
	Day 36	<input type="checkbox"/>
	Day 37	<input type="checkbox"/>
	Day 38	<input type="checkbox"/>
	Day 39	<input type="checkbox"/>
	Day 40	<input type="checkbox"/>
Date	10 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 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 type="radio"/>
v6.020 DTW (1102)	353 of 2431	

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Form: Symptom Log (4)

Generated On: 26 Nov 2020 10:51:05

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

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Folder: Covid-19 Assessment 13 Oct 2020

Form: Symptom Log (4)

Generated On: 26 Nov 2020 10:51:05

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

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Folder: Covid-19 Assessment 13 Oct 2020

Form: Symptom Log (5)

Generated On: 26 Nov 2020 10:51:05

Symptom Day

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

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Folder: Covid-19 Assessment 13 Oct 2020

Form: Symptom Log (5)

Generated On: 26 Nov 2020 10:51:05

	Day 34	<input type="checkbox"/>
	Day 35	<input type="checkbox"/>
	Day 36	<input type="checkbox"/>
	Day 37	<input type="checkbox"/>
	Day 38	<input type="checkbox"/>
	Day 39	<input type="checkbox"/>
	Day 40	<input type="checkbox"/>
Date	11 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 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 type="radio"/>
v6.020 DTW (1102)	357 of 2431	

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Form: Symptom Log (5)

Generated On: 26 Nov 2020 10:51:05

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

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Folder: Covid-19 Assessment 13 Oct 2020

Form: Symptom Log (5)

Generated On: 26 Nov 2020 10:51:05

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



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Form: Symptom Log (6)

Generated On: 26 Nov 2020 10:51:05

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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Folder: Covid-19 Assessment 13 Oct 2020

Form: Symptom Log (6)

Generated On: 26 Nov 2020 10:51:05

	Day 34	<input type="checkbox"/>
	Day 35	<input type="checkbox"/>
	Day 36	<input type="checkbox"/>
	Day 37	<input type="checkbox"/>
	Day 38	<input type="checkbox"/>
	Day 39	<input type="checkbox"/>
	Day 40	<input type="checkbox"/>
Date	12 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 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 type="radio"/>
v6.020 DTW (1102)	361 of 2431	

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Form: Symptom Log (6)

Generated On: 26 Nov 2020 10:51:05

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

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Form: Symptom Log (6)

Generated On: 26 Nov 2020 10:51:05

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

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Form: Symptom Log (7)

Generated On: 26 Nov 2020 10:51:05

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 10:51:05

	Day 34	<input type="checkbox"/>
	Day 35	<input type="checkbox"/>
	Day 36	<input type="checkbox"/>
	Day 37	<input type="checkbox"/>
	Day 38	<input type="checkbox"/>
	Day 39	<input type="checkbox"/>
	Day 40	<input type="checkbox"/>
Date	13 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 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 type="radio"/>
v6.020 DTW (1102)	365 of 2431	

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Form: Symptom Log (7)

Generated On: 26 Nov 2020 10:51:05

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

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Folder: Covid-19 Assessment 13 Oct 2020

Form: Symptom Log (7)

Generated On: 26 Nov 2020 10:51:05

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



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Folder: Covid-19 Assessment 13 Oct 2020

Form: Symptom Log (8)

Generated On: 26 Nov 2020 10:51:05

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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Folder: Covid-19 Assessment 13 Oct 2020

Form: Symptom Log (8)

Generated On: 26 Nov 2020 10:51:05

	Day 34	<input type="checkbox"/>
	Day 35	<input type="checkbox"/>
	Day 36	<input type="checkbox"/>
	Day 37	<input type="checkbox"/>
	Day 38	<input type="checkbox"/>
	Day 39	<input type="checkbox"/>
	Day 40	<input type="checkbox"/>
Date	14 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 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 type="radio"/>
v6.020 DTW (1102)	369 of 2431	

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Form: Symptom Log (8)

Generated On: 26 Nov 2020 10:51:05

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

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Form: Symptom Log (8)

Generated On: 26 Nov 2020 10:51:05

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

US3312046

Folder: Covid-19 Assessment 13 Oct 2020

Form: Symptom Log (9)

Generated On: 26 Nov 2020 10:51:05

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"/>

US3312046

Folder: Covid-19 Assessment 13 Oct 2020

Form: Symptom Log (9)

Generated On: 26 Nov 2020 10:51:05

	Day 34	<input type="checkbox"/>
	Day 35	<input type="checkbox"/>
	Day 36	<input type="checkbox"/>
	Day 37	<input type="checkbox"/>
	Day 38	<input type="checkbox"/>
	Day 39	<input type="checkbox"/>
	Day 40	<input type="checkbox"/>
Date	15 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 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 type="radio"/>
v6.020 DTW (1102)	373 of 2431	

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Folder: Covid-19 Assessment 13 Oct 2020

Form: Symptom Log (9)

Generated On: 26 Nov 2020 10:51:05

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

US3312046

Folder: Covid-19 Assessment 13 Oct 2020

Form: Symptom Log (9)

Generated On: 26 Nov 2020 10:51:05

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



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Folder: Covid-19 Assessment 13 Oct 2020

Form: Symptom Log (10)

Generated On: 26 Nov 2020 10:51:05

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 13 Oct 2020

Form: Symptom Log (10)

Generated On: 26 Nov 2020 10:51:05

	Day 34	<input type="checkbox"/>
	Day 35	<input type="checkbox"/>
	Day 36	<input type="checkbox"/>
	Day 37	<input type="checkbox"/>
	Day 38	<input type="checkbox"/>
	Day 39	<input type="checkbox"/>
	Day 40	<input type="checkbox"/>
Date	16 OCT 2020	
Assessment Not Done	False	
O2 Saturation	99 %	
O2 Saturation Units	%	
Temperature	97.2 F	
Chills	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Cough	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Shortness of Breath	None	<input 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)	377 of 2431	

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Form: Symptom Log (10)

Generated On: 26 Nov 2020 10:51:05

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

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Folder: Covid-19 Assessment 13 Oct 2020

Form: Symptom Log (10)

Generated On: 26 Nov 2020 10:51:05

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

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Folder: Covid-19 Assessment 13 Oct 2020

Form: Symptom Log (11)

Generated On: 26 Nov 2020 10:51:05

[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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Folder: Covid-19 Assessment 13 Oct 2020

Form: Symptom Log (11)

Generated On: 26 Nov 2020 10:51:05

	Day 34	<input type="checkbox"/>
	Day 35	<input type="checkbox"/>
	Day 36	<input type="checkbox"/>
	Day 37	<input type="checkbox"/>
	Day 38	<input type="checkbox"/>
	Day 39	<input type="checkbox"/>
	Day 40	<input type="checkbox"/>
Date	17 OCT 2020	
Assessment Not Done	False	
O2 Saturation	97 %	
O2 Saturation Units	%	
Temperature	96.8 F	
Chills	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Cough	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Shortness of Breath	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Difficulty Breathing	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Fatigue	None	<input type="radio"/>
v6.020 DTW (1102)	381 of 2431	

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Form: Symptom Log (11)

Generated On: 26 Nov 2020 10:51:05

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

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Form: Symptom Log (11)

Generated On: 26 Nov 2020 10:51:05

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



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Folder: Covid-19 Assessment 13 Oct 2020

Form: Symptom Log (12)

Generated On: 26 Nov 2020 10:51:05

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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Form: Symptom Log (12)

Generated On: 26 Nov 2020 10:51:05

	Day 34	<input type="checkbox"/>
	Day 35	<input type="checkbox"/>
	Day 36	<input type="checkbox"/>
	Day 37	<input type="checkbox"/>
	Day 38	<input type="checkbox"/>
	Day 39	<input type="checkbox"/>
	Day 40	<input type="checkbox"/>
Date	18 OCT 2020	
Assessment Not Done	False	
O2 Saturation	96 %	
O2 Saturation Units	%	
Temperature	96.8 F	
Chills	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Cough	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Shortness of Breath	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Difficulty Breathing	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Fatigue	None	<input type="radio"/>
v6.020 DTW (1102)	385 of 2431	

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Folder: Covid-19 Assessment 13 Oct 2020

Form: Symptom Log (12)

Generated On: 26 Nov 2020 10:51:05

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

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Folder: Covid-19 Assessment 13 Oct 2020

Form: Symptom Log (12)

Generated On: 26 Nov 2020 10:51:05

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

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Folder: Covid-19 Assessment 13 Oct 2020

Form: Symptom Log (13)

Generated On: 26 Nov 2020 10:51:05

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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Folder: Covid-19 Assessment 13 Oct 2020

Form: Symptom Log (13)

Generated On: 26 Nov 2020 10:51:05

	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	96 %	
O2 Saturation Units	%	
Temperature	96.8 F	
Chills	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Cough	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Shortness of Breath	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Difficulty Breathing	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Fatigue	None	<input type="radio"/>
v6.020 DTW (1102)	389 of 2431	

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Form: Symptom Log (13)

Generated On: 26 Nov 2020 10:51:05

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

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Folder: Covid-19 Assessment 13 Oct 2020

Form: Symptom Log (13)

Generated On: 26 Nov 2020 10:51:05

	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Runny Nose (Rhinorrhea)	None	<input type="checkbox"/>
	Mild	<input checked="" type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Nausea	None	<input checked="" type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Vomiting	None	<input checked="" type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Diarrhea	None	<input 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 13 Oct 2020

Form: Symptom Log (14)

Generated On: 26 Nov 2020 10:51:05

[Symptom Day](#)

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

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Folder: Covid-19 Assessment 13 Oct 2020

Form: Symptom Log (14)

Generated On: 26 Nov 2020 10:51:05

	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	98 %	
O2 Saturation Units	%	
Temperature	97.2 F	
Chills	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Cough	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Shortness of Breath	None	<input 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"/>
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Folder: Covid-19 Assessment 13 Oct 2020

Form: Symptom Log (14)

Generated On: 26 Nov 2020 10:51:05

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

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Folder: Covid-19 Assessment 13 Oct 2020

Form: Symptom Log (14)

Generated On: 26 Nov 2020 10:51:05

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

US3312046

Folder: Covid-19 Assessment 13 Oct 2020

Form: COVID Diagnostic Test

Generated On: 26 Nov 2020 10:51:05

Date of Visit	16 OCT 2020
Was the Subject Tested For SARS-CoV-2 by RT-PCR?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Did Subject Test Positive For SARS-CoV-2 by RT-PCR?	Yes <input type="radio"/> No <input checked="" type="radio"/>
Date of Test	16 OCT 2020
Type of Test Performed	Nasopharyngeal Swab <input checked="" type="radio"/> Nasal Swab <input type="radio"/> Saliva Test <input type="radio"/> Other <input type="radio"/>
Other, specify _____	
Was this diagnostic test performed at a lab other than the Study Central Lab?	Yes <input type="radio"/> No <input checked="" type="radio"/>
If yes, provide lab information below	
Lab/ Institution Test Performed	_____
CLIA Certified?	Yes <input type="radio"/> No <input type="radio"/>
COVID-19 Positive (CSA Programming Field Only)	0

US3312046

Folder: Covid-19 Assessment 13 Oct 2020

Form: Generate Next COVID-19 Assessment

Generated On: 26 Nov 2020 10:51:05

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[Generate Next COVID-19 Assessment](#)

Yes ☐

No ☒

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**US3312046**

**Folder: Illness Visit (1)**

**Form: Saliva Collection**

**Generated On: 26 Nov 2020 10:51:05**

Visit	Was Saliva Collected?	Date of Collection
Day 3	Yes	18 OCT 2020
Day 5	Yes	20 OCT 2020
Day 7	NA (COVID-19 Negative)	
Day 9	NA (COVID-19 Negative)	
Day 14	NA (COVID-19 Negative)	
Day 21	NA (COVID-19 Negative)	
Day 28	NA (COVID-19 Negative)	

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Folder: Illness Visit Day 1 (1)

Form: Visit Date

Generated On: 26 Nov 2020 10:51:05

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	16 OCT 2020
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	SICKD1



US3312046

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 10:51:05

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment ( <i>dd MMM yyyy</i> )	16 OCT 2020
Time of assessment ( <i>00:00-23:59</i> )	09:40 (24 HR)
Vital Signs Date and Time (derived)	16 OCT 2020 09:40
Height ( <i>xxx.x</i> )	63 in
Weight ( <i>xxx.x</i> )	140 lb
Temperature ( <i>xxx.x</i> )	97.2 F
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse ( <i>xxx</i> )	59 beats/min
Pulse units	BPM
Respiratory Rate ( <i>xxx</i> )	14 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure ( <i>xxx</i> )	134 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure ( <i>xxx</i> )	76 mmHg
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

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Folder: Illness Visit Day 1 (1)

Form: Physical Examination

Generated On: 26 Nov 2020 10:51:05

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

16 OCT 2020

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

US3312046

Folder: Illness Visit Day 1 (1)

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

Generated On: 26 Nov 2020 10:51:05

Was Blood Sample Taken for Immunologic Assessment of  
SARS\_COV-2 Infection?

Yes ☒

No ☐

NA (COVID-19 Negative) ☐

Date of Collection

16 OCT 2020

US3312046

Folder: Convalescence Visit Day 28 (1)

Form: Visit Date

Generated On: 26 Nov 2020 10:51:05

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

Visit date (dd MMM yyyy)	
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Was visit performed at the participant's home or at the clinic?	Home <input type="checkbox"/>
	Clinic <input type="checkbox"/>

Folder OID	SICKD28
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US3312046

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 10:51:05

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

US3312046

Folder: Convalescence Visit Day 28 (1)

Form: Physical Examination

Generated On: 26 Nov 2020 10:51:05

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: Convalescence Visit Day 28 (1)

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

Generated On: 26 Nov 2020 10:51:05

Was Blood Sample Taken for Immunologic Assessment of  
SARS\_COV-2 Infection?

Yes ☐

No ☒

NA (COVID-19 Negative) ☐

Date of Collection

US3312046

Folder: Adverse Events

Form: Adverse Events Summary

Generated On: 26 Nov 2020 10:51:05

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Did the participant experience any adverse events?

Yes ☒

No ☐

---

If Yes, enter details on the Adverse Events form.

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US3312046

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 10:51:05

AEID	USA-US300-2020-MRNA-1273-P30 1000005
Adverse event	VIRAL PHARYNGITIS
Was this a medically-attended AE?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Was this a Solicited Adverse Reaction?	Yes <input type="radio"/> No <input checked="" type="radio"/>
Is this event a confirmed diagnosis of Symptomatic Covid-19?	Yes <input type="radio"/> No <input checked="" type="radio"/>
Start date (dd MMM yyyy)	07 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)	15 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 checked="" type="radio"/> Grade 3/Severe <input 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)	07 OCT 2020
Hospital Discharge Date (dd MMM yyyy)	09 OCT 2020
Admitted to ICU?	Yes <input type="radio"/> No <input checked="" type="radio"/> Unknown <input type="radio"/>
Number of Days in ICU	
v6.020 DTW (1102)	408 of 2431

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 10:51:05

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	

US3312046

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 10:51:05

---

SUBJECT CALLED 10/7/2020 TO REPORT SYMPTOMS OF LOW GRADE FEVER (100 DEGREES FARENHEIT), MILD SORE THROAT AND MILD NAUSEA THAT HAD BEGUN AT 0300 THAT DAY. SYMPTOMS DID NOT MEET ILLNESS VISIT CRITERIA AT THAT TIME AND SUBJECT WAS INSTRUCTED TO CALL BACK WITH WORSENING; D57 VISIT APPOINTMENT WAS RESCHEDULED TO A LATER DATE. ATTEMPTS TO FOLLOW-UP WITH SUBJECT TO ASSESS NEED FOR ILLNESS VISIT WERE UNSUCCESSFUL.

ON 10/13/2020, SUBJECT REPORTED (VIA TELEPHONE) A HOSPITALIZATION FOR "INFECTION. " SUBJECT HAD GONE IN TO ER ON 10/7/2020, DUE TO FEVER (TEMPERATURE 101 DEGREES FARENHEIT), AND ADMITTED. PER SUBJECT'S VERBAL REPORT SHE RECEIVED IV HYDRATION, ACETAMINOPHEN AND IBUPROFEN AND WAS TESTED FOR COVID-19 AND INFLUENZA WHICH WERE BOTH NEGATIVE.

AN ELEVATED TOTAL WBC WAS IDENTIFIED. AT TIME OF CALL, 10/13/2020, SUBJECT CONTINUED TO FEEL FATIGUED WITH LAST FEVER REPORTED ON 10/12/2020. SHE

US3312046

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 10:51:05

---

IS SCHEDULED TO FOLLOW-UP  
WITH PCP ON THE AFTERNOON  
OF 10/14/2020.  
THIS IS AN SAE,  
HOSPITALIZATION, NOT  
RELATED TO IP. MEDICAL  
RECORDS WILL BE  
REQUESTED, UPON RECEIPT OF  
SIGNED MEDICAL RECORDS  
RELEASE FROM SUBJECT.  
MEDICAL RECORDS  
REVIEWED, AE TERM UPDATED  
TO VIRAL PHARYNGITIS,  
SUBJECT HAS RETURNED TO  
BASELINE, AE CLOSED. PER  
SUBJECT COVID TEST DONE IN  
HOSPITAL WAS NEGATIVE.  
HOSPITALIZATION (PER MED  
RECORD) WAS MORE FOR  
OBSERVATION SINCE SUBJECT  
LIVES ALONE AND WAS NOT  
COMFORTABLE BEING BY  
HERSELF

---

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

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US3312046

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 10:51:05

AEID	
Adverse event	FATIGUE
Was this a medically-attended AE?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Was this a Solicited Adverse Reaction?	Yes <input type="radio"/> No <input checked="" type="radio"/>
Is this event a confirmed diagnosis of Symptomatic Covid-19?	Yes <input type="radio"/> No <input checked="" type="radio"/>
Start date (dd MMM yyyy)	09 OCT 2020
Start time (00:00-23:59)	
AE start date and time (derived)	
Ongoing?	Yes <input checked="" type="radio"/> No <input type="radio"/>
If not Ongoing, end date (dd MMM yyyy)	
End time (00:00-23:59)	
AE End Date and Time (derived)	
Severity	Grade 1/Mild <input checked="" type="radio"/> Grade 2/Moderate <input type="radio"/> Grade 3/Severe <input type="radio"/> Grade 4 <input type="radio"/>
Is the adverse event serious?	Yes <input type="radio"/> No <input checked="" type="radio"/>
AE is serious due To (check all that apply)	
Death	False
Life threatening	False
Requires inpatient or prolongation of existing Hospitalization	False
Hospital Admission Date (dd MMM yyyy)	
Hospital Discharge Date (dd MMM yyyy)	
Admitted to ICU?	Yes <input type="radio"/> No <input type="radio"/> Unknown <input type="radio"/>
Number of Days in ICU	
Persistent or significant disability or incapacity	False

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 10:51:05

Congenital anomaly or birth defect	False
Other medically important event	False
Relationship to investigational product	Not Related <input checked="" type="radio"/> Related <input type="radio"/> Not Applicable <input type="radio"/>
Relationship to Study Procedure	Not Related <input checked="" type="radio"/> Related <input type="radio"/> Not Applicable <input type="radio"/>
Action taken with investigational product	None <input type="radio"/> Dose Delayed <input type="radio"/> Investigational Product Withdrawn <input type="radio"/> Not Applicable <input checked="" type="radio"/>
Other action taken (check all that apply)	
None	True
Concomitant Medication	False
Concomitant Procedure	False
Outcome	Fatal <input type="radio"/> Not Recovered/Not Resolved <input checked="" type="radio"/> Recovered/Resolved <input type="radio"/> Recovered/Resolved with Sequelae <input type="radio"/> Recovering/Resolving <input type="radio"/> Unknown <input type="radio"/>
If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:	
Narrative	
Serious Adverse Event Derived (CSA Programming Field Only)	0
Medically Attended AE Derived (CSA Programming Field Only)	1
Admitted to ICU Derived (CSA Programming Field Only)	

US3312046

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 10:51:05

AEID	
Adverse event	BODY ACHES
Was this a medically-attended AE?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Was this a Solicited Adverse Reaction?	Yes <input type="radio"/> No <input checked="" type="radio"/>
Is this event a confirmed diagnosis of Symptomatic Covid-19?	Yes <input type="radio"/> No <input checked="" type="radio"/>
Start date (dd MMM yyyy)	18 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)	18 OCT 2020
End time (00:00-23:59)	
AE End Date and Time (derived)	
Severity	Grade 1/Mild <input checked="" type="radio"/> Grade 2/Moderate <input type="radio"/> Grade 3/Severe <input type="radio"/> Grade 4 <input type="radio"/>
Is the adverse event serious?	Yes <input type="radio"/> No <input checked="" type="radio"/>
AE is serious due To (check all that apply)	
Death	False
Life threatening	False
Requires inpatient or prolongation of existing Hospitalization	False
Hospital Admission Date (dd MMM yyyy)	
Hospital Discharge Date (dd MMM yyyy)	
Admitted to ICU?	Yes <input type="radio"/> No <input type="radio"/> Unknown <input type="radio"/>
Number of Days in ICU	
Persistent or significant disability or incapacity	False
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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 10:51:05

Congenital anomaly or birth defect	False
Other medically important event	False
Relationship to investigational product	Not Related <input checked="" type="radio"/> Related <input type="radio"/> Not Applicable <input type="radio"/>
Relationship to Study Procedure	Not Related <input checked="" type="radio"/> Related <input type="radio"/> Not Applicable <input type="radio"/>
Action taken with investigational product	None <input type="radio"/> Dose Delayed <input type="radio"/> Investigational Product Withdrawn <input type="radio"/> Not Applicable <input checked="" type="radio"/>
Other action taken (check all that apply)	
None	True
Concomitant Medication	False
Concomitant Procedure	False
Outcome	Fatal <input type="radio"/> Not Recovered/Not Resolved <input type="radio"/> Recovered/Resolved <input checked="" type="radio"/> Recovered/Resolved with Sequelae <input type="radio"/> Recovering/Resolving <input type="radio"/> Unknown <input type="radio"/>
If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:	
Narrative	
Serious Adverse Event Derived (CSA Programming Field Only)	0
Medically Attended AE Derived (CSA Programming Field Only)	1
Admitted to ICU Derived (CSA Programming Field Only)	



US3312046

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 26 Nov 2020 10:51:05

AEID	
Adverse event	RUNNY NOSE
Was this a medically-attended AE?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Was this a Solicited Adverse Reaction?	Yes <input type="radio"/> No <input checked="" type="radio"/>
Is this event a confirmed diagnosis of Symptomatic Covid-19?	Yes <input type="radio"/> No <input checked="" type="radio"/>
Start date (dd MMM yyyy)	18 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)	20 OCT 2020
End time (00:00-23:59)	
AE End Date and Time (derived)	
Severity	Grade 1/Mild <input checked="" type="radio"/> Grade 2/Moderate <input type="radio"/> Grade 3/Severe <input type="radio"/> Grade 4 <input type="radio"/>
Is the adverse event serious?	Yes <input type="radio"/> No <input checked="" type="radio"/>
AE is serious due To (check all that apply)	
Death	False
Life threatening	False
Requires inpatient or prolongation of existing Hospitalization	False
Hospital Admission Date (dd MMM yyyy)	
Hospital Discharge Date (dd MMM yyyy)	
Admitted to ICU?	Yes <input type="radio"/> No <input type="radio"/> Unknown <input type="radio"/>
Number of Days in ICU	
Persistent or significant disability or incapacity	False

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 26 Nov 2020 10:51:05

Congenital anomaly or birth defect	False
Other medically important event	False
Relationship to investigational product	Not Related <input checked="" type="radio"/> Related <input type="radio"/> Not Applicable <input type="radio"/>
Relationship to Study Procedure	Not Related <input checked="" type="radio"/> Related <input type="radio"/> Not Applicable <input type="radio"/>
Action taken with investigational product	None <input type="radio"/> Dose Delayed <input type="radio"/> Investigational Product Withdrawn <input type="radio"/> Not Applicable <input checked="" type="radio"/>
Other action taken (check all that apply)	
None	True
Concomitant Medication	False
Concomitant Procedure	False
Outcome	Fatal <input type="radio"/> Not Recovered/Not Resolved <input type="radio"/> Recovered/Resolved <input checked="" type="radio"/> Recovered/Resolved with Sequelae <input type="radio"/> Recovering/Resolving <input type="radio"/> Unknown <input type="radio"/>
If outcome is Recovered/Resolved with Sequelae, please specify the sequelae: _____	
Narrative _____	
Serious Adverse Event Derived (CSA Programming Field Only)	0
Medically Attended AE Derived (CSA Programming Field Only)	1
Admitted to ICU Derived (CSA Programming Field Only) _____	

US3312046

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 26 Nov 2020 10:51:05

AEID	
Adverse event	NAUSEA
Was this a medically-attended AE?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Was this a Solicited Adverse Reaction?	Yes <input type="radio"/> No <input checked="" type="radio"/>
Is this event a confirmed diagnosis of Symptomatic Covid-19?	Yes <input type="radio"/> No <input checked="" type="radio"/>
Start date (dd MMM yyyy)	07 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)	19 OCT 2020
End time (00:00-23:59)	
AE End Date and Time (derived)	
Severity	Grade 1/Mild <input checked="" type="radio"/> Grade 2/Moderate <input type="radio"/> Grade 3/Severe <input type="radio"/> Grade 4 <input type="radio"/>
Is the adverse event serious?	Yes <input type="radio"/> No <input checked="" type="radio"/>
AE is serious due To (check all that apply)	
Death	False
Life threatening	False
Requires inpatient or prolongation of existing Hospitalization	False
Hospital Admission Date (dd MMM yyyy)	
Hospital Discharge Date (dd MMM yyyy)	
Admitted to ICU?	Yes <input type="radio"/> No <input type="radio"/> Unknown <input type="radio"/>
Number of Days in ICU	
Persistent or significant disability or incapacity	False
v6.020 DTW (1102)	418 of 2431

US3312046

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 26 Nov 2020 10:51:05

Congenital anomaly or birth defect	False
Other medically important event	False
Relationship to investigational product	Not Related <input checked="" type="radio"/> Related <input type="radio"/> Not Applicable <input type="radio"/>
Relationship to Study Procedure	Not Related <input checked="" type="radio"/> Related <input type="radio"/> Not Applicable <input type="radio"/>
Action taken with investigational product	None <input type="radio"/> Dose Delayed <input type="radio"/> Investigational Product Withdrawn <input type="radio"/> Not Applicable <input checked="" type="radio"/>
Other action taken (check all that apply)	
None	True
Concomitant Medication	False
Concomitant Procedure	False
Outcome	Fatal <input type="radio"/> Not Recovered/Not Resolved <input type="radio"/> Recovered/Resolved <input checked="" type="radio"/> Recovered/Resolved with Sequelae <input type="radio"/> Recovering/Resolving <input type="radio"/> Unknown <input type="radio"/>
If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:	
Narrative	
Serious Adverse Event Derived (CSA Programming Field Only)	0
Medically Attended AE Derived (CSA Programming Field Only)	1
Admitted to ICU Derived (CSA Programming Field Only)	

US3312046

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 26 Nov 2020 10:51:05

AEID	
Adverse event	FEVER
Was this a medically-attended AE?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Was this a Solicited Adverse Reaction?	Yes <input type="radio"/> No <input checked="" type="radio"/>
Is this event a confirmed diagnosis of Symptomatic Covid-19?	Yes <input type="radio"/> No <input checked="" type="radio"/>
Start date (dd MMM yyyy)	07 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)	14 OCT 2020
End time (00:00-23:59)	
AE End Date and Time (derived)	
Severity	Grade 1/Mild <input checked="" type="radio"/> Grade 2/Moderate <input type="radio"/> Grade 3/Severe <input type="radio"/> Grade 4 <input type="radio"/>
Is the adverse event serious?	Yes <input type="radio"/> No <input checked="" type="radio"/>
AE is serious due To (check all that apply)	
Death	False
Life threatening	False
Requires inpatient or prolongation of existing Hospitalization	False
Hospital Admission Date (dd MMM yyyy)	
Hospital Discharge Date (dd MMM yyyy)	
Admitted to ICU?	Yes <input type="radio"/> No <input type="radio"/> Unknown <input type="radio"/>
Number of Days in ICU	
Persistent or significant disability or incapacity	False
v6.020 DTW (1102)	420 of 2431

US3312046

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 26 Nov 2020 10:51:05

Congenital anomaly or birth defect	False
Other medically important event	False
Relationship to investigational product	Not Related <input checked="" type="radio"/> Related <input type="radio"/> Not Applicable <input type="radio"/>
Relationship to Study Procedure	Not Related <input checked="" type="radio"/> Related <input type="radio"/> Not Applicable <input type="radio"/>
Action taken with investigational product	None <input type="radio"/> Dose Delayed <input type="radio"/> Investigational Product Withdrawn <input type="radio"/> Not Applicable <input checked="" type="radio"/>
Other action taken (check all that apply)	
None	True
Concomitant Medication	False
Concomitant Procedure	False
Outcome	Fatal <input type="radio"/> Not Recovered/Not Resolved <input type="radio"/> Recovered/Resolved <input checked="" type="radio"/> Recovered/Resolved with Sequelae <input type="radio"/> Recovering/Resolving <input type="radio"/> Unknown <input type="radio"/>
If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:	
Narrative	
Serious Adverse Event Derived (CSA Programming Field Only)	0
Medically Attended AE Derived (CSA Programming Field Only)	1
Admitted to ICU Derived (CSA Programming Field Only)	

US3312046

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 26 Nov 2020 10:51:05

AEID	
Adverse event	HEADACHE
Was this a medically-attended AE?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Was this a Solicited Adverse Reaction?	Yes <input type="radio"/> No <input checked="" type="radio"/>
Is this event a confirmed diagnosis of Symptomatic Covid-19?	Yes <input type="radio"/> No <input checked="" type="radio"/>
Start date (dd MMM yyyy)	07 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)	07 OCT 2020
End time (00:00-23:59)	
AE End Date and Time (derived)	
Severity	Grade 1/Mild <input checked="" type="radio"/> Grade 2/Moderate <input type="radio"/> Grade 3/Severe <input type="radio"/> Grade 4 <input type="radio"/>
Is the adverse event serious?	Yes <input type="radio"/> No <input checked="" type="radio"/>
AE is serious due To (check all that apply)	
Death	False
Life threatening	False
Requires inpatient or prolongation of existing Hospitalization	False
Hospital Admission Date (dd MMM yyyy)	
Hospital Discharge Date (dd MMM yyyy)	
Admitted to ICU?	Yes <input type="radio"/> No <input type="radio"/> Unknown <input type="radio"/>
Number of Days in ICU	
Persistent or significant disability or incapacity	False
v6.020 DTW (1102)	422 of 2431

US3312046

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 26 Nov 2020 10:51:05

Congenital anomaly or birth defect	False
Other medically important event	False
Relationship to investigational product	Not Related <input checked="" type="radio"/> Related <input type="radio"/> Not Applicable <input type="radio"/>
Relationship to Study Procedure	Not Related <input checked="" type="radio"/> Related <input type="radio"/> Not Applicable <input type="radio"/>
Action taken with investigational product	None <input type="radio"/> Dose Delayed <input type="radio"/> Investigational Product Withdrawn <input type="radio"/> Not Applicable <input checked="" type="radio"/>
Other action taken (check all that apply)	
None	True
Concomitant Medication	False
Concomitant Procedure	False
Outcome	Fatal <input type="radio"/> Not Recovered/Not Resolved <input type="radio"/> Recovered/Resolved <input checked="" type="radio"/> Recovered/Resolved with Sequelae <input type="radio"/> Recovering/Resolving <input type="radio"/> Unknown <input type="radio"/>
If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:	
Narrative	
Serious Adverse Event Derived (CSA Programming Field Only)	0
Medically Attended AE Derived (CSA Programming Field Only)	1
Admitted to ICU Derived (CSA Programming Field Only)	



US3312046

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 26 Nov 2020 10:51:05

AEID	
Adverse event	VOMITING
Was this a medically-attended AE?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Was this a Solicited Adverse Reaction?	Yes <input type="radio"/> No <input checked="" type="radio"/>
Is this event a confirmed diagnosis of Symptomatic Covid-19?	Yes <input type="radio"/> No <input checked="" type="radio"/>
Start date (dd MMM yyyy)	07 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)	07 OCT 2020
End time (00:00-23:59)	
AE End Date and Time (derived)	
Severity	Grade 1/Mild <input checked="" type="radio"/> Grade 2/Moderate <input type="radio"/> Grade 3/Severe <input type="radio"/> Grade 4 <input type="radio"/>
Is the adverse event serious?	Yes <input type="radio"/> No <input checked="" type="radio"/>
AE is serious due To (check all that apply)	
Death	False
Life threatening	False
Requires inpatient or prolongation of existing Hospitalization	False
Hospital Admission Date (dd MMM yyyy)	
Hospital Discharge Date (dd MMM yyyy)	
Admitted to ICU?	Yes <input type="radio"/> No <input type="radio"/> Unknown <input type="radio"/>
Number of Days in ICU	
Persistent or significant disability or incapacity	False
v6.020 DTW (1102)	424 of 2431

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Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 26 Nov 2020 10:51:05

Congenital anomaly or birth defect	False
Other medically important event	False
Relationship to investigational product	Not Related <input checked="" type="radio"/> Related <input type="radio"/> Not Applicable <input type="radio"/>
Relationship to Study Procedure	Not Related <input checked="" type="radio"/> Related <input type="radio"/> Not Applicable <input type="radio"/>
Action taken with investigational product	None <input checked="" type="radio"/> Dose Delayed <input type="radio"/> Investigational Product Withdrawn <input type="radio"/> Not Applicable <input type="radio"/>
Other action taken (check all that apply)	
None	True
Concomitant Medication	False
Concomitant Procedure	False
Outcome	Fatal <input type="radio"/> Not Recovered/Not Resolved <input type="radio"/> Recovered/Resolved <input checked="" type="radio"/> Recovered/Resolved with Sequelae <input type="radio"/> Recovering/Resolving <input type="radio"/> Unknown <input type="radio"/>
If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:	
Narrative	
Serious Adverse Event Derived (CSA Programming Field Only)	0
Medically Attended AE Derived (CSA Programming Field Only)	1
Admitted to ICU Derived (CSA Programming Field Only)	

US3312046

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 26 Nov 2020 10:51:05

AEID	
Adverse event	SORE THROAT
Was this a medically-attended AE?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Was this a Solicited Adverse Reaction?	Yes <input type="radio"/> No <input checked="" type="radio"/>
Is this event a confirmed diagnosis of Symptomatic Covid-19?	Yes <input type="radio"/> No <input checked="" type="radio"/>
Start date (dd MMM yyyy)	07 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)	16 OCT 2020
End time (00:00-23:59)	
AE End Date and Time (derived)	
Severity	Grade 1/Mild <input checked="" type="radio"/> Grade 2/Moderate <input type="radio"/> Grade 3/Severe <input type="radio"/> Grade 4 <input type="radio"/>
Is the adverse event serious?	Yes <input type="radio"/> No <input checked="" type="radio"/>
AE is serious due To (check all that apply)	
Death	False
Life threatening	False
Requires inpatient or prolongation of existing Hospitalization	False
Hospital Admission Date (dd MMM yyyy)	
Hospital Discharge Date (dd MMM yyyy)	
Admitted to ICU?	Yes <input type="radio"/> No <input type="radio"/> Unknown <input type="radio"/>
Number of Days in ICU	
Persistent or significant disability or incapacity	False
v6.020 DTW (1102)	426 of 2431

US3312046

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 26 Nov 2020 10:51:05

Congenital anomaly or birth defect	False
Other medically important event	False
Relationship to investigational product	Not Related <input checked="" type="radio"/> Related <input type="radio"/> Not Applicable <input type="radio"/>
Relationship to Study Procedure	Not Related <input checked="" type="radio"/> Related <input type="radio"/> Not Applicable <input type="radio"/>
Action taken with investigational product	None <input type="radio"/> Dose Delayed <input type="radio"/> Investigational Product Withdrawn <input type="radio"/> Not Applicable <input checked="" type="radio"/>
Other action taken (check all that apply)	
None	False
Concomitant Medication	True
Concomitant Procedure	False
Outcome	Fatal <input type="radio"/> Not Recovered/Not Resolved <input type="radio"/> Recovered/Resolved <input checked="" type="radio"/> Recovered/Resolved with Sequelae <input type="radio"/> Recovering/Resolving <input type="radio"/> Unknown <input type="radio"/>
If outcome is Recovered/Resolved with Sequelae, please specify the sequelae: _____	
Narrative _____	
Serious Adverse Event Derived (CSA Programming Field Only)	0
Medically Attended AE Derived (CSA Programming Field Only)	1
Admitted to ICU Derived (CSA Programming Field Only) _____	

US3312046

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Generated On: 26 Nov 2020 10:51:05

---

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

Yes ☒

No ☐

---

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

---

US3312046

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 10:51:05

Name of Medication	ACETOMINOPHEN
Prophylaxis	Yes <input type="radio"/> No <input checked="" type="radio"/>
Indication	LOWER BACK PAIN
Dose per administration	1000
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"/>

US3312046

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 10:51:05

	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)	UN	UNK 2000
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
<hr/>		
If not Ongoing, End date (dd MMM yyyy) <input type="text"/>		
<hr/>		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
<hr/>		
Separate Dosage Number (derived)	<input type="text"/>	
Interval Dosage Unit Number (derived)	<input type="text"/>	
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input type="radio"/>

US3312046

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 10:51:05

Name of Medication	ACETAMINOPHEN
Prophylaxis	Yes <input type="radio"/> No <input checked="" type="radio"/>
Indication	INJECTION SITE PAIN
Dose per administration	1000
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"/>



US3312046

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 10:51:05

	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)		11 SEP 2020
Start date completely unknown		False
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)		12 SEP 2020
Was this medication taken for solicited event?	Yes	<input checked="" type="checkbox"/>
	No	<input 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"/>

US3312046

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 10:51:05

Name of Medication	ACETAMINOPHEN
Prophylaxis	Yes <input type="radio"/> No <input checked="" type="radio"/>
Indication	VIRAL PHARYNGITIS
Dose per administration	1000
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"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 10:51:05

	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)		07 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)		17 OCT 2020
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"/>

US3312046

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 10:51:05

Name of Medication	IBUPROFEN
Prophylaxis	Yes <input type="radio"/> No <input checked="" type="radio"/>
Indication	VIRAL PHARYNGITIS
Dose per administration	200
Dose unit	mg <input checked="" type="radio"/> ug <input type="radio"/> mL <input type="radio"/> g <input type="radio"/> IU <input type="radio"/> tablet <input type="radio"/> capsule <input type="radio"/> puff <input type="radio"/> Other <input type="radio"/>
If dose unit is Other, specify	
Frequency	once daily <input type="radio"/> twice daily <input type="radio"/> three times daily <input type="radio"/> four times daily <input type="radio"/> every other day <input type="radio"/> every week <input type="radio"/> every month <input type="radio"/> as needed <input 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"/>

US3312046

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 10:51:05

	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> )		07 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> )		17 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"/>

**US3312046**

**Folder: Concomitant Procedures (1)**

**Form: Concomitant Procedures Summary**

**Generated On: 26 Nov 2020 10:51:05**

---

Were any concomitant procedures performed?

Yes ☐

No ☐

---

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

---

US3312046

Folder: End of Study (1)

Form: Dosing Discontinuation

Generated On: 26 Nov 2020 10:51:05

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

US3312046

Folder: End of Study (1)

Form: End of Study / Study Discontinuation

Generated On: 26 Nov 2020 10:51:05

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 ☐



US3312046

Folder: SAE USA-US300-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 26 Nov 2020 10:51:05

SAEID	USA-US300-2020-MRNA-1273-P301000005
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input type="radio"/> No <input checked="" type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input checked="" type="radio"/> No <input type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input type="radio"/> No <input checked="" type="radio"/>
Investigator's First Name	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

US3312046

Folder: SAE USA-US300-2020-MRNA-1273-P301000005

Form: Safety Report Form (1)

Generated On: 26 Nov 2020 10:51:05

SAEID	USA-US300-2020-MRNA-1273-P301000005
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input type="radio"/> No <input checked="" type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input checked="" type="radio"/> No <input type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input type="radio"/> No <input checked="" type="radio"/>
Investigator's First Name	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)	15/OCT/2020 12:50
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

US3312046

Folder: SAE USA-US300-2020-MRNA-1273-P301000005

Form: Safety Report Form (2)

Generated On: 26 Nov 2020 10:51:05

SAEID	USA-US300-2020-MRNA-1273-P301000005
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input type="radio"/> No <input checked="" type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input checked="" type="radio"/> No <input type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input type="radio"/> No <input checked="" type="radio"/>
Investigator's First Name	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)	10/NOV/2020 10:30
Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.	True

US3312046

Folder: SAE USA-US300-2020-MRNA-1273-P301000005

Form: Safety Report Form (3)

Generated On: 26 Nov 2020 10:51:05

SAEID	USA-US300-2020-MRNA-1273-P301000005
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input type="radio"/> No <input checked="" type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input checked="" type="radio"/> No <input type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input type="radio"/> No <input checked="" type="radio"/>
Investigator's First Name	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)	17/NOV/2020 15:49
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

US3312046 (Prod: Johnson County Clin-Trials)

**US3312046**

**Form: Participant Creation**

**Generated On: 26 Nov 2020 10:51:05**

[Participant ID](#)

Audit	User	Time (GMT)
User entered 'US3312046'	RWS_ENDPOINT ENDPOINT (b) (4) <div></div>	12 Aug 2020 16:29:23

**US3312046**

**Folder: Screening**

**Form: Visit Date**

**Generated On: 26 Nov 2020 10:51:05**

[Was this visit performed?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Christa Estrada (b) (4) (b) (4)	12 Aug 2020 17:27:50

**US3312046**

**Folder: Screening**

**Form: Visit Date**

**Generated On: 26 Nov 2020 10:51:05**

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

Audit	User	Time (GMT)
User entered '12 AUG 2020'	RWS_ENDPOINT ENDPOINT (b) (4) [REDACTED]	12 Aug 2020 16:29:24



US3312046

Folder: Screening

Form: Visit Date

Generated On: 26 Nov 2020 10:51:05

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)	12 Aug 2020 17:27:50

**US3312046**

**Folder: Screening**

**Form: Visit Date**

**Generated On: 26 Nov 2020 10:51:05**

[Folder OID](#)

Audit	User	Time (GMT)
User entered 'SCRN'	System	12 Aug 2020 17:27:50

US3312046

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 10:51:05

Date of Birth (MMM yyyy)

Audit	User	Time (GMT)
User entered (b) (6) 1937'	RWS_ENDPOINT ENDPOINT (b) (4) [REDACTED]	12 Aug 2020 16:29:25

**US3312046**

**Folder: Screening**

**Form: Demographics**

**Generated On: 26 Nov 2020 10:51:05**

[Age](#)

Audit	User	Time (GMT)
User entered '82'	Karol Moore (b) (4) (b) (4)	14 Aug 2020 17:38:59

**US3312046**

**Folder: Screening**

**Form: Demographics**

**Generated On: 26 Nov 2020 10:51:05**

[Age Units](#)

Audit	User	Time (GMT)
User entered 'YEARS'	System	14 Aug 2020 17:38:59

**US3312046**

**Folder: Screening**

**Form: Demographics**

**Generated On: 26 Nov 2020 10:51:05**

[Age \(Derived\)](#)

Audit	User	Time (GMT)
User entered '82'	System	12 Aug 2020 17:28:05

**US3312046**

**Folder: Screening**

**Form: Demographics**

**Generated On: 26 Nov 2020 10:51:05**

[Sex](#)

Audit	User	Time (GMT)
User entered 'Female (F)'	Karol Moore (b) (4) (b) (4)	14 Aug 2020 17:38:59

US3312046

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 10:51:05

[Ethnicity](#)

Audit	User	Time (GMT)
User entered 'Not Hispanic or Latino (NOT HISPANIC OR LATINO)'	Karol Moore (b) (4) (b) (4)	14 Aug 2020 17:38:59



**US3312046**

**Folder: Screening**

**Form: Demographics**

**Generated On: 26 Nov 2020 10:51:05**

[White](#)

Audit	User	Time (GMT)
User entered 'I'	Karol Moore (b) (4) (b) (4)	14 Aug 2020 17:38:59

**US3312046**

**Folder: Screening**

**Form: Demographics**

**Generated On: 26 Nov 2020 10:51:05**

[Black](#)

Audit	User	Time (GMT)
User entered '0'	Karol Moore (b) (4) (b) (4)	14 Aug 2020 17:38:59

**US3312046**

**Folder: Screening**

**Form: Demographics**

**Generated On: 26 Nov 2020 10:51:05**

[Asian](#)

Audit	User	Time (GMT)
User entered '0'	Karol Moore (b) (4) (b) (4)	14 Aug 2020 17:38:59

US3312046

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 10:51:05

[American Indian or Alaska Native](#)

Audit	User	Time (GMT)
User entered '0'	Karol Moore (b) (4) (b) (4)	14 Aug 2020 17:38:59

**US3312046**

**Folder: Screening**

**Form: Demographics**

**Generated On: 26 Nov 2020 10:51:05**

[Native Hawaiian or other Pacific Islander](#)

Audit	User	Time (GMT)
User entered '0'	Karol Moore (b) (4) (b) (4)	14 Aug 2020 17:38:59

**US3312046**

**Folder: Screening**

**Form: Demographics**

**Generated On: 26 Nov 2020 10:51:05**

[Other](#)

Audit	User	Time (GMT)
User entered '0'	Karol Moore (b) (4) (b) (4)	14 Aug 2020 17:38:59

**US3312046**

**Folder: Screening**

**Form: Demographics**

**Generated On: 26 Nov 2020 10:51:05**

[If race is Other, specify](#)

Audit	User	Time (GMT)
User entered empty.	Karol Moore (b) (4) (b) (4)	14 Aug 2020 17:38:59

**US3312046**

**Folder: Screening**

**Form: Demographics**

**Generated On: 26 Nov 2020 10:51:05**

[Unknown](#)

Audit	User	Time (GMT)
User entered '0'	Karol Moore (b) (4) (b) (4)	14 Aug 2020 17:38:59



**US3312046**

**Folder: Screening**

**Form: Demographics**

**Generated On: 26 Nov 2020 10:51:05**

[Not reported](#)

Audit	User	Time (GMT)
User entered '0'	Karol Moore (b) (4) (b) (4)	14 Aug 2020 17:38:59

US3312046

Folder: Screening

Form: Enrollment

Generated On: 26 Nov 2020 10:51:05

Date of Informed Consent (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered '12 Aug 2020'	Christa Estrada (b) (4) (b) (4)	12 Aug 2020 17:28:05

**US3312046**

**Folder: Screening**

**Form: Enrollment**

**Generated On: 26 Nov 2020 10:51:05**

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

Audit	User	Time (GMT)
User entered 'Aug 2020'	System	12 Aug 2020 17:28:05

**US3312046**

**Folder: Screening**

**Form: Enrollment**

**Generated On: 26 Nov 2020 10:51:05**

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

Audit	User	Time (GMT)
User entered '2020'	System	12 Aug 2020 17:28:05

**US3312046**

**Folder: Screening**

**Form: Enrollment**

**Generated On: 26 Nov 2020 10:51:05**

[Protocol Version](#)

Audit	User	Time (GMT)
User entered 'Amendment 2 (2)' reason for change: Data Entry Error	Christa Estrada (b) (4) (b) (4)	12 Aug 2020 21:20:38
User entered 'Amendment 1 (1)'	Christa Estrada (b) (4) (b) (4)	12 Aug 2020 17:28:05

**US3312046**

**Folder: Screening**

**Form: Enrollment**

**Generated On: 26 Nov 2020 10:51:05**

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

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Christa Estrada (b) (4) (b) (4)	12 Aug 2020 17:28:05

**US3312046**

**Folder: Screening**

**Form: Enrollment**

**Generated On: 26 Nov 2020 10:51:05**

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

Audit	User	Time (GMT)
User entered empty.	Christa Estrada (b) (4) (b) (4)	12 Aug 2020 17:28:05

**US3312046**

**Folder: Screening**

**Form: Enrollment**

**Generated On: 26 Nov 2020 10:51:05**

If reason for screen fail is Other, specify

Audit	User	Time (GMT)
User entered empty.	Christa Estrada (b) (4) (b) (4)	12 Aug 2020 17:28:05



US3312046

Folder: Screening

Form: Enrollment

Generated On: 26 Nov 2020 10:51:05

[Was this participant screened previously?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Christa Estrada (b) (4) (b) (4)	12 Aug 2020 17:28:05

**US3312046**

**Folder: Screening**

**Form: Enrollment**

**Generated On: 26 Nov 2020 10:51:05**

[If Yes, previous participant number](#)

Audit	User	Time (GMT)
User entered empty.	RWS_ENDPOINT ENDPOINT (b) (4) [REDACTED]	12 Aug 2020 16:29:24

**US3312046**

**Folder: Screening**

**Form: Enrollment**

**Generated On: 26 Nov 2020 10:51:05**

[Enrollment Trigger](#)

Audit	User	Time (GMT)
User entered 'I'	System	12 Aug 2020 17:28:11

**US3312046**

**Folder: Screening**

**Form: Inclusion/Exclusion Criteria Summary**

**Generated On: 26 Nov 2020 10:51:05**

[Did the participant meet all eligibility criteria?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Christa Estrada (b) (4) (b) (4)	12 Aug 2020 17:28:11

US3312046

Folder: Screening

Form: Medical History Summary

Generated On: 26 Nov 2020 10:51:05

[Were any significant conditions reported?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Karol Moore (b) (4) (b) (4)	14 Aug 2020 17:39:08

US3312046

Folder: Screening

Form: Medical History (1)

Generated On: 26 Nov 2020 10:51:05

[Condition](#)

Audit	User	Time (GMT)
User coded data point as SOC: Musculoskeletal and connective tissue disorders, HLGT: Musculoskeletal and connective tissue disorders NEC, HLT: Musculoskeletal and connective tissue pain and discomfort, PT: Back pain, LLT: Low back pain - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	14 Aug 2020 17:41:30
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	14 Aug 2020 17:41:30
Data point term sent to Coder	System	14 Aug 2020 17:40:01
User entered 'lower back pain'	Karol Moore (b) (4) (b) (4)	14 Aug 2020 17:39:47

**US3312046**

**Folder: Screening**

**Form: Medical History (1)**

**Generated On: 26 Nov 2020 10:51:05**

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

Audit	User	Time (GMT)
User entered 'un UNK 2000'	Karol Moore (b) (4) (b) (4)	14 Aug 2020 17:39:47

**US3312046**

**Folder: Screening**

**Form: Medical History (1)**

**Generated On: 26 Nov 2020 10:51:05**

[Start date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	Karol Moore (b) (4) (b) (4)	14 Aug 2020 17:39:47



**US3312046**

**Folder: Screening**

**Form: Medical History (1)**

**Generated On: 26 Nov 2020 10:51:05**

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Karol Moore (b) (4) (b) (4)	14 Aug 2020 17:39:47

**US3312046**

**Folder: Screening**

**Form: Medical History (1)**

**Generated On: 26 Nov 2020 10:51:05**

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

Audit	User	Time (GMT)
User entered empty.	Karol Moore (b) (4) (b) (4)	14 Aug 2020 17:39:47

**US3312046**

**Folder: Screening**

**Form: Medical History (1)**

**Generated On: 26 Nov 2020 10:51:05**

[Stop date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	Karol Moore (b) (4) (b) (4)	14 Aug 2020 17:39:47

**US3312046**

**Folder: Screening**

**Form: Medical History (1)**

**Generated On: 26 Nov 2020 10:51:05**

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

Audit	User	Time (GMT)
User entered 'Jan 2000'	System	14 Aug 2020 17:39:47

**US3312046**

**Folder: Screening**

**Form: Medical History (1)**

**Generated On: 26 Nov 2020 10:51:05**

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

Audit	User	Time (GMT)
User entered '2000'	System	14 Aug 2020 17:39:47

**US3312046**

**Folder: Screening**

**Form: Medical History (1)**

**Generated On: 26 Nov 2020 10:51:05**

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

Audit	User	Time (GMT)
User entered empty.	System	14 Aug 2020 17:39:47

**US3312046**

**Folder: Screening**

**Form: Medical History (1)**

**Generated On: 26 Nov 2020 10:51:05**

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

Audit	User	Time (GMT)
User entered empty.	System	14 Aug 2020 17:39:47

US3312046

Folder: Screening

Form: Medical History (2)

Generated On: 26 Nov 2020 10:51:05

Condition

Audit	User	Time (GMT)
User coded data point as SOC: Injury, poisoning and procedural complications, HLG: Bone and joint injuries, HLT: Spinal fractures and dislocations, PT: Lumbar vertebral fracture, LLT: Lumbar vertebral fracture L5 - version MedDRA\\23.0.	Coder Import (b) (4)	15 Aug 2020 10:42:14
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4)	15 Aug 2020 10:42:14
Data point term sent to Coder	System	14 Aug 2020 17:41:02
User entered 'L5 vertebral fracture'	Karol Moore (b) (4)	14 Aug 2020 17:40:39
	(b) (4)	



**US3312046**

**Folder: Screening**

**Form: Medical History (2)**

**Generated On: 26 Nov 2020 10:51:05**

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

Audit	User	Time (GMT)
User entered 'un UNK 2000'	Karol Moore (b) (4) (b) (4)	14 Aug 2020 17:40:39

**US3312046**

**Folder: Screening**

**Form: Medical History (2)**

**Generated On: 26 Nov 2020 10:51:05**

[Start date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	Karol Moore (b) (4) (b) (4)	14 Aug 2020 17:40:39

US3312046

Folder: Screening

Form: Medical History (2)

Generated On: 26 Nov 2020 10:51:05

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Karol Moore (b) (4) (b) (4)	14 Aug 2020 17:40:39

**US3312046**

**Folder: Screening**

**Form: Medical History (2)**

**Generated On: 26 Nov 2020 10:51:05**

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

Audit	User	Time (GMT)
User entered 'un UNK 2000'	Karol Moore (b) (4) (b) (4)	14 Aug 2020 17:40:39

**US3312046**

**Folder: Screening**

**Form: Medical History (2)**

**Generated On: 26 Nov 2020 10:51:05**

[Stop date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	Karol Moore (b) (4) (b) (4)	14 Aug 2020 17:40:39

**US3312046**

**Folder: Screening**

**Form: Medical History (2)**

**Generated On: 26 Nov 2020 10:51:05**

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

Audit	User	Time (GMT)
User entered 'Jan 2000'	System	14 Aug 2020 17:40:39

**US3312046**

**Folder: Screening**

**Form: Medical History (2)**

**Generated On: 26 Nov 2020 10:51:05**

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

Audit	User	Time (GMT)
User entered '2000'	System	14 Aug 2020 17:40:39

**US3312046**

**Folder: Screening**

**Form: Medical History (2)**

**Generated On: 26 Nov 2020 10:51:05**

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

Audit	User	Time (GMT)
User entered 'Jan 2000'	System	14 Aug 2020 17:40:39



**US3312046**

**Folder: Screening**

**Form: Medical History (2)**

**Generated On: 26 Nov 2020 10:51:05**

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

Audit	User	Time (GMT)
User entered '2000'	System	14 Aug 2020 17:40:39

US3312046

Folder: Screening

Form: Medical History (3)

Generated On: 26 Nov 2020 10:51:05

Condition

Audit	User	Time (GMT)
User coded data point as SOC: Surgical and medical procedures, HLG: Nervous system, skull and spine therapeutic procedures, HLT: Spine and spinal cord therapeutic procedures, PT: Spinal fusion surgery, LLT: Fusion lumbar spine - version MedDRA\\23.0.	Coder Import (b) (4)	17 Aug 2020 23:25:21
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4)	17 Aug 2020 23:25:21
Data point term sent to Coder	System	14 Aug 2020 17:42:04
User entered 'L4-5 vertebral fusion'	Karol Moore (b) (4)	14 Aug 2020 17:41:04
	(b) (4)	

**US3312046**

**Folder: Screening**

**Form: Medical History (3)**

**Generated On: 26 Nov 2020 10:51:05**

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

Audit	User	Time (GMT)
User entered 'un UNK 2000'	Karol Moore (b) (4) (b) (4)	14 Aug 2020 17:41:04

**US3312046**

**Folder: Screening**

**Form: Medical History (3)**

**Generated On: 26 Nov 2020 10:51:05**

[Start date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	Karol Moore (b) (4) (b) (4)	14 Aug 2020 17:41:04

**US3312046**

**Folder: Screening**

**Form: Medical History (3)**

**Generated On: 26 Nov 2020 10:51:05**

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Karol Moore (b) (4) (b) (4)	14 Aug 2020 17:41:04

**US3312046**

**Folder: Screening**

**Form: Medical History (3)**

**Generated On: 26 Nov 2020 10:51:05**

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

Audit	User	Time (GMT)
User entered 'un UNK 2000'	Karol Moore (b) (4) (b) (4)	14 Aug 2020 17:41:04

**US3312046**

**Folder: Screening**

**Form: Medical History (3)**

**Generated On: 26 Nov 2020 10:51:05**

[Stop date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	Karol Moore (b) (4) (b) (4)	14 Aug 2020 17:41:04

**US3312046**

**Folder: Screening**

**Form: Medical History (3)**

**Generated On: 26 Nov 2020 10:51:05**

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

Audit	User	Time (GMT)
User entered 'Jan 2000'	System	14 Aug 2020 17:41:04



**US3312046**

**Folder: Screening**

**Form: Medical History (3)**

**Generated On: 26 Nov 2020 10:51:05**

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

Audit	User	Time (GMT)
User entered '2000'	System	14 Aug 2020 17:41:04

**US3312046**

**Folder: Screening**

**Form: Medical History (3)**

**Generated On: 26 Nov 2020 10:51:05**

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

Audit	User	Time (GMT)
User entered 'Jan 2000'	System	14 Aug 2020 17:41:04

**US3312046**

**Folder: Screening**

**Form: Medical History (3)**

**Generated On: 26 Nov 2020 10:51:05**

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

Audit	User	Time (GMT)
User entered '2000'	System	14 Aug 2020 17:41:04

US3312046

Folder: Screening

Form: Medical History (4)

Generated On: 26 Nov 2020 10:51:05

Condition

Audit	User	Time (GMT)
User coded data point as SOC: Investigations, HLGT: Cardiac and vascular investigations (excl enzyme tests), HLT: Cardiac auscultatory investigations, PT: Cardiac murmur, LLT: Systolic murmur - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	11 Nov 2020 05:20:45
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	11 Nov 2020 05:20:45
User closed query 'Per MM, please update the MH condition to specify cause or medical diagnosis' (Site from DM).	(b) (4), (b) (6)	10 Nov 2020 10:49:06
Data point term sent to Coder	System	09 Nov 2020 20:25:44
Query 'Per MM, please update the MH condition to specify cause or medical diagnosis' answered with 'UPDATED' (Site from DM).	Karol Moore (b) (4) (b) (4)	09 Nov 2020 20:25:32
Coding entries removed.	Karol Moore (b) (4) (b) (4)	09 Nov 2020 20:25:23
User entered 'CONGENITAL SYSTOLIC HEART MURMUR' reason for change: Data Entry Error	Karol Moore (b) (4) (b) (4)	09 Nov 2020 20:25:23
User opened query 'Per MM, please update the MH condition to specify cause or medical diagnosis' (Site from DM).	(b) (4), (b) (6)	05 Oct 2020 13:23:48
User coded data point as SOC: Investigations, HLGT: Cardiac and vascular investigations (excl enzyme tests), HLT: Cardiac auscultatory investigations, PT: Cardiac murmur, LLT: Systolic murmur - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	15 Aug 2020 08:55:13
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	15 Aug 2020 08:55:13
Data point term sent to Coder	System	14 Aug 2020 17:43:07
User entered 'systolic heart murmur'	Karol Moore (b) (4) (b) (4)	14 Aug 2020 17:42:10

US3312046

Folder: Screening

Form: Medical History (4)

Generated On: 26 Nov 2020 10:51:05

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

Audit	User	Time (GMT)
User closed query 'Start date is prior to Date of Birth. System Please correct.' (Site from System).		14 Aug 2020 17:51:20
User entered 'UN (b) (6) 1937' reason for change: Data Entry Error	Karol Moore (b) (4) (b) (4)	14 Aug 2020 17:51:20
User opened query 'Start date is prior to Date of Birth. Please correct.' (Site from System).	System	14 Aug 2020 17:42:10
User entered 'un UNK 1937'	Karol Moore (b) (4) (b) (4)	14 Aug 2020 17:42:10

**US3312046**

**Folder: Screening**

**Form: Medical History (4)**

**Generated On: 26 Nov 2020 10:51:05**

[Start date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	Karol Moore (b) (4) (b) (4)	14 Aug 2020 17:42:10

**US3312046**

**Folder: Screening**

**Form: Medical History (4)**

**Generated On: 26 Nov 2020 10:51:05**

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Karol Moore (b) (4) (b) (4)	14 Aug 2020 17:42:10

**US3312046**

**Folder: Screening**

**Form: Medical History (4)**

**Generated On: 26 Nov 2020 10:51:05**

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

Audit	User	Time (GMT)
User entered empty.	Karol Moore (b) (4) (b) (4)	14 Aug 2020 17:42:10



**US3312046**

**Folder: Screening**

**Form: Medical History (4)**

**Generated On: 26 Nov 2020 10:51:05**

[Stop date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	Karol Moore (b) (4) (b) (4)	14 Aug 2020 17:42:10

**US3312046**

**Folder: Screening**

**Form: Medical History (4)**

**Generated On: 26 Nov 2020 10:51:05**

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

Audit	User	Time (GMT)
User entered (b) (6) 1937'	System	14 Aug 2020 17:51:20
User entered 'Jan 1937'	System	14 Aug 2020 17:42:10

**US3312046**

**Folder: Screening**

**Form: Medical History (4)**

**Generated On: 26 Nov 2020 10:51:05**

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

Audit	User	Time (GMT)
User entered '1937'	System	14 Aug 2020 17:42:10

**US3312046**

**Folder: Screening**

**Form: Medical History (4)**

**Generated On: 26 Nov 2020 10:51:05**

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

Audit	User	Time (GMT)
User entered empty.	System	14 Aug 2020 17:42:10

**US3312046**

**Folder: Screening**

**Form: Medical History (4)**

**Generated On: 26 Nov 2020 10:51:05**

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

Audit	User	Time (GMT)
User entered empty.	System	14 Aug 2020 17:42:10

US3312046

Folder: Screening

Form: Medical History (5)

Generated On: 26 Nov 2020 10:51:05

Condition

Audit	User	Time (GMT)
User coded data point as SOC: Ear and labyrinth disorders, HLGT: Hearing disorders, HLT: Hearing losses, PT: Deafness bilateral, LLT: Hearing loss bilateral - version MedDRA\\23.0.	Coder Import (b) (4)	14 Aug 2020 17:44:19
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	(b) (4)	14 Aug 2020 17:44:19
Data point term sent to Coder	System	14 Aug 2020 17:43:07
User entered 'bilateral hearing loss'	Karol Moore (b) (4)	14 Aug 2020 17:42:25
	(b) (4)	

**US3312046**

**Folder: Screening**

**Form: Medical History (5)**

**Generated On: 26 Nov 2020 10:51:05**

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

Audit	User	Time (GMT)
User entered 'un UNK 2009'	Karol Moore (b) (4) (b) (4)	14 Aug 2020 17:42:25

**US3312046**

**Folder: Screening**

**Form: Medical History (5)**

**Generated On: 26 Nov 2020 10:51:05**

[Start date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	Karol Moore (b) (4) (b) (4)	14 Aug 2020 17:42:25



**US3312046**

**Folder: Screening**

**Form: Medical History (5)**

**Generated On: 26 Nov 2020 10:51:05**

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Karol Moore (b) (4) (b) (4)	14 Aug 2020 17:42:25

**US3312046**

**Folder: Screening**

**Form: Medical History (5)**

**Generated On: 26 Nov 2020 10:51:05**

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

Audit	User	Time (GMT)
User entered empty.	Karol Moore (b) (4) (b) (4)	14 Aug 2020 17:42:25

**US3312046**

**Folder: Screening**

**Form: Medical History (5)**

**Generated On: 26 Nov 2020 10:51:05**

[Stop date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	Karol Moore (b) (4) (b) (4)	14 Aug 2020 17:42:25

**US3312046**

**Folder: Screening**

**Form: Medical History (5)**

**Generated On: 26 Nov 2020 10:51:05**

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

Audit	User	Time (GMT)
User entered 'Jan 2009'	System	14 Aug 2020 17:42:25

**US3312046**

**Folder: Screening**

**Form: Medical History (5)**

**Generated On: 26 Nov 2020 10:51:05**

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

Audit	User	Time (GMT)
User entered '2009'	System	14 Aug 2020 17:42:25

**US3312046**

**Folder: Screening**

**Form: Medical History (5)**

**Generated On: 26 Nov 2020 10:51:05**

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

Audit	User	Time (GMT)
User entered empty.	System	14 Aug 2020 17:42:25

**US3312046**

**Folder: Screening**

**Form: Medical History (5)**

**Generated On: 26 Nov 2020 10:51:05**

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

Audit	User	Time (GMT)
User entered empty.	System	14 Aug 2020 17:42:25

US3312046

Folder: Screening

Form: Medical History (6)

Generated On: 26 Nov 2020 10:51:05

[Condition](#)

Audit	User	Time (GMT)
User coded data point as SOC: Surgical and medical procedures, HLGT: Obstetric and gynaecological therapeutic procedures, HLT: Uterine therapeutic procedures, PT: Hysterectomy, LLT: Subtotal hysterectomy - version MedDRA\\23.0.	Coder Import (b) (4)	14 Aug 2020 17:44:19
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	14 Aug 2020 17:44:19
Data point term sent to Coder	System	14 Aug 2020 17:43:08
User entered 'partial hysterectomy'	Karol Moore (b) (4)	14 Aug 2020 17:42:50
	(b) (4)	



**US3312046**

**Folder: Screening**

**Form: Medical History (6)**

**Generated On: 26 Nov 2020 10:51:05**

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

Audit	User	Time (GMT)
User entered 'un UNK 1985'	Karol Moore (b) (4) (b) (4)	14 Aug 2020 17:42:50

**US3312046**

**Folder: Screening**

**Form: Medical History (6)**

**Generated On: 26 Nov 2020 10:51:05**

[Start date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	Karol Moore (b) (4) (b) (4)	14 Aug 2020 17:42:50

**US3312046**

**Folder: Screening**

**Form: Medical History (6)**

**Generated On: 26 Nov 2020 10:51:05**

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Karol Moore (b) (4) (b) (4)	14 Aug 2020 17:42:50

**US3312046**

**Folder: Screening**

**Form: Medical History (6)**

**Generated On: 26 Nov 2020 10:51:05**

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

Audit	User	Time (GMT)
User entered 'un UNK 1985'	Karol Moore (b) (4) (b) (4)	14 Aug 2020 17:42:50

**US3312046**

**Folder: Screening**

**Form: Medical History (6)**

**Generated On: 26 Nov 2020 10:51:05**

[Stop date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	Karol Moore (b) (4) (b) (4)	14 Aug 2020 17:42:50

**US3312046**

**Folder: Screening**

**Form: Medical History (6)**

**Generated On: 26 Nov 2020 10:51:05**

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

Audit	User	Time (GMT)
User entered 'Jan 1985'	System	14 Aug 2020 17:42:50

**US3312046**

**Folder: Screening**

**Form: Medical History (6)**

**Generated On: 26 Nov 2020 10:51:05**

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

Audit	User	Time (GMT)
User entered '1985'	System	14 Aug 2020 17:42:50

**US3312046**

**Folder: Screening**

**Form: Medical History (6)**

**Generated On: 26 Nov 2020 10:51:05**

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

Audit	User	Time (GMT)
User entered 'Jan 1985'	System	14 Aug 2020 17:42:50



**US3312046**

**Folder: Screening**

**Form: Medical History (6)**

**Generated On: 26 Nov 2020 10:51:05**

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

Audit	User	Time (GMT)
User entered '1985'	System	14 Aug 2020 17:42:50

US3312046

Folder: Screening

Form: Medical History (7)

Generated On: 26 Nov 2020 10:51:05

[Condition](#)

Audit	User	Time (GMT)
User coded data point as SOC: Reproductive system and breast disorders, HLG: Menstrual cycle and uterine bleeding disorders, HLT: Menstruation with increased bleeding, PT: Menorrhagia, LLT: Menorrhagia - version MedDRA\\23.0.	Coder Import (b) (4)	14 Aug 2020 17:45:23
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	14 Aug 2020 17:45:23
Data point term sent to Coder	System	14 Aug 2020 17:44:09
User entered 'menorrhagia'	Karol Moore (b) (4)	14 Aug 2020 17:43:12
	(b) (4)	

**US3312046**

**Folder: Screening**

**Form: Medical History (7)**

**Generated On: 26 Nov 2020 10:51:05**

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

Audit	User	Time (GMT)
User entered 'un UNK 1985'	Karol Moore (b) (4) (b) (4)	14 Aug 2020 17:43:12

**US3312046**

**Folder: Screening**

**Form: Medical History (7)**

**Generated On: 26 Nov 2020 10:51:05**

[Start date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	Karol Moore (b) (4) (b) (4)	14 Aug 2020 17:43:12

**US3312046**

**Folder: Screening**

**Form: Medical History (7)**

**Generated On: 26 Nov 2020 10:51:05**

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Karol Moore (b) (4) (b) (4)	14 Aug 2020 17:43:12

**US3312046**

**Folder: Screening**

**Form: Medical History (7)**

**Generated On: 26 Nov 2020 10:51:05**

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

Audit	User	Time (GMT)
User entered 'un UNK 1985'	Karol Moore (b) (4) (b) (4)	14 Aug 2020 17:43:12

**US3312046**

**Folder: Screening**

**Form: Medical History (7)**

**Generated On: 26 Nov 2020 10:51:05**

[Stop date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	Karol Moore (b) (4) (b) (4)	14 Aug 2020 17:43:12

**US3312046**

**Folder: Screening**

**Form: Medical History (7)**

**Generated On: 26 Nov 2020 10:51:05**

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

Audit	User	Time (GMT)
User entered 'Jan 1985'	System	14 Aug 2020 17:43:12



**US3312046**

**Folder: Screening**

**Form: Medical History (7)**

**Generated On: 26 Nov 2020 10:51:05**

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

Audit	User	Time (GMT)
User entered '1985'	System	14 Aug 2020 17:43:12

**US3312046**

**Folder: Screening**

**Form: Medical History (7)**

**Generated On: 26 Nov 2020 10:51:05**

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

Audit	User	Time (GMT)
User entered 'Jan 1985'	System	14 Aug 2020 17:43:12

**US3312046**

**Folder: Screening**

**Form: Medical History (7)**

**Generated On: 26 Nov 2020 10:51:05**

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

Audit	User	Time (GMT)
User entered '1985'	System	14 Aug 2020 17:43:12

US3312046

Folder: Screening

Form: Medical History (8)

Generated On: 26 Nov 2020 10:51:05

[Condition](#)

Audit	User	Time (GMT)
User coded data point as SOC: Social circumstances, HLGT: Age related factors, HLT: Age related issues, PT: Postmenopause, LLT: Postmenopause - version MedDRA\\23.0.	Coder Import (b) (4)	14 Aug 2020 17:47:17
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	(b) (4)	14 Aug 2020 17:47:17
Data point term sent to Coder	System	14 Aug 2020 17:46:14
User entered 'post menopausal'	Karol Moore (b) (4)	14 Aug 2020 17:45:19
	(b) (4)	

**US3312046**

**Folder: Screening**

**Form: Medical History (8)**

**Generated On: 26 Nov 2020 10:51:05**

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

Audit	User	Time (GMT)
User entered 'un UNK 2002'	Karol Moore (b) (4) (b) (4)	14 Aug 2020 17:45:19

**US3312046**

**Folder: Screening**

**Form: Medical History (8)**

**Generated On: 26 Nov 2020 10:51:05**

[Start date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	Karol Moore (b) (4) (b) (4)	14 Aug 2020 17:45:19

**US3312046**

**Folder: Screening**

**Form: Medical History (8)**

**Generated On: 26 Nov 2020 10:51:05**

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Karol Moore (b) (4) (b) (4)	14 Aug 2020 17:45:19

**US3312046**

**Folder: Screening**

**Form: Medical History (8)**

**Generated On: 26 Nov 2020 10:51:05**

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

Audit	User	Time (GMT)
User entered empty.	Karol Moore (b) (4) (b) (4)	14 Aug 2020 17:45:19



**US3312046**

**Folder: Screening**

**Form: Medical History (8)**

**Generated On: 26 Nov 2020 10:51:05**

[Stop date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	Karol Moore (b) (4) (b) (4)	14 Aug 2020 17:45:19

**US3312046**

**Folder: Screening**

**Form: Medical History (8)**

**Generated On: 26 Nov 2020 10:51:05**

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

Audit	User	Time (GMT)
User entered 'Jan 2002'	System	14 Aug 2020 17:45:19

**US3312046**

**Folder: Screening**

**Form: Medical History (8)**

**Generated On: 26 Nov 2020 10:51:05**

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

Audit	User	Time (GMT)
User entered '2002'	System	14 Aug 2020 17:45:19

**US3312046**

**Folder: Screening**

**Form: Medical History (8)**

**Generated On: 26 Nov 2020 10:51:05**

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

Audit	User	Time (GMT)
User entered empty.	System	14 Aug 2020 17:45:19

**US3312046**

**Folder: Screening**

**Form: Medical History (8)**

**Generated On: 26 Nov 2020 10:51:05**

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

Audit	User	Time (GMT)
User entered empty.	System	14 Aug 2020 17:45:19

US3312046

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 10:51:05

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Karol Moore (b) (4) (b) (4)	14 Aug 2020 17:45:47

US3312046

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 10:51:05

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered '12 Aug 2020'	Karol Moore (b) (4) (b) (4)	14 Aug 2020 17:45:47

**US3312046**

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 26 Nov 2020 10:51:05**

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

Audit	User	Time (GMT)
User entered '11:05'	Karol Moore (b) (4) (b) (4)	14 Aug 2020 17:45:47



**US3312046**

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 26 Nov 2020 10:51:05**

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

Audit	User	Time (GMT)
User entered '12 Aug 2020 11:05'	System	14 Aug 2020 17:45:47

**US3312046**

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 26 Nov 2020 10:51:05**

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

Audit	User	Time (GMT)
User entered '63' in	Karol Moore (b) (4)	14 Aug 2020 17:45:47
DataPoint set to visible.	(b) (4) System	12 Aug 2020 17:28:11

**US3312046**

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 26 Nov 2020 10:51:05**

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

Audit	User	Time (GMT)
User entered '146' lb	Karol Moore (b) (4)	14 Aug 2020 17:45:47
DataPoint set to visible.	(b) (4) System	12 Aug 2020 17:28:11

**US3312046**

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 26 Nov 2020 10:51:05**

**BMI (xxx.x)**

Audit	User	Time (GMT)
Amendment Manager: User entered '25.91682'	System	16 Sep 2020 23:53:41
User entered '25.9'	System	14 Aug 2020 17:45:47
DataPoint set to visible.	System	12 Aug 2020 17:28:11

**US3312046**

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 26 Nov 2020 10:51:05**

[BMI units](#)

Audit	User	Time (GMT)
User entered 'kg/m2'	System	14 Aug 2020 17:45:47
DataPoint set to visible.	System	12 Aug 2020 17:28:11

US3312046

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 10:51:05

Temperature (xxx.x)

Audit	User	Time (GMT)
User entered missing code ND - Not Done.	Karol Moore (b) (4) (b) (4)	14 Aug 2020 17:45:47

US3312046

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 10:51:05

[Route of measurement](#)

Audit	User	Time (GMT)
User entered 'Oral (Oral)'	Karol Moore (b) (4) (b) (4)	14 Aug 2020 17:45:47

**US3312046**

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 26 Nov 2020 10:51:05**

[If Other, specify](#)

Audit	User	Time (GMT)
User entered empty.	Karol Moore (b) (4) (b) (4)	14 Aug 2020 17:45:47



**US3312046**

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 26 Nov 2020 10:51:05**

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
User entered missing code ND - Not Done.	Karol Moore (b) (4) (b) (4)	14 Aug 2020 17:45:47

**US3312046**

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 26 Nov 2020 10:51:05**

[Pulse units](#)

Audit	User	Time (GMT)
User entered 'bpm'	System	14 Aug 2020 17:45:47

US3312046

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 10:51:05

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

Audit	User	Time (GMT)
User entered missing code ND - Not Done.	Karol Moore (b) (4) (b) (4)	14 Aug 2020 17:45:47

**US3312046**

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 26 Nov 2020 10:51:05**

[Respiratory Rate units](#)

Audit	User	Time (GMT)
User entered 'breaths/min'	System	14 Aug 2020 17:45:47

US3312046

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 10:51:05

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
User entered missing code ND - Not Done.	Karol Moore (b) (4) (b) (4)	14 Aug 2020 17:45:47

**US3312046**

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 26 Nov 2020 10:51:05**

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	14 Aug 2020 17:45:47

US3312046

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 10:51:05

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
User entered missing code ND - Not Done.	Karol Moore (b) (4) (b) (4)	14 Aug 2020 17:45:47

**US3312046**

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 26 Nov 2020 10:51:05**

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	14 Aug 2020 17:45:47



US3312046

Folder: Screening

Form: Physical Examination

Generated On: 26 Nov 2020 10:51:05

Was the physical examination performed?

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Karol Moore (b) (4) (b) (4)	14 Aug 2020 17:45:58

US3312046

Folder: Screening

Form: Physical Examination

Generated On: 26 Nov 2020 10:51:05

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Query 'The Physical Examination Date is prior to the Screening Visit Date. Please review and reconcile.' canceled (Site from System).	(b) (4), (b) (6)	11 Sep 2020 21:53:49
User opened query 'The Physical Examination Date is prior to the Screening Visit Date. Please review and reconcile.' (Site from System).		09 Sep 2020 18:56:51
User entered '12 Aug 2020'	Karol Moore (b) (4) (b) (4)	14 Aug 2020 17:45:58

**US3312046**

**Folder: Screening**

**Form: Childbearing Potential**

**Generated On: 26 Nov 2020 10:51:05**

**Date of assessment** (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered '12 Aug 2020'	Karol Moore (b) (4) (b) (4)	14 Aug 2020 17:46:34

US3312046

Folder: Screening

Form: Childbearing Potential

Generated On: 26 Nov 2020 10:51:05

Is the participant of childbearing potential?

Audit	User	Time (GMT)
User entered 'No (N)'	Karol Moore (b) (4) (b) (4)	14 Aug 2020 17:46:34

**US3312046**

**Folder: Screening**

**Form: Childbearing Potential**

**Generated On: 26 Nov 2020 10:51:05**

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

Audit	User	Time (GMT)
User entered 'Surgically sterile (SURGICALLY STERILE)'	Karol Moore (b) (4) (b) (4)	14 Aug 2020 17:46:34

**US3312046**

**Folder: Screening**

**Form: Childbearing Potential**

**Generated On: 26 Nov 2020 10:51:05**

[If Partner medically sterile or Other, specify](#)

Audit	User	Time (GMT)
User entered empty.	Karol Moore (b) (4) (b) (4)	14 Aug 2020 17:46:34

**US3312046**

**Folder: Screening**

**Form: Childbearing Potential**

**Generated On: 26 Nov 2020 10:51:05**

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

Audit	User	Time (GMT)
User entered 'un UNK 1985'	Karol Moore (b) (4) (b) (4)	14 Aug 2020 17:46:34

**US3312046**

**Folder: Screening**

**Form: Childbearing Potential**

**Generated On: 26 Nov 2020 10:51:05**

[Date of surgery unknown](#)

Audit	User	Time (GMT)
User entered '0'	Karol Moore (b) (4) (b) (4)	14 Aug 2020 17:46:34



US3312046

Folder: Screening

Form: Childbearing Potential

Generated On: 26 Nov 2020 10:51:05

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

Audit	User	Time (GMT)
User entered empty.	Karol Moore (b) (4) (b) (4)	14 Aug 2020 17:46:34

**US3312046**

**Folder: Screening**

**Form: Childbearing Potential**

**Generated On: 26 Nov 2020 10:51:05**

[Date of last menstruation unknown](#)

Audit	User	Time (GMT)
User entered '0'	Karol Moore (b) (4) (b) (4)	14 Aug 2020 17:46:34

US3312046

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 10:51:05

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

Audit	User	Time (GMT)
User entered 'No (N)'	Karol Moore (b) (4) (b) (4)	14 Aug 2020 17:47:31

US3312046

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 10:51:05

**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)	14 Aug 2020 17:47:31

US3312046

Folder: Screening

Form: Risk of Exposure

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**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)	14 Aug 2020 17:47:31

US3312046

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 10:51:05

**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)	14 Aug 2020 17:47:31

US3312046

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 10:51:05

[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)	14 Aug 2020 17:47:31

US3312046

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 10:51:05

[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)	14 Aug 2020 17:47:31



US3312046

Folder: Screening

Form: Risk of Exposure

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**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)	14 Aug 2020 17:47:31

US3312046

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 10:51:05

**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)	14 Aug 2020 17:47:31

US3312046

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 10:51:05

**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)	14 Aug 2020 17:47:31

US3312046

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 10:51:05

**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)	14 Aug 2020 17:47:31

US3312046

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 10:51:05

**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)	14 Aug 2020 17:47:31

US3312046

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 10:51:05

[Other](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Karol Moore (b) (4) (b) (4)	14 Aug 2020 17:47:31

US3312046

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 10:51:05

[Specify](#)

Audit	User	Time (GMT)
User entered 'foster rescue dogs and frequently visits rescue center'	Karol Moore (b) (4) (b) (4)	14 Aug 2020 17:47:31

US3312046

Folder: Screening

Form: Risk of Exposure

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No Risk Identified

Audit	User	Time (GMT)
User entered '0'	Karol Moore (b) (4) (b) (4)	14 Aug 2020 17:47:31



US3312046

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 10:51:05

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

Audit	User	Time (GMT)
User entered '0'	Karol Moore (b) (4) (b) (4)	14 Aug 2020 17:47:31

US3312046

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 10:51:05

**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)	14 Aug 2020 17:47:31

US3312046

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 10:51:05

[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)	14 Aug 2020 17:47:31

US3312046

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 10:51:05

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)	14 Aug 2020 17:47:31

US3312046

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 10:51:05

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

Audit	User	Time (GMT)
User entered '0'	Karol Moore (b) (4) (b) (4)	14 Aug 2020 17:47:31

**US3312046**

**Folder: Screening**

**Form: Risk of Exposure**

**Generated On: 26 Nov 2020 10:51:05**

**Other**

Audit	User	Time (GMT)
User entered 'I'	Karol Moore (b) (4) (b) (4)	14 Aug 2020 17:47:31

US3312046

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 10:51:05

[Specify](#)

Audit	User	Time (GMT)
User entered 'resides in community with ongoing person to person transmission'	Karol Moore (b) (4) (b) (4)	14 Aug 2020 17:47:31

**US3312046**

**Folder: Visit 1 Day 1**

**Form: Visit Date**

**Generated On: 26 Nov 2020 10:51:05**

[Was this visit performed?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Christa Estrada (b) (4) (b) (4)	12 Aug 2020 17:28:26



US3312046

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 26 Nov 2020 10:51:05

Visit date (dd MMM yyyy)

Audit	User	Time (GMT)
User entered '12 Aug 2020'	Christa Estrada (b) (4) (b) (4)	12 Aug 2020 17:28:26

US3312046

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 26 Nov 2020 10:51:05

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)	12 Aug 2020 17:28:26

**US3312046**

**Folder: Visit 1 Day 1**

**Form: Visit Date**

**Generated On: 26 Nov 2020 10:51:05**

[Folder OID](#)

Audit	User	Time (GMT)
User entered 'VISIT1'	System	12 Aug 2020 17:28:26

US3312046

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 26 Nov 2020 10:51:05

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

Audit	User	Time (GMT)
User entered '12 AUG 2020'	RWS_ENDPOINT ENDPOINT (b) (4) <div></div>	12 Aug 2020 16:49:42

US3312046

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 26 Nov 2020 10:51:05

What was the participant's randomization number?

Audit	User	Time (GMT)
Amendment Manager: User closed query 'Data entered is non-conformant. Please correct.' (Site from System).	System	21 Aug 2020 03:53:47
Amendment Manager: Data point set to conformant.	System	21 Aug 2020 03:53:47
User opened query 'Data entered is non-conformant. Please correct.' (Site from System).	System	12 Aug 2020 16:49:42
User entered '185756' (non-conformant).	RWS_ENDPOINT ENDPOINT (b) (4) [REDACTED]	12 Aug 2020 16:49:42

US3312046

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 26 Nov 2020 10:51:05

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

Audit	User	Time (GMT)
User entered '>=65 years (3)'	RWS_ENDPOINT ENDPOINT (b) (4) <div></div>	12 Aug 2020 16:49:42

**US3312046**

**Folder: Visit 1 Day 1**

**Form: Randomization**

**Generated On: 26 Nov 2020 10:51:05**

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)	12 Aug 2020 17:28:40

**US3312046**

**Folder: Visit 1 Day 1**

**Form: Randomization**

**Generated On: 26 Nov 2020 10:51:05**

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)	12 Aug 2020 17:28:40



US3312046

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 26 Nov 2020 10:51:05

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

Audit	User	Time (GMT)
User entered 'No (N)'	Christa Estrada (b) (4) (b) (4)	12 Aug 2020 17:28:40

**US3312046**

**Folder: Visit 1 Day 1**

**Form: Randomization**

**Generated On: 26 Nov 2020 10:51:05**

[Diabetes \(Type I, Type 2, or gestational\)](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Christa Estrada (b) (4) (b) (4)	12 Aug 2020 17:28:40

US3312046

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 26 Nov 2020 10:51:05

[Liver Disease](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Christa Estrada (b) (4) (b) (4)	12 Aug 2020 17:28:40

**US3312046**

**Folder: Visit 1 Day 1**

**Form: Randomization**

**Generated On: 26 Nov 2020 10:51:05**

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

Audit	User	Time (GMT)
User entered 'No (N)'	Heather Barker (b) (4)	30 Oct 2020 17:21:46
Amendment Manager: DataPoint set to visible.	(b) (4)	19 Sep 2020 10:18:42
Amendment Manager inserted this DataPoint.	System	19 Sep 2020 06:47:38

US3312046

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 26 Nov 2020 10:51:05

Height

Audit	User	Time (GMT)
User entered missing code ND - Not Done.	Karol Moore (b) (4) (b) (4)	14 Aug 2020 17:51:04

US3312046

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 26 Nov 2020 10:51:05

Weight

Audit	User	Time (GMT)
User entered missing code ND - Not Done.	Karol Moore (b) (4) (b) (4)	14 Aug 2020 17:51:04

US3312046

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 26 Nov 2020 10:51:05

Height

Audit	User	Time (GMT)
User entered missing code ND - Not Done.	Karol Moore (b) (4) (b) (4)	14 Aug 2020 17:51:04

US3312046

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 26 Nov 2020 10:51:05

Weight

Audit	User	Time (GMT)
User entered missing code ND - Not Done.	Karol Moore (b) (4) (b) (4)	14 Aug 2020 17:51:04



US3312046

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 10:51:05

[Timepoint](#)

Audit	User	Time (GMT)
User accepted default value 'Pre-Dose (PREDOSE)'	Karol Moore (b) (4) (b) (4)	14 Aug 2020 17:51:04

US3312046

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 10:51:05

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Karol Moore (b) (4) (b) (4)	14 Aug 2020 17:51:04

US3312046

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 10:51:05

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered '12 Aug 2020'	Karol Moore (b) (4) (b) (4)	14 Aug 2020 17:51:04

US3312046

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 10:51:05

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

Audit	User	Time (GMT)
User entered '11:05'	Karol Moore (b) (4) (b) (4)	14 Aug 2020 17:51:04

**US3312046**

**Folder: Visit 1 Day 1**

**Form: Vital Signs - Dosing (1)**

**Generated On: 26 Nov 2020 10:51:05**

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

Audit	User	Time (GMT)
User entered '12 Aug 2020 11:05'	System	14 Aug 2020 17:51:04

US3312046

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 10:51:05

Temperature (xxx.x)

Audit	User	Time (GMT)
User entered '98.1' F	Karol Moore (b) (4) (b) (4)	14 Aug 2020 17:51:04

US3312046

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 10:51:05

[Route of measurement](#)

Audit	User	Time (GMT)
User entered 'Oral (Oral)'	Karol Moore (b) (4) (b) (4)	14 Aug 2020 17:51:04

**US3312046**

**Folder: Visit 1 Day 1**

**Form: Vital Signs - Dosing (1)**

**Generated On: 26 Nov 2020 10:51:05**

[If Other, specify](#)

Audit	User	Time (GMT)
User entered empty.	Karol Moore (b) (4) (b) (4)	14 Aug 2020 17:51:04



US3312046

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 10:51:05

Pulse (xxx)

Audit	User	Time (GMT)
User entered '62'	Karol Moore (b) (4) (b) (4)	14 Aug 2020 17:51:04

**US3312046**

**Folder: Visit 1 Day 1**

**Form: Vital Signs - Dosing (1)**

**Generated On: 26 Nov 2020 10:51:05**

[Pulse units](#)

Audit	User	Time (GMT)
User entered 'bpm'	System	14 Aug 2020 17:51:04

US3312046

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 10:51:05

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

Audit	User	Time (GMT)
User entered '14'	Karol Moore (b) (4) (b) (4)	14 Aug 2020 17:51:04

**US3312046**

**Folder: Visit 1 Day 1**

**Form: Vital Signs - Dosing (1)**

**Generated On: 26 Nov 2020 10:51:05**

[Respiratory Rate units](#)

Audit	User	Time (GMT)
User entered 'breaths/min'	System	14 Aug 2020 17:51:04

US3312046

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 10:51:05

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
User entered '125'	Karol Moore (b) (4) (b) (4)	14 Aug 2020 17:51:04

**US3312046**

**Folder: Visit 1 Day 1**

**Form: Vital Signs - Dosing (1)**

**Generated On: 26 Nov 2020 10:51:05**

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	14 Aug 2020 17:51:04

US3312046

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 10:51:05

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
User entered '72'	Karol Moore (b) (4) (b) (4)	14 Aug 2020 17:51:04

**US3312046**

**Folder: Visit 1 Day 1**

**Form: Vital Signs - Dosing (1)**

**Generated On: 26 Nov 2020 10:51:05**

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	14 Aug 2020 17:51:04



US3312046

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 26 Nov 2020 10:51:05

Height

Audit	User	Time (GMT)
User entered missing code ND - Not Done.	Karol Moore (b) (4) (b) (4)	14 Aug 2020 17:51:04

US3312046

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 26 Nov 2020 10:51:05

Weight

Audit	User	Time (GMT)
User entered missing code ND - Not Done.	Karol Moore (b) (4) (b) (4)	14 Aug 2020 17:51:04

US3312046

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 10:51:05

[Timepoint](#)

Audit	User	Time (GMT)
User accepted default value 'Post-Dose (POSTDOSE)'	Karol Moore (b) (4) (b) (4)	14 Aug 2020 17:51:04

US3312046

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 10:51:05

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Karol Moore (b) (4) (b) (4)	14 Aug 2020 17:51:04

US3312046

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 10:51:05

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered '12 Aug 2020'	Karol Moore (b) (4) (b) (4)	14 Aug 2020 17:51:04

US3312046

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 10:51:05

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

Audit	User	Time (GMT)
Query 'Post-dose vital signs time is prior to or less than 60 minutes after the Dose Time. Please review and reconcile.' canceled (Site from System).	(b) (4), (b) (6)	17 Aug 2020 07:16:48
User opened query 'Post-dose vital signs time is prior System to or less than 60 minutes after the Dose Time. Please review and reconcile.' (Site from System).		14 Aug 2020 17:51:04
User entered '12:53'	Karol Moore (b) (4) (b) (4)	14 Aug 2020 17:51:04

**US3312046**

**Folder: Visit 1 Day 1**

**Form: Vital Signs - Dosing (2)**

**Generated On: 26 Nov 2020 10:51:05**

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

Audit	User	Time (GMT)
User entered '12 Aug 2020 12:53'	System	14 Aug 2020 17:51:04

US3312046

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 10:51:05

Temperature (xxx.x)

Audit	User	Time (GMT)
User entered '97.4' F	Karol Moore (b) (4) (b) (4)	14 Aug 2020 17:51:04



US3312046

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 10:51:05

[Route of measurement](#)

Audit	User	Time (GMT)
User entered 'Oral (Oral)'	Karol Moore (b) (4) (b) (4)	14 Aug 2020 17:51:04

US3312046

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 10:51:05

[If Other, specify](#)

Audit	User	Time (GMT)
User entered empty.	Karol Moore (b) (4) (b) (4)	14 Aug 2020 17:51:04

**US3312046**

**Folder: Visit 1 Day 1**

**Form: Vital Signs - Dosing (2)**

**Generated On: 26 Nov 2020 10:51:05**

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
User entered '60'	Karol Moore (b) (4) (b) (4)	14 Aug 2020 17:51:04

**US3312046**

**Folder: Visit 1 Day 1**

**Form: Vital Signs - Dosing (2)**

**Generated On: 26 Nov 2020 10:51:05**

[Pulse units](#)

Audit	User	Time (GMT)
User entered 'bpm'	System	14 Aug 2020 17:51:04

US3312046

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 10:51:05

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

Audit	User	Time (GMT)
User entered '16'	Karol Moore (b) (4) (b) (4)	14 Aug 2020 17:51:04

**US3312046**

**Folder: Visit 1 Day 1**

**Form: Vital Signs - Dosing (2)**

**Generated On: 26 Nov 2020 10:51:05**

[Respiratory Rate units](#)

Audit	User	Time (GMT)
User entered 'breaths/min'	System	14 Aug 2020 17:51:04

US3312046

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 10:51:05

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
User entered '134'	Karol Moore (b) (4) (b) (4)	14 Aug 2020 17:51:04

**US3312046**

**Folder: Visit 1 Day 1**

**Form: Vital Signs - Dosing (2)**

**Generated On: 26 Nov 2020 10:51:05**

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	14 Aug 2020 17:51:04



US3312046

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 10:51:05

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
User entered '77'	Karol Moore (b) (4) (b) (4)	14 Aug 2020 17:51:04

**US3312046**

**Folder: Visit 1 Day 1**

**Form: Vital Signs - Dosing (2)**

**Generated On: 26 Nov 2020 10:51:05**

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	14 Aug 2020 17:51:04

US3312046

Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 26 Nov 2020 10:51:05

Was the physical examination performed?

Audit	User	Time (GMT)
User entered 'No (N)'	Karol Moore (b) (4) (b) (4)	14 Aug 2020 17:54:39

US3312046

Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 26 Nov 2020 10:51:05

Date of examination (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered empty.	Karol Moore (b) (4) (b) (4)	14 Aug 2020 17:54:39

US3312046

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 26 Nov 2020 10:51:05

[Was study treatment given?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Christa Estrada (b) (4) (b) (4)	12 Aug 2020 17:29:06

US3312046

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 26 Nov 2020 10:51:05

If No, reason not given

Audit	User	Time (GMT)
User entered empty.	Christa Estrada (b) (4) (b) (4)	12 Aug 2020 17:29:06

**US3312046**

**Folder: Visit 1 Day 1**

**Form: Exposure**

**Generated On: 26 Nov 2020 10:51:05**

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)	12 Aug 2020 17:29:06

**US3312046**

**Folder: Visit 1 Day 1**

**Form: Exposure**

**Generated On: 26 Nov 2020 10:51:05**

[What was the study treatment?](#)

Audit	User	Time (GMT)
User entered 'MRNA-1273 OR PLACEBO'	System	12 Aug 2020 17:29:06



US3312046

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 26 Nov 2020 10:51:05

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
User entered '12 Aug 2020'	Christa Estrada (b) (4) (b) (4)	12 Aug 2020 17:29:06

US3312046

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 26 Nov 2020 10:51:05

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

Audit	User	Time (GMT)
User entered '12:22'	Christa Estrada (b) (4) (b) (4)	12 Aug 2020 17:29:06

**US3312046**

**Folder: Visit 1 Day 1**

**Form: Exposure**

**Generated On: 26 Nov 2020 10:51:05**

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

Audit	User	Time (GMT)
User entered '12 Aug 2020 12:22'	System	12 Aug 2020 17:29:06

US3312046

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 26 Nov 2020 10:51:05

Which arm was used to give treatment?

Audit	User	Time (GMT)
User entered 'Left Arm (LEFT ARM)'	Christa Estrada (b) (4) (b) (4)	12 Aug 2020 17:29:06

**US3312046**

**Folder: Visit 1 Day 1**

**Form: Exposure**

**Generated On: 26 Nov 2020 10:51:05**

[What was the frequency of the study treatment dosing?](#)

Audit	User	Time (GMT)
User entered 'ONCE'	System	12 Aug 2020 17:29:06

**US3312046**

**Folder: Visit 1 Day 1**

**Form: Exposure**

**Generated On: 26 Nov 2020 10:51:05**

[What was the route of administration for the study treatment?](#)

Audit	User	Time (GMT)
User entered 'INTRAMUSCULAR'	System	12 Aug 2020 17:29:06

**US3312046**

**Folder: Visit 1 Day 1**

**Form: Immunogenicity Assessment**

**Generated On: 26 Nov 2020 10:51:05**

[Was the sample collected?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Karol Moore (b) (4) (b) (4)	14 Aug 2020 17:55:20

US3312046

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 10:51:05

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered '12 Aug 2020'	Karol Moore (b) (4) (b) (4)	14 Aug 2020 17:55:20



**US3312046**

**Folder: Visit 1 Day 1**

**Form: Immunogenicity Assessment**

**Generated On: 26 Nov 2020 10:51:05**

[Collection time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
User entered '11:37'	Karol Moore (b) (4) (b) (4)	14 Aug 2020 17:55:20

**US3312046**

**Folder: Visit 1 Day 1**

**Form: Immunogenicity Assessment**

**Generated On: 26 Nov 2020 10:51:05**

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

Audit	User	Time (GMT)
User entered '12 Aug 2020 11:37'	System	14 Aug 2020 17:55:20

US3312046

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 26 Nov 2020 10:51:05

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered '12 Aug 2020'	Karol Moore (b) (4) (b) (4)	14 Aug 2020 17:55:35

US3312046

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 26 Nov 2020 10:51:05

[Lab Test](#)

Audit	User	Time (GMT)
User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)'	Karol Moore (b) (4) (b) (4)	14 Aug 2020 17:55:35

US3312046

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 26 Nov 2020 10:51:05

[Was the sample collected?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Karol Moore (b) (4) (b) (4)	14 Aug 2020 17:55:35

**US3312046**

**Folder: Visit 1 Day 1**

**Form: Central Laboratory - Nasopharyngeal Swab (1)**

**Generated On: 26 Nov 2020 10:51:05**

**Collection time (00:00 - 23:59)**

Audit	User	Time (GMT)
User entered '11:15'	Karol Moore (b) (4) (b) (4)	14 Aug 2020 17:55:35

**US3312046**

**Folder: Visit 1 Day 1**

**Form: Central Laboratory - Nasopharyngeal Swab (1)**

**Generated On: 26 Nov 2020 10:51:05**

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

Audit	User	Time (GMT)
User entered '12 Aug 2020 11:15'	System	14 Aug 2020 17:55:35

US3312046

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 26 Nov 2020 10:51:05

[Lab Test](#)

Audit	User	Time (GMT)
User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)'	Karol Moore (b) (4) (b) (4)	14 Aug 2020 17:55:35



US3312046

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 26 Nov 2020 10:51:05

[Was the sample collected?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Karol Moore (b) (4) (b) (4)	14 Aug 2020 17:55:35

**US3312046**

**Folder: Visit 1 Day 1**

**Form: Central Laboratory - Nasopharyngeal Swab (2)**

**Generated On: 26 Nov 2020 10:51:05**

**Collection time (00:00 - 23:59)**

Audit	User	Time (GMT)
User entered empty.	Karol Moore (b) (4) (b) (4)	14 Aug 2020 17:55:35

**US3312046**

**Folder: Visit 1 Day 1**

**Form: Central Laboratory - Nasopharyngeal Swab (2)**

**Generated On: 26 Nov 2020 10:51:05**

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

Audit	User	Time (GMT)
User entered empty.	System	14 Aug 2020 17:55:35

US3312046

Folder: Visit 1 Day 1

Form: Continuing

Generated On: 26 Nov 2020 10:51:05

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

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Karol Moore (b) (4) (b) (4)	14 Aug 2020 17:55:46

**US3312046**

**Folder: Visit 1 Day 1**

**Form: Continuing**

**Generated On: 26 Nov 2020 10:51:05**

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered '1'	System	14 Aug 2020 17:55:46

**US3312046**

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

**Form: Temperature\_Day(1/1)**

**Generated On: 26 Nov 2020 10:51:05**

**TIMEPOINT**

Audit	User	Time (GMT)
Data entry locked.	System	12 Aug 2020 17:29:06
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	12 Aug 2020 17:29:06

**US3312046**

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

**Form: Temperature\_Day(1/1)**

**Generated On: 26 Nov 2020 10:51:05**

**Was TEMPERATURE taken?**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E037D92C-2F6A-4B91-B9C7-F8A20B33EADC)', Time: '2020-08-12T12:54:55', User OID: 'PatientReportedOutcome (US3312046)', ODM File OID: 'aa935fcb-bdc7-402d-978c-4654b7de13e0'	System	12 Aug 2020 17:55:49
User entered 'Yes (Y)'	System	12 Aug 2020 17:55:49

**US3312046**

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

**Form: Temperature\_Day(1/1)**

**Generated On: 26 Nov 2020 10:51:05**

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E037D92C-2F6A-4B91-B9C7-F8A20B33EADC)', Time: '2020-08-12T12:55:14', User OID: 'PatientReportedOutcome (US3312046)', ODM File OID: 'aa935fcb-bdc7-402d-978c-4654b7de13e0'	System	12 Aug 2020 17:55:49
User entered '97.4'	System	12 Aug 2020 17:55:49



US3312046

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/1)

Generated On: 26 Nov 2020 10:51:05

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E037D92C-2F6A-4B91-B9C7-F8A20B33EADC)', Time: '2020-08-12T12:55:34', User OID: 'PatientReportedOutcome (US3312046)', ODM File OID: 'aa935fcb-bdc7-402d-978c-4654b7de13e0'	System	12 Aug 2020 17:55:49
User entered 'No (N)'	System	12 Aug 2020 17:55:49

**US3312046**

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

**Form: Temperature\_Day(1/1)**

**Generated On: 26 Nov 2020 10:51:05**

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E037D92C-2F6A-4B91-B9C7-F8A20B33EADC)', Time: '2020-08-12T12:55:47', User OID: 'PatientReportedOutcome (US3312046)', ODM File OID: 'aa935fcb-bdc7-402d-978c-4654b7de13e0'	System	12 Aug 2020 17:55:49
User entered '12 Aug 2020 12:55'	System	12 Aug 2020 17:55:49

**US3312046**

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

**Form: Temperature\_Day(1/1)**

**Generated On: 26 Nov 2020 10:51:05**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '12 Aug 2020 12:42'	System	12 Aug 2020 17:29:06

**US3312046**

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

**Form: Temperature\_Day(1/1)**

**Generated On: 26 Nov 2020 10:51:05**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '12 Aug 2020 15:12'	System	12 Aug 2020 17:29:06

**US3312046**

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

**Form: Temperature\_Day(1/2)**

**Generated On: 26 Nov 2020 10:51:05**

**TIMEPOINT**

Audit	User	Time (GMT)
Data entry locked.	System	12 Aug 2020 17:29:06
User entered 'Day 1, after vaccination (at home)'	System	12 Aug 2020 17:29:06

**US3312046**

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

**Form: Temperature\_Day(1/2)**

**Generated On: 26 Nov 2020 10:51:05**

**Was TEMPERATURE taken?**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E037D92C-2F6A-4B91-B9C7-F8A20B33EADC)', Time: '2020-08-12T19:43:36', User OID: 'PatientReportedOutcome (US3312046)', ODM File OID: '9be8de0f-ab22-4651-a298-7ac431ee5ea2'	System	13 Aug 2020 00:44:11
User entered 'Yes (Y)'	System	13 Aug 2020 00:44:11

**US3312046**

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

**Form: Temperature\_Day(1/2)**

**Generated On: 26 Nov 2020 10:51:05**

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E037D92C-2F6A-4B91-B9C7-F8A20B33EADC)', Time: '2020-08-12T19:43:46', User OID: 'PatientReportedOutcome (US3312046)', ODM File OID: '9be8de0f-ab22-4651-a298-7ac431ee5ea2'	System	13 Aug 2020 00:44:11
User entered '97.1'	System	13 Aug 2020 00:44:11

**US3312046**

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

**Form: Temperature\_Day(1/2)**

**Generated On: 26 Nov 2020 10:51:05**

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E037D92C-2F6A-4B91-B9C7-F8A20B33EADC)', Time: '2020-08-12T19:43:52', User OID: 'PatientReportedOutcome (US3312046)', ODM File OID: '9be8de0f-ab22-4651-a298-7ac431ee5ea2'	System	13 Aug 2020 00:44:11
User entered 'No (N)'	System	13 Aug 2020 00:44:11



**US3312046**

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

**Form: Temperature\_Day(1/2)**

**Generated On: 26 Nov 2020 10:51:05**

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E037D92C-2F6A-4B91-B9C7-F8A20B33EADC)', Time: '2020-08-12T19:44:08', User OID: 'PatientReportedOutcome (US3312046)', ODM File OID: '9be8de0f-ab22-4651-a298-7ac431ee5ea2'	System	13 Aug 2020 00:44:11
User entered '12 Aug 2020 19:44'	System	13 Aug 2020 00:44:11

**US3312046**

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

**Form: Temperature\_Day(1/2)**

**Generated On: 26 Nov 2020 10:51:05**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '12 Aug 2020 16:07'	System	12 Aug 2020 17:29:06

**US3312046**

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

**Form: Temperature\_Day(1/2)**

**Generated On: 26 Nov 2020 10:51:05**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '13 Aug 2020 11:59'	System	12 Aug 2020 17:29:06

**US3312046**

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

**Form: Temperature\_Day(2)**

**Generated On: 26 Nov 2020 10:51:05**

**TIMEPOINT**

Audit	User	Time (GMT)
Data entry locked.	System	12 Aug 2020 17:29:06
User entered 'Day 2'	System	12 Aug 2020 17:29:06

**US3312046**

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

**Form: Temperature\_Day(2)**

**Generated On: 26 Nov 2020 10:51:05**

**Was TEMPERATURE taken?**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E037D92C-2F6A-4B91-B9C7-F8A20B33EADC)', Time: '2020-08-13T21:05:04', User OID: 'PatientReportedOutcome (US3312046)', ODM File OID: '0cf4effe-4890-4cb6-bef1-e6ae3cbc3ace'	System	14 Aug 2020 02:05:31
User entered 'Yes (Y)'	System	14 Aug 2020 02:05:31

**US3312046**

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

**Form: Temperature\_Day(2)**

**Generated On: 26 Nov 2020 10:51:05**

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E037D92C-2F6A-4B91-B9C7-F8A20B33EADC)', Time: '2020-08-13T21:05:14', User OID: 'PatientReportedOutcome (US3312046)', ODM File OID: '0cf4effe-4890-4cb6-bef1-e6ae3cbc3ace'	System	14 Aug 2020 02:05:31
User entered '97.1'	System	14 Aug 2020 02:05:31

**US3312046**

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

**Form: Temperature\_Day(2)**

**Generated On: 26 Nov 2020 10:51:05**

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E037D92C-2F6A-4B91-B9C7-F8A20B33EADC)', Time: '2020-08-13T21:05:20', User OID: 'PatientReportedOutcome (US3312046)', ODM File OID: '0cf4effe-4890-4cb6-bef1-e6ae3cbc3ace'	System	14 Aug 2020 02:05:31
User entered 'No (N)'	System	14 Aug 2020 02:05:31

**US3312046**

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

**Form: Temperature\_Day(2)**

**Generated On: 26 Nov 2020 10:51:05**

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E037D92C-2F6A-4B91-B9C7-F8A20B33EADC)', Time: '2020-08-13T21:05:27', User OID: 'PatientReportedOutcome (US3312046)', ODM File OID: '0cf4effe-4890-4cb6-bef1-e6ae3cbc3ace'	System	14 Aug 2020 02:05:31
User entered '13 Aug 2020 21:05'	System	14 Aug 2020 02:05:31



**US3312046**

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

**Form: Temperature\_Day(2)**

**Generated On: 26 Nov 2020 10:51:05**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '13 Aug 2020 12:00'	System	12 Aug 2020 17:29:06

**US3312046**

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

**Form: Temperature\_Day(2)**

**Generated On: 26 Nov 2020 10:51:05**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '14 Aug 2020 11:59'	System	12 Aug 2020 17:29:06

**US3312046**

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

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

**Generated On: 26 Nov 2020 10:51:05**

**TIMEPOINT**

Audit	User	Time (GMT)
Data entry locked.	System	12 Aug 2020 17:29:06
User entered 'Day 3'	System	12 Aug 2020 17:29:06

**US3312046**

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

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

**Generated On: 26 Nov 2020 10:51:05**

**Was TEMPERATURE taken?**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E037D92C-2F6A-4B91-B9C7-F8A20B33EADC)', Time: '2020-08-14T21:05:00', User OID: 'PatientReportedOutcome (US3312046)', ODM File OID: '138fc189-5e17-4915-a191-fa6c185da884'	System	15 Aug 2020 02:05:27
User entered 'Yes (Y)'	System	15 Aug 2020 02:05:27

**US3312046**

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

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

**Generated On: 26 Nov 2020 10:51:05**

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E037D92C-2F6A-4B91-B9C7-F8A20B33EADC)', Time: '2020-08-14T21:05:08', User OID: 'PatientReportedOutcome (US3312046)', ODM File OID: '138fc189-5e17-4915-a191-fa6c185da884'	System	15 Aug 2020 02:05:27
User entered '97.1'	System	15 Aug 2020 02:05:27

US3312046

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(3)

Generated On: 26 Nov 2020 10:51:05

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E037D92C-2F6A-4B91-B9C7-F8A20B33EADC)', Time: '2020-08-14T21:05:14', User OID: 'PatientReportedOutcome (US3312046)', ODM File OID: '138fc189-5e17-4915-a191-fa6c185da884'	System	15 Aug 2020 02:05:27
User entered 'No (N)'	System	15 Aug 2020 02:05:27

**US3312046**

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

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

**Generated On: 26 Nov 2020 10:51:05**

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E037D92C-2F6A-4B91-B9C7-F8A20B33EADC)', Time: '2020-08-14T21:05:23', User OID: 'PatientReportedOutcome (US3312046)', ODM File OID: '138fc189-5e17-4915-a191-fa6c185da884'	System	15 Aug 2020 02:05:27
User entered '14 Aug 2020 21:05'	System	15 Aug 2020 02:05:27

**US3312046**

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

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

**Generated On: 26 Nov 2020 10:51:05**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '14 Aug 2020 12:00'	System	12 Aug 2020 17:29:06



**US3312046**

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

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

**Generated On: 26 Nov 2020 10:51:05**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '15 Aug 2020 11:59'	System	12 Aug 2020 17:29:06

**US3312046**

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

**Form: Temperature\_Day(4)**

**Generated On: 26 Nov 2020 10:51:05**

**TIMEPOINT**

Audit	User	Time (GMT)
Data entry locked.	System	12 Aug 2020 17:29:06
User entered 'Day 4'	System	12 Aug 2020 17:29:06

**US3312046**

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

**Form: Temperature\_Day(4)**

**Generated On: 26 Nov 2020 10:51:05**

**Was TEMPERATURE taken?**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E037D92C-2F6A-4B91-B9C7-F8A20B33EADC)', Time: '2020-08-15T19:35:20', User OID: 'PatientReportedOutcome (US3312046)', ODM File OID: '8b54b160-2ef8-4eab-823b-7e055bdd31fa'	System	16 Aug 2020 00:35:45
User entered 'Yes (Y)'	System	16 Aug 2020 00:35:45

**US3312046**

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

**Form: Temperature\_Day(4)**

**Generated On: 26 Nov 2020 10:51:05**

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E037D92C-2F6A-4B91-B9C7-F8A20B33EADC)', Time: '2020-08-15T19:35:29', User OID: 'PatientReportedOutcome (US3312046)', ODM File OID: '8b54b160-2ef8-4eab-823b-7e055bdd31fa'	System	16 Aug 2020 00:35:45
User entered '96.8'	System	16 Aug 2020 00:35:45

US3312046

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(4)

Generated On: 26 Nov 2020 10:51:05

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E037D92C-2F6A-4B91-B9C7-F8A20B33EADC)', Time: '2020-08-15T19:35:36', User OID: 'PatientReportedOutcome (US3312046)', ODM File OID: '8b54b160-2ef8-4eab-823b-7e055bdd31fa'	System	16 Aug 2020 00:35:45
User entered 'No (N)'	System	16 Aug 2020 00:35:45

**US3312046**

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

**Form: Temperature\_Day(4)**

**Generated On: 26 Nov 2020 10:51:05**

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E037D92C-2F6A-4B91-B9C7-F8A20B33EADC)', Time: '2020-08-15T19:35:43', User OID: 'PatientReportedOutcome (US3312046)', ODM File OID: '8b54b160-2ef8-4eab-823b-7e055bdd31fa'	System	16 Aug 2020 00:35:45
User entered '15 Aug 2020 19:35'	System	16 Aug 2020 00:35:45

**US3312046**

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

**Form: Temperature\_Day(4)**

**Generated On: 26 Nov 2020 10:51:05**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '15 Aug 2020 12:00'	System	12 Aug 2020 17:29:06

**US3312046**

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

**Form: Temperature\_Day(4)**

**Generated On: 26 Nov 2020 10:51:05**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '16 Aug 2020 11:59'	System	12 Aug 2020 17:29:06



**US3312046**

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

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

**Generated On: 26 Nov 2020 10:51:05**

**TIMEPOINT**

Audit	User	Time (GMT)
Data entry locked.	System	12 Aug 2020 17:29:06
User entered 'Day 5'	System	12 Aug 2020 17:29:06

**US3312046**

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

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

**Generated On: 26 Nov 2020 10:51:05**

**Was TEMPERATURE taken?**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E037D92C-2F6A-4B91-B9C7-F8A20B33EADC)', Time: '2020-08-16T20:23:44', User OID: 'PatientReportedOutcome (US3312046)', ODM File OID: '172b22c2-be6f-4ab7-8f0d-d095d317b7ab'	System	17 Aug 2020 01:24:16
User entered 'Yes (Y)'	System	17 Aug 2020 01:24:16

**US3312046**

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

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

**Generated On: 26 Nov 2020 10:51:05**

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E037D92C-2F6A-4B91-B9C7-F8A20B33EADC)', Time: '2020-08-16T20:24:02', User OID: 'PatientReportedOutcome (US3312046)', ODM File OID: '172b22c2-be6f-4ab7-8f0d-d095d317b7ab'	System	17 Aug 2020 01:24:16
User entered '96.9'	System	17 Aug 2020 01:24:16

US3312046

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(5)

Generated On: 26 Nov 2020 10:51:05

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E037D92C-2F6A-4B91-B9C7-F8A20B33EADC)', Time: '2020-08-16T20:24:08', User OID: 'PatientReportedOutcome (US3312046)', ODM File OID: '172b22c2-be6f-4ab7-8f0d-d095d317b7ab'	System	17 Aug 2020 01:24:16
User entered 'No (N)'	System	17 Aug 2020 01:24:16

**US3312046**

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

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

**Generated On: 26 Nov 2020 10:51:05**

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E037D92C-2F6A-4B91-B9C7-F8A20B33EADC)', Time: '2020-08-16T20:24:13', User OID: 'PatientReportedOutcome (US3312046)', ODM File OID: '172b22c2-be6f-4ab7-8f0d-d095d317b7ab'	System	17 Aug 2020 01:24:16
User entered '16 Aug 2020 20:24'	System	17 Aug 2020 01:24:16

**US3312046**

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

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

**Generated On: 26 Nov 2020 10:51:05**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '16 Aug 2020 12:00'	System	12 Aug 2020 17:29:06

**US3312046**

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

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

**Generated On: 26 Nov 2020 10:51:05**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '17 Aug 2020 11:59'	System	12 Aug 2020 17:29:06

**US3312046**

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

**Form: Temperature\_Day(6)**

**Generated On: 26 Nov 2020 10:51:05**

**TIMEPOINT**

Audit	User	Time (GMT)
Data entry locked.	System	12 Aug 2020 17:29:06
User entered 'Day 6'	System	12 Aug 2020 17:29:06



**US3312046**

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

**Form: Temperature\_Day(6)**

**Generated On: 26 Nov 2020 10:51:05**

**Was TEMPERATURE taken?**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E037D92C-2F6A-4B91-B9C7-F8A20B33EADC)', Time: '2020-08-17T21:53:19', User OID: 'PatientReportedOutcome (US3312046)', ODM File OID: 'bbb7a75a-a6ae-4400-b1a8-588928e8496d'	System	18 Aug 2020 02:53:41
User entered 'Yes (Y)'	System	18 Aug 2020 02:53:41

**US3312046**

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

**Form: Temperature\_Day(6)**

**Generated On: 26 Nov 2020 10:51:05**

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E037D92C-2F6A-4B91-B9C7-F8A20B33EADC)', Time: '2020-08-17T21:53:26', User OID: 'PatientReportedOutcome (US3312046)', ODM File OID: 'bbb7a75a-a6ae-4400-b1a8-588928e8496d'	System	18 Aug 2020 02:53:41
User entered '97.3'	System	18 Aug 2020 02:53:41

US3312046

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(6)

Generated On: 26 Nov 2020 10:51:05

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E037D92C-2F6A-4B91-B9C7-F8A20B33EADC)', Time: '2020-08-17T21:53:33', User OID: 'PatientReportedOutcome (US3312046)', ODM File OID: 'bbb7a75a-a6ae-4400-b1a8-588928e8496d'	System	18 Aug 2020 02:53:41
User entered 'No (N)'	System	18 Aug 2020 02:53:41

**US3312046**

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

**Form: Temperature\_Day(6)**

**Generated On: 26 Nov 2020 10:51:05**

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E037D92C-2F6A-4B91-B9C7-F8A20B33EADC)', Time: '2020-08-17T21:53:38', User OID: 'PatientReportedOutcome (US3312046)', ODM File OID: 'bbb7a75a-a6ae-4400-b1a8-588928e8496d'	System	18 Aug 2020 02:53:41
User entered '17 Aug 2020 21:53'	System	18 Aug 2020 02:53:41

**US3312046**

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

**Form: Temperature\_Day(6)**

**Generated On: 26 Nov 2020 10:51:05**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '17 Aug 2020 12:00'	System	12 Aug 2020 17:29:06

**US3312046**

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

**Form: Temperature\_Day(6)**

**Generated On: 26 Nov 2020 10:51:05**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '18 Aug 2020 11:59'	System	12 Aug 2020 17:29:06

**US3312046**

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

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

**Generated On: 26 Nov 2020 10:51:05**

**TIMEPOINT**

Audit	User	Time (GMT)
Data entry locked.	System	12 Aug 2020 17:29:06
User entered 'Day 7'	System	12 Aug 2020 17:29:06

**US3312046**

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

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

**Generated On: 26 Nov 2020 10:51:05**

**Was TEMPERATURE taken?**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E037D92C-2F6A-4B91-B9C7-F8A20B33EADC)', Time: '2020-08-18T21:26:45', User OID: 'PatientReportedOutcome (US3312046)', ODM File OID: '0b0ffe49-584c-4e3a-95ff-e2fd5584b19b'	System	19 Aug 2020 02:27:08
User entered 'Yes (Y)'	System	19 Aug 2020 02:27:08



**US3312046**

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

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

**Generated On: 26 Nov 2020 10:51:05**

Please record your **TEMPERATURE in °F**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E037D92C-2F6A-4B91-B9C7-F8A20B33EADC)', Time: '2020-08-18T21:26:52', User OID: 'PatientReportedOutcome (US3312046)', ODM File OID: '0b0ffe49-584c-4e3a-95ff-e2fd5584b19b'	System	19 Aug 2020 02:27:08
User entered '97.3'	System	19 Aug 2020 02:27:08

US3312046

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(7)

Generated On: 26 Nov 2020 10:51:05

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E037D92C-2F6A-4B91-B9C7-F8A20B33EADC)', Time: '2020-08-18T21:26:59', User OID: 'PatientReportedOutcome (US3312046)', ODM File OID: '0b0ffe49-584c-4e3a-95ff-e2fd5584b19b'	System	19 Aug 2020 02:27:08
User entered 'No (N)'	System	19 Aug 2020 02:27:08

**US3312046**

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

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

**Generated On: 26 Nov 2020 10:51:05**

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E037D92C-2F6A-4B91-B9C7-F8A20B33EADC)', Time: '2020-08-18T21:27:04', User OID: 'PatientReportedOutcome (US3312046)', ODM File OID: '0b0ffe49-584c-4e3a-95ff-e2fd5584b19b'	System	19 Aug 2020 02:27:08
User entered '18 Aug 2020 21:27'	System	19 Aug 2020 02:27:08

**US3312046**

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

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

**Generated On: 26 Nov 2020 10:51:05**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '18 Aug 2020 12:00'	System	12 Aug 2020 17:29:06

**US3312046**

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

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

**Generated On: 26 Nov 2020 10:51:05**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '19 Aug 2020 11:59'	System	12 Aug 2020 17:29:06

**US3312046**

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

**Form: Injection Site\_Day(1/1)**

**Generated On: 26 Nov 2020 10:51:05**

**TIMEPOINT**

Audit	User	Time (GMT)
Data entry locked.	System	12 Aug 2020 17:29:06
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	12 Aug 2020 17:29:06

**US3312046**

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

**Form: Injection Site\_Day(1/1)**

**Generated On: 26 Nov 2020 10:51:05**

[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 (E037D92C-2F6A-4B91-B9C7-F8A20B33EADC)', Time: '2020-08-12T12:56:22', User OID: 'PatientReportedOutcome (US3312046)', ODM File OID: '8a9987e3-522a-4721-9ffa-80c56f81b994'	System	12 Aug 2020 17:56:51
User entered 'None (1)'	System	12 Aug 2020 17:56:51

**US3312046**

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

**Form: Injection Site\_Day(1/1)**

**Generated On: 26 Nov 2020 10:51:05**

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E037D92C-2F6A-4B91-B9C7-F8A20B33EADC)', Time: '2020-08-12T12:56:30', User OID: 'PatientReportedOutcome (US3312046)', ODM File OID: '8a9987e3-522a-4721-9ffa-80c56f81b994'	System	12 Aug 2020 17:56:51
User entered 'No (N)'	System	12 Aug 2020 17:56:51



**US3312046**

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

**Form: Injection Site\_Day(1/1)**

**Generated On: 26 Nov 2020 10:51:05**

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E037D92C-2F6A-4B91-B9C7-F8A20B33EADC)', Time: '2020-08-12T12:56:33', User OID: 'PatientReportedOutcome (US3312046)', ODM File OID: '8a9987e3-522a-4721-9ffa-80c56f81b994'	System	12 Aug 2020 17:56:51
User entered 'No (N)'	System	12 Aug 2020 17:56:51

US3312046

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 26 Nov 2020 10:51:05

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 (E037D92C-2F6A-4B91-B9C7-F8A20B33EADC)', Time: '2020-08-12T12:56:42', User OID: 'PatientReportedOutcome (US3312046)', ODM File OID: '8a9987e3-522a-4721-9ffa-80c56f81b994'	System	12 Aug 2020 17:56:51
User entered 'None (1)'	System	12 Aug 2020 17:56:51

**US3312046**

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

**Form: Injection Site\_Day(1/1)**

**Generated On: 26 Nov 2020 10:51:05**

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E037D92C-2F6A-4B91-B9C7-F8A20B33EADC)', Time: '2020-08-12T12:56:48', User OID: 'PatientReportedOutcome (US3312046)', ODM File OID: '8a9987e3-522a-4721-9ffa-80c56f81b994'	System	12 Aug 2020 17:56:51
User entered '12 Aug 2020 12:56'	System	12 Aug 2020 17:56:51

**US3312046**

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

**Form: Injection Site\_Day(1/1)**

**Generated On: 26 Nov 2020 10:51:05**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '12 Aug 2020 12:42'	System	12 Aug 2020 17:29:06

**US3312046**

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

**Form: Injection Site\_Day(1/1)**

**Generated On: 26 Nov 2020 10:51:05**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '12 Aug 2020 15:12'	System	12 Aug 2020 17:29:06

**US3312046**

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

**Form: Injection Site\_Day(1/2)**

**Generated On: 26 Nov 2020 10:51:05**

**TIMEPOINT**

Audit	User	Time (GMT)
Data entry locked.	System	12 Aug 2020 17:29:06
User entered 'Day 1, after vaccination (at home)'	System	12 Aug 2020 17:29:06

**US3312046**

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

**Form: Injection Site\_Day(1/2)**

**Generated On: 26 Nov 2020 10:51:05**

[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 (E037D92C-2F6A-4B91-B9C7-F8A20B33EADC)', Time: '2020-08-12T19:44:26', User OID: 'PatientReportedOutcome (US3312046)', ODM File OID: 'bf5c8562-4f6e-44f9-8a12-9e3f71c5c18e'	System	13 Aug 2020 00:44:48
User entered 'None (1)'	System	13 Aug 2020 00:44:48

**US3312046**

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

**Form: Injection Site\_Day(1/2)**

**Generated On: 26 Nov 2020 10:51:05**

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E037D92C-2F6A-4B91-B9C7-F8A20B33EADC)', Time: '2020-08-12T19:44:31', User OID: 'PatientReportedOutcome (US3312046)', ODM File OID: 'bf5c8562-4f6e-44f9-8a12-9e3f71c5c18e'	System	13 Aug 2020 00:44:48
User entered 'No (N)'	System	13 Aug 2020 00:44:48



**US3312046**

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

**Form: Injection Site\_Day(1/2)**

**Generated On: 26 Nov 2020 10:51:05**

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E037D92C-2F6A-4B91-B9C7-F8A20B33EADC)', Time: '2020-08-12T19:44:35', User OID: 'PatientReportedOutcome (US3312046)', ODM File OID: 'bf5c8562-4f6e-44f9-8a12-9e3f71c5c18e'	System	13 Aug 2020 00:44:48
User entered 'No (N)'	System	13 Aug 2020 00:44:48

US3312046

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 26 Nov 2020 10:51:05

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 (E037D92C-2F6A-4B91-B9C7-F8A20B33EADC)', Time: '2020-08-12T19:44:40', User OID: 'PatientReportedOutcome (US3312046)', ODM File OID: 'bf5c8562-4f6e-44f9-8a12-9e3f71c5c18e'	System	13 Aug 2020 00:44:48
User entered 'None (1)'	System	13 Aug 2020 00:44:48

**US3312046**

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

**Form: Injection Site\_Day(1/2)**

**Generated On: 26 Nov 2020 10:51:05**

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E037D92C-2F6A-4B91-B9C7-F8A20B33EADC)', Time: '2020-08-12T19:44:47', User OID: 'PatientReportedOutcome (US3312046)', ODM File OID: 'bf5c8562-4f6e-44f9-8a12-9e3f71c5c18e'	System	13 Aug 2020 00:44:48
User entered '12 Aug 2020 19:44'	System	13 Aug 2020 00:44:48

**US3312046**

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

**Form: Injection Site\_Day(1/2)**

**Generated On: 26 Nov 2020 10:51:05**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '12 Aug 2020 16:07'	System	12 Aug 2020 17:29:06

**US3312046**

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

**Form: Injection Site\_Day(1/2)**

**Generated On: 26 Nov 2020 10:51:05**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '13 Aug 2020 11:59'	System	12 Aug 2020 17:29:06

**US3312046**

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

**Form: Injection Site\_Day(2)**

**Generated On: 26 Nov 2020 10:51:05**

**TIMEPOINT**

Audit	User	Time (GMT)
Data entry locked.	System	12 Aug 2020 17:29:06
User entered 'Day 2'	System	12 Aug 2020 17:29:06

**US3312046**

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

**Form: Injection Site\_Day(2)**

**Generated On: 26 Nov 2020 10:51:05**

[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 (E037D92C-2F6A-4B91-B9C7-F8A20B33EADC)', Time: '2020-08-13T21:05:38', User OID: 'PatientReportedOutcome (US3312046)', ODM File OID: '2cfadd81-787d-46e8-9f4a-88c5a00e6da4'	System	14 Aug 2020 02:06:18
User entered 'None (1)'	System	14 Aug 2020 02:06:18

**US3312046**

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

**Form: Injection Site\_Day(2)**

**Generated On: 26 Nov 2020 10:51:05**

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E037D92C-2F6A-4B91-B9C7-F8A20B33EADC)', Time: '2020-08-13T21:05:43', User OID: 'PatientReportedOutcome (US3312046)', ODM File OID: '2cfadd81-787d-46e8-9f4a-88c5a00e6da4'	System	14 Aug 2020 02:06:18
User entered 'No (N)'	System	14 Aug 2020 02:06:18



**US3312046**

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

**Form: Injection Site\_Day(2)**

**Generated On: 26 Nov 2020 10:51:05**

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E037D92C-2F6A-4B91-B9C7-F8A20B33EADC)', Time: '2020-08-13T21:05:47', User OID: 'PatientReportedOutcome (US3312046)', ODM File OID: '2cfadd81-787d-46e8-9f4a-88c5a00e6da4'	System	14 Aug 2020 02:06:18
User entered 'No (N)'	System	14 Aug 2020 02:06:18

US3312046

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 26 Nov 2020 10:51:05

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 (E037D92C-2F6A-4B91-B9C7-F8A20B33EADC)', Time: '2020-08-13T21:05:52', User OID: 'PatientReportedOutcome (US3312046)', ODM File OID: '2cfadd81-787d-46e8-9f4a-88c5a00e6da4'	System	14 Aug 2020 02:06:18
User entered 'None (1)'	System	14 Aug 2020 02:06:18

**US3312046**

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

**Form: Injection Site\_Day(2)**

**Generated On: 26 Nov 2020 10:51:05**

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E037D92C-2F6A-4B91-B9C7-F8A20B33EADC)', Time: '2020-08-13T21:06:13', User OID: 'PatientReportedOutcome (US3312046)', ODM File OID: '2cfadd81-787d-46e8-9f4a-88c5a00e6da4'	System	14 Aug 2020 02:06:18
User entered '13 Aug 2020 21:06'	System	14 Aug 2020 02:06:18

**US3312046**

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

**Form: Injection Site\_Day(2)**

**Generated On: 26 Nov 2020 10:51:05**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '13 Aug 2020 12:00'	System	12 Aug 2020 17:29:06

**US3312046**

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

**Form: Injection Site\_Day(2)**

**Generated On: 26 Nov 2020 10:51:05**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '14 Aug 2020 11:59'	System	12 Aug 2020 17:29:06

**US3312046**

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

**Form: Injection Site\_Day(3)**

**Generated On: 26 Nov 2020 10:51:05**

**TIMEPOINT**

Audit	User	Time (GMT)
Data entry locked.	System	12 Aug 2020 17:29:06
User entered 'Day 3'	System	12 Aug 2020 17:29:06

**US3312046**

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

**Form: Injection Site\_Day(3)**

**Generated On: 26 Nov 2020 10:51:05**

[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 (E037D92C-2F6A-4B91-B9C7-F8A20B33EADC)', Time: '2020-08-14T21:05:30', User OID: 'PatientReportedOutcome (US3312046)', ODM File OID: 'b1a7be09-eb3c-493c-a5de-dbc6ed0950b9'	System	15 Aug 2020 02:05:56
User entered 'None (1)'	System	15 Aug 2020 02:05:56

**US3312046**

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

**Form: Injection Site\_Day(3)**

**Generated On: 26 Nov 2020 10:51:05**

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E037D92C-2F6A-4B91-B9C7-F8A20B33EADC)', Time: '2020-08-14T21:05:35', User OID: 'PatientReportedOutcome (US3312046)', ODM File OID: 'b1a7be09-eb3c-493c-a5de-dbc6ed0950b9'	System	15 Aug 2020 02:05:56
User entered 'No (N)'	System	15 Aug 2020 02:05:56



**US3312046**

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

**Form: Injection Site\_Day(3)**

**Generated On: 26 Nov 2020 10:51:05**

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E037D92C-2F6A-4B91-B9C7-F8A20B33EADC)', Time: '2020-08-14T21:05:39', User OID: 'PatientReportedOutcome (US3312046)', ODM File OID: 'b1a7be09-eb3c-493c-a5de-dbc6ed0950b9'	System	15 Aug 2020 02:05:56
User entered 'No (N)'	System	15 Aug 2020 02:05:56

US3312046

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 26 Nov 2020 10:51:05

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 (E037D92C-2F6A-4B91-B9C7-F8A20B33EADC)', Time: '2020-08-14T21:05:44', User OID: 'PatientReportedOutcome (US3312046)', ODM File OID: 'b1a7be09-eb3c-493c-a5de-dbc6ed0950b9'	System	15 Aug 2020 02:05:56
User entered 'None (1)'	System	15 Aug 2020 02:05:56

**US3312046**

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

**Form: Injection Site\_Day(3)**

**Generated On: 26 Nov 2020 10:51:05**

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E037D92C-2F6A-4B91-B9C7-F8A20B33EADC)', Time: '2020-08-14T21:05:53', User OID: 'PatientReportedOutcome (US3312046)', ODM File OID: 'b1a7be09-eb3c-493c-a5de-dbc6ed0950b9'	System	15 Aug 2020 02:05:56
User entered '14 Aug 2020 21:05'	System	15 Aug 2020 02:05:56

**US3312046**

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

**Form: Injection Site\_Day(3)**

**Generated On: 26 Nov 2020 10:51:05**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '14 Aug 2020 12:00'	System	12 Aug 2020 17:29:06

**US3312046**

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

**Form: Injection Site\_Day(3)**

**Generated On: 26 Nov 2020 10:51:05**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '15 Aug 2020 11:59'	System	12 Aug 2020 17:29:06

**US3312046**

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

**Form: Injection Site\_Day(4)**

**Generated On: 26 Nov 2020 10:51:05**

**TIMEPOINT**

Audit	User	Time (GMT)
Data entry locked.	System	12 Aug 2020 17:29:06
User entered 'Day 4'	System	12 Aug 2020 17:29:06

**US3312046**

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

**Form: Injection Site\_Day(4)**

**Generated On: 26 Nov 2020 10:51:05**

[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 (E037D92C-2F6A-4B91-B9C7-F8A20B33EADC)', Time: '2020-08-15T19:35:53', User OID: 'PatientReportedOutcome (US3312046)', ODM File OID: 'cb9263d1-0be2-4475-b1a6-d37d6b59eccb'	System	16 Aug 2020 00:36:23
User entered 'None (1)'	System	16 Aug 2020 00:36:23

**US3312046**

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

**Form: Injection Site\_Day(4)**

**Generated On: 26 Nov 2020 10:51:05**

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E037D92C-2F6A-4B91-B9C7-F8A20B33EADC)', Time: '2020-08-15T19:36:00', User OID: 'PatientReportedOutcome (US3312046)', ODM File OID: 'cb9263d1-0be2-4475-b1a6-d37d6b59eccb'	System	16 Aug 2020 00:36:23
User entered 'No (N)'	System	16 Aug 2020 00:36:23



**US3312046**

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

**Form: Injection Site\_Day(4)**

**Generated On: 26 Nov 2020 10:51:05**

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E037D92C-2F6A-4B91-B9C7-F8A20B33EADC)', Time: '2020-08-15T19:36:05', User OID: 'PatientReportedOutcome (US3312046)', ODM File OID: 'cb9263d1-0be2-4475-b1a6-d37d6b59eccb'	System	16 Aug 2020 00:36:23
User entered 'No (N)'	System	16 Aug 2020 00:36:23

**US3312046**

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

**Form: Injection Site\_Day(4)**

**Generated On: 26 Nov 2020 10:51:05**

[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 (E037D92C-2F6A-4B91-B9C7-F8A20B33EADC)', Time: '2020-08-15T19:36:10', User OID: 'PatientReportedOutcome (US3312046)', ODM File OID: 'cb9263d1-0be2-4475-b1a6-d37d6b59eccb'	System	16 Aug 2020 00:36:23
User entered 'None (1)'	System	16 Aug 2020 00:36:23

**US3312046**

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

**Form: Injection Site\_Day(4)**

**Generated On: 26 Nov 2020 10:51:05**

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E037D92C-2F6A-4B91-B9C7-F8A20B33EADC)', Time: '2020-08-15T19:36:20', User OID: 'PatientReportedOutcome (US3312046)', ODM File OID: 'cb9263d1-0be2-4475-b1a6-d37d6b59eccb'	System	16 Aug 2020 00:36:23
User entered '15 Aug 2020 19:36'	System	16 Aug 2020 00:36:23

**US3312046**

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

**Form: Injection Site\_Day(4)**

**Generated On: 26 Nov 2020 10:51:05**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '15 Aug 2020 12:00'	System	12 Aug 2020 17:29:06

**US3312046**

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

**Form: Injection Site\_Day(4)**

**Generated On: 26 Nov 2020 10:51:05**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '16 Aug 2020 11:59'	System	12 Aug 2020 17:29:06

**US3312046**

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

**Form: Injection Site\_Day(5)**

**Generated On: 26 Nov 2020 10:51:05**

**TIMEPOINT**

Audit	User	Time (GMT)
Data entry locked.	System	12 Aug 2020 17:29:06
User entered 'Day 5'	System	12 Aug 2020 17:29:06

**US3312046**

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

**Form: Injection Site\_Day(5)**

**Generated On: 26 Nov 2020 10:51:05**

[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 (E037D92C-2F6A-4B91-B9C7-F8A20B33EADC)', Time: '2020-08-16T20:24:24', User OID: 'PatientReportedOutcome (US3312046)', ODM File OID: '52aca1b6-d7d9-414a-ae9d-47ecef4abd02'	System	17 Aug 2020 01:24:55
User entered 'None (1)'	System	17 Aug 2020 01:24:55

**US3312046**

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

**Form: Injection Site\_Day(5)**

**Generated On: 26 Nov 2020 10:51:05**

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E037D92C-2F6A-4B91-B9C7-F8A20B33EADC)', Time: '2020-08-16T20:24:27', User OID: 'PatientReportedOutcome (US3312046)', ODM File OID: '52aca1b6-d7d9-414a-ae9d-47ecef4abd02'	System	17 Aug 2020 01:24:55
User entered 'No (N)'	System	17 Aug 2020 01:24:55



**US3312046**

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

**Form: Injection Site\_Day(5)**

**Generated On: 26 Nov 2020 10:51:05**

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E037D92C-2F6A-4B91-B9C7-F8A20B33EADC)', Time: '2020-08-16T20:24:31', User OID: 'PatientReportedOutcome (US3312046)', ODM File OID: '52aca1b6-d7d9-414a-ae9d-47ecef4abd02'	System	17 Aug 2020 01:24:55
User entered 'No (N)'	System	17 Aug 2020 01:24:55

**US3312046**

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

**Form: Injection Site\_Day(5)**

**Generated On: 26 Nov 2020 10:51:05**

[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 (E037D92C-2F6A-4B91-B9C7-F8A20B33EADC)', Time: '2020-08-16T20:24:45', User OID: 'PatientReportedOutcome (US3312046)', ODM File OID: '52aca1b6-d7d9-414a-ae9d-47ecef4abd02'	System	17 Aug 2020 01:24:55
User entered 'None (1)'	System	17 Aug 2020 01:24:55

**US3312046**

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

**Form: Injection Site\_Day(5)**

**Generated On: 26 Nov 2020 10:51:05**

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E037D92C-2F6A-4B91-B9C7-F8A20B33EADC)', Time: '2020-08-16T20:24:54', User OID: 'PatientReportedOutcome (US3312046)', ODM File OID: '52aca1b6-d7d9-414a-ae9d-47ecef4abd02'	System	17 Aug 2020 01:24:55
User entered '16 Aug 2020 20:24'	System	17 Aug 2020 01:24:55

**US3312046**

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

**Form: Injection Site\_Day(5)**

**Generated On: 26 Nov 2020 10:51:05**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '16 Aug 2020 12:00'	System	12 Aug 2020 17:29:06

**US3312046**

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

**Form: Injection Site\_Day(5)**

**Generated On: 26 Nov 2020 10:51:05**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '17 Aug 2020 11:59'	System	12 Aug 2020 17:29:06

**US3312046**

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

**Form: Injection Site\_Day(6)**

**Generated On: 26 Nov 2020 10:51:05**

**TIMEPOINT**

Audit	User	Time (GMT)
Data entry locked.	System	12 Aug 2020 17:29:06
User entered 'Day 6'	System	12 Aug 2020 17:29:06

**US3312046**

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

**Form: Injection Site\_Day(6)**

**Generated On: 26 Nov 2020 10:51:05**

[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 (E037D92C-2F6A-4B91-B9C7-F8A20B33EADC)', Time: '2020-08-17T21:53:44', User OID: 'PatientReportedOutcome (US3312046)', ODM File OID: 'ee8170fc-a02d-4ef8-8b03-bfc8af955b0c'	System	18 Aug 2020 02:54:12
User entered 'None (1)'	System	18 Aug 2020 02:54:12

**US3312046**

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

**Form: Injection Site\_Day(6)**

**Generated On: 26 Nov 2020 10:51:05**

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E037D92C-2F6A-4B91-B9C7-F8A20B33EADC)', Time: '2020-08-17T21:53:49', User OID: 'PatientReportedOutcome (US3312046)', ODM File OID: 'ee8170fc-a02d-4ef8-8b03-bfc8af955b0c'	System	18 Aug 2020 02:54:12
User entered 'No (N)'	System	18 Aug 2020 02:54:12



**US3312046**

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

**Form: Injection Site\_Day(6)**

**Generated On: 26 Nov 2020 10:51:05**

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E037D92C-2F6A-4B91-B9C7-F8A20B33EADC)', Time: '2020-08-17T21:53:55', User OID: 'PatientReportedOutcome (US3312046)', ODM File OID: 'ee8170fc-a02d-4ef8-8b03-bfc8af955b0c'	System	18 Aug 2020 02:54:12
User entered 'No (N)'	System	18 Aug 2020 02:54:12

US3312046

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(6)

Generated On: 26 Nov 2020 10:51:05

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 (E037D92C-2F6A-4B91-B9C7-F8A20B33EADC)', Time: '2020-08-17T21:54:00', User OID: 'PatientReportedOutcome (US3312046)', ODM File OID: 'ee8170fc-a02d-4ef8-8b03-bfc8af955b0c'	System	18 Aug 2020 02:54:12
User entered 'None (1)'	System	18 Aug 2020 02:54:12

**US3312046**

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

**Form: Injection Site\_Day(6)**

**Generated On: 26 Nov 2020 10:51:05**

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E037D92C-2F6A-4B91-B9C7-F8A20B33EADC)', Time: '2020-08-17T21:54:06', User OID: 'PatientReportedOutcome (US3312046)', ODM File OID: 'ee8170fc-a02d-4ef8-8b03-bfc8af955b0c'	System	18 Aug 2020 02:54:12
User entered '17 Aug 2020 21:54'	System	18 Aug 2020 02:54:12

**US3312046**

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

**Form: Injection Site\_Day(6)**

**Generated On: 26 Nov 2020 10:51:05**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '17 Aug 2020 12:00'	System	12 Aug 2020 17:29:06

**US3312046**

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

**Form: Injection Site\_Day(6)**

**Generated On: 26 Nov 2020 10:51:05**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '18 Aug 2020 11:59'	System	12 Aug 2020 17:29:06

**US3312046**

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

**Form: Injection Site\_Day(7)**

**Generated On: 26 Nov 2020 10:51:05**

**TIMEPOINT**

Audit	User	Time (GMT)
Data entry locked.	System	12 Aug 2020 17:29:06
User entered 'Day 7'	System	12 Aug 2020 17:29:06

**US3312046**

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

**Form: Injection Site\_Day(7)**

**Generated On: 26 Nov 2020 10:51:05**

[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 (E037D92C-2F6A-4B91-B9C7-F8A20B33EADC)', Time: '2020-08-18T21:27:10', User OID: 'PatientReportedOutcome (US3312046)', ODM File OID: 'ad860b01-3832-4c1d-9363-b2d6b8ec2586'	System	19 Aug 2020 02:28:16
User entered 'None (1)'	System	19 Aug 2020 02:28:16

**US3312046**

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

**Form: Injection Site\_Day(7)**

**Generated On: 26 Nov 2020 10:51:05**

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E037D92C-2F6A-4B91-B9C7-F8A20B33EADC)', Time: '2020-08-18T21:27:58', User OID: 'PatientReportedOutcome (US3312046)', ODM File OID: 'ad860b01-3832-4c1d-9363-b2d6b8ec2586'	System	19 Aug 2020 02:28:16
User entered 'No (N)'	System	19 Aug 2020 02:28:16



**US3312046**

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

**Form: Injection Site\_Day(7)**

**Generated On: 26 Nov 2020 10:51:05**

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E037D92C-2F6A-4B91-B9C7-F8A20B33EADC)', Time: '2020-08-18T21:28:02', User OID: 'PatientReportedOutcome (US3312046)', ODM File OID: 'ad860b01-3832-4c1d-9363-b2d6b8ec2586'	System	19 Aug 2020 02:28:16
User entered 'No (N)'	System	19 Aug 2020 02:28:16

US3312046

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 26 Nov 2020 10:51:05

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 (E037D92C-2F6A-4B91-B9C7-F8A20B33EADC)', Time: '2020-08-18T21:28:07', User OID: 'PatientReportedOutcome (US3312046)', ODM File OID: 'ad860b01-3832-4c1d-9363-b2d6b8ec2586'	System	19 Aug 2020 02:28:16
User entered 'None (1)'	System	19 Aug 2020 02:28:16

**US3312046**

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

**Form: Injection Site\_Day(7)**

**Generated On: 26 Nov 2020 10:51:05**

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E037D92C-2F6A-4B91-B9C7-F8A20B33EADC)', Time: '2020-08-18T21:28:14', User OID: 'PatientReportedOutcome (US3312046)', ODM File OID: 'ad860b01-3832-4c1d-9363-b2d6b8ec2586'	System	19 Aug 2020 02:28:16
User entered '18 Aug 2020 21:28'	System	19 Aug 2020 02:28:16

**US3312046**

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

**Form: Injection Site\_Day(7)**

**Generated On: 26 Nov 2020 10:51:05**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '18 Aug 2020 12:00'	System	12 Aug 2020 17:29:06

**US3312046**

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

**Form: Injection Site\_Day(7)**

**Generated On: 26 Nov 2020 10:51:05**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '19 Aug 2020 11:59'	System	12 Aug 2020 17:29:06

**US3312046**

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

**Form: General\_Day(1/1)**

**Generated On: 26 Nov 2020 10:51:05**

**TIMEPOINT**

Audit	User	Time (GMT)
Data entry locked.	System	12 Aug 2020 17:29:06
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	12 Aug 2020 17:29:06

**US3312046**

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

**Form: General\_Day(1/1)**

**Generated On: 26 Nov 2020 10:51:05**

**HEADACHE**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E037D92C-2F6A-4B91-B9C7-F8A20B33EADC)', Time: '2020-08-12T12:57:05', User OID: 'PatientReportedOutcome (US3312046)', ODM File OID: '8ce25c15-bfda-4798-851f-3fb6fa7fa124'	System	12 Aug 2020 17:57:52
User entered 'None (0)'	System	12 Aug 2020 17:57:52

**US3312046**

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

**Form: General\_Day(1/1)**

**Generated On: 26 Nov 2020 10:51:05**

**FATIGUE**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E037D92C-2F6A-4B91-B9C7-F8A20B33EADC)', Time: '2020-08-12T12:57:08', User OID: 'PatientReportedOutcome (US3312046)', ODM File OID: '8ce25c15-bfda-4798-851f-3fb6fa7fa124'	System	12 Aug 2020 17:57:52
User entered 'None (0)'	System	12 Aug 2020 17:57:52



**US3312046**

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

**Form: General\_Day(1/1)**

**Generated On: 26 Nov 2020 10:51:05**

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E037D92C-2F6A-4B91-B9C7-F8A20B33EADC)', Time: '2020-08-12T12:57:13', User OID: 'PatientReportedOutcome (US3312046)', ODM File OID: '8ce25c15-bfda-4798-851f-3fb6fa7fa124'	System	12 Aug 2020 17:57:52
User entered 'None (0)'	System	12 Aug 2020 17:57:52

**US3312046**

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

**Form: General\_Day(1/1)**

**Generated On: 26 Nov 2020 10:51:05**

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E037D92C-2F6A-4B91-B9C7-F8A20B33EADC)', Time: '2020-08-12T12:57:18', User OID: 'PatientReportedOutcome (US3312046)', ODM File OID: '8ce25c15-bfda-4798-851f-3fb6fa7fa124'	System	12 Aug 2020 17:57:52
User entered 'None (0)'	System	12 Aug 2020 17:57:52

**US3312046**

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

**Form: General\_Day(1/1)**

**Generated On: 26 Nov 2020 10:51:05**

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E037D92C-2F6A-4B91-B9C7-F8A20B33EADC)', Time: '2020-08-12T12:57:21', User OID: 'PatientReportedOutcome (US3312046)', ODM File OID: '8ce25c15-bfda-4798-851f-3fb6fa7fa124'	System	12 Aug 2020 17:57:52
User entered 'None (0)'	System	12 Aug 2020 17:57:52

**US3312046**

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

**Form: General\_Day(1/1)**

**Generated On: 26 Nov 2020 10:51:05**

**CHILLS**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E037D92C-2F6A-4B91-B9C7-F8A20B33EADC)', Time: '2020-08-12T12:57:24', User OID: 'PatientReportedOutcome (US3312046)', ODM File OID: '8ce25c15-bfda-4798-851f-3fb6fa7fa124'	System	12 Aug 2020 17:57:52
User entered 'None (0)'	System	12 Aug 2020 17:57:52

**US3312046**

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

**Form: General\_Day(1/1)**

**Generated On: 26 Nov 2020 10:51:05**

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 (E037D92C-2F6A-4B91-B9C7-F8A20B33EADC)', Time: '2020-08-12T12:57:43', User OID: 'PatientReportedOutcome (US3312046)', ODM File OID: '8ce25c15-bfda-4798-851f-3fb6fa7fa124'	System	12 Aug 2020 17:57:52
User entered 'No (N)'	System	12 Aug 2020 17:57:52

**US3312046**

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

**Form: General\_Day(1/1)**

**Generated On: 26 Nov 2020 10:51:05**

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E037D92C-2F6A-4B91-B9C7-F8A20B33EADC)', Time: '2020-08-12T12:57:48', User OID: 'PatientReportedOutcome (US3312046)', ODM File OID: '8ce25c15-bfda-4798-851f-3fb6fa7fa124'	System	12 Aug 2020 17:57:52
User entered '12 Aug 2020 12:57'	System	12 Aug 2020 17:57:52

**US3312046**

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

**Form: General\_Day(1/1)**

**Generated On: 26 Nov 2020 10:51:05**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '12 Aug 2020 12:42'	System	12 Aug 2020 17:29:06

**US3312046**

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

**Form: General\_Day(1/1)**

**Generated On: 26 Nov 2020 10:51:05**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '12 Aug 2020 15:12'	System	12 Aug 2020 17:29:06



**US3312046**

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

**Form: General\_Day(1/2)**

**Generated On: 26 Nov 2020 10:51:05**

**TIMEPOINT**

Audit	User	Time (GMT)
Data entry locked.	System	12 Aug 2020 17:29:06
User entered 'Day 1, after vaccination (at home)'	System	12 Aug 2020 17:29:06

**US3312046**

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

**Form: General\_Day(1/2)**

**Generated On: 26 Nov 2020 10:51:05**

**HEADACHE**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E037D92C-2F6A-4B91-B9C7-F8A20B33EADC)', Time: '2020-08-12T19:44:55', User OID: 'PatientReportedOutcome (US3312046)', ODM File OID: 'd690f6be-9aa4-41b9-912b-d40668c065e3'	System	13 Aug 2020 00:45:46
User entered 'None (0)'	System	13 Aug 2020 00:45:46

**US3312046**

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

**Form: General\_Day(1/2)**

**Generated On: 26 Nov 2020 10:51:05**

**FATIGUE**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E037D92C-2F6A-4B91-B9C7-F8A20B33EADC)', Time: '2020-08-12T19:45:01', User OID: 'PatientReportedOutcome (US3312046)', ODM File OID: 'd690f6be-9aa4-41b9-912b-d40668c065e3'	System	13 Aug 2020 00:45:46
User entered 'None (0)'	System	13 Aug 2020 00:45:46

**US3312046**

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

**Form: General\_Day(1/2)**

**Generated On: 26 Nov 2020 10:51:05**

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E037D92C-2F6A-4B91-B9C7-F8A20B33EADC)', Time: '2020-08-12T19:45:07', User OID: 'PatientReportedOutcome (US3312046)', ODM File OID: 'd690f6be-9aa4-41b9-912b-d40668c065e3'	System	13 Aug 2020 00:45:46
User entered 'None (0)'	System	13 Aug 2020 00:45:46

**US3312046**

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

**Form: General\_Day(1/2)**

**Generated On: 26 Nov 2020 10:51:05**

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E037D92C-2F6A-4B91-B9C7-F8A20B33EADC)', Time: '2020-08-12T19:45:14', User OID: 'PatientReportedOutcome (US3312046)', ODM File OID: 'd690f6be-9aa4-41b9-912b-d40668c065e3'	System	13 Aug 2020 00:45:46
User entered 'None (0)'	System	13 Aug 2020 00:45:46

**US3312046**

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

**Form: General\_Day(1/2)**

**Generated On: 26 Nov 2020 10:51:05**

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E037D92C-2F6A-4B91-B9C7-F8A20B33EADC)', Time: '2020-08-12T19:45:19', User OID: 'PatientReportedOutcome (US3312046)', ODM File OID: 'd690f6be-9aa4-41b9-912b-d40668c065e3'	System	13 Aug 2020 00:45:46
User entered 'None (0)'	System	13 Aug 2020 00:45:46

**US3312046**

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

**Form: General\_Day(1/2)**

**Generated On: 26 Nov 2020 10:51:05**

**CHILLS**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E037D92C-2F6A-4B91-B9C7-F8A20B33EADC)', Time: '2020-08-12T19:45:22', User OID: 'PatientReportedOutcome (US3312046)', ODM File OID: 'd690f6be-9aa4-41b9-912b-d40668c065e3'	System	13 Aug 2020 00:45:46
User entered 'None (0)'	System	13 Aug 2020 00:45:46

**US3312046**

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

**Form: General\_Day(1/2)**

**Generated On: 26 Nov 2020 10:51:05**

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 (E037D92C-2F6A-4B91-B9C7-F8A20B33EADC)', Time: '2020-08-12T19:45:31', User OID: 'PatientReportedOutcome (US3312046)', ODM File OID: 'd690f6be-9aa4-41b9-912b-d40668c065e3'	System	13 Aug 2020 00:45:46
User entered 'No (N)'	System	13 Aug 2020 00:45:46



**US3312046**

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

**Form: General\_Day(1/2)**

**Generated On: 26 Nov 2020 10:51:05**

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E037D92C-2F6A-4B91-B9C7-F8A20B33EADC)', Time: '2020-08-12T19:45:43', User OID: 'PatientReportedOutcome (US3312046)', ODM File OID: 'd690f6be-9aa4-41b9-912b-d40668c065e3'	System	13 Aug 2020 00:45:46
User entered '12 Aug 2020 19:45'	System	13 Aug 2020 00:45:46

**US3312046**

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

**Form: General\_Day(1/2)**

**Generated On: 26 Nov 2020 10:51:05**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '12 Aug 2020 16:07'	System	12 Aug 2020 17:29:06

**US3312046**

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

**Form: General\_Day(1/2)**

**Generated On: 26 Nov 2020 10:51:05**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '13 Aug 2020 11:59'	System	12 Aug 2020 17:29:06

**US3312046**

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

**Form: General\_Day(2)**

**Generated On: 26 Nov 2020 10:51:05**

**TIMEPOINT**

Audit	User	Time (GMT)
Data entry locked.	System	12 Aug 2020 17:29:06
User entered 'Day 2'	System	12 Aug 2020 17:29:06

**US3312046**

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

**Form: General\_Day(2)**

**Generated On: 26 Nov 2020 10:51:05**

**HEADACHE**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E037D92C-2F6A-4B91-B9C7-F8A20B33EADC)', Time: '2020-08-13T21:06:23', User OID: 'PatientReportedOutcome (US3312046)', ODM File OID: '80a78d38-0d05-40fa-8071-67243bace9e1'	System	14 Aug 2020 02:07:07
User entered 'None (0)'	System	14 Aug 2020 02:07:07

**US3312046**

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

**Form: General\_Day(2)**

**Generated On: 26 Nov 2020 10:51:05**

**FATIGUE**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E037D92C-2F6A-4B91-B9C7-F8A20B33EADC)', Time: '2020-08-13T21:06:27', User OID: 'PatientReportedOutcome (US3312046)', ODM File OID: '80a78d38-0d05-40fa-8071-67243bace9e1'	System	14 Aug 2020 02:07:07
User entered 'None (0)'	System	14 Aug 2020 02:07:07

**US3312046**

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

**Form: General\_Day(2)**

**Generated On: 26 Nov 2020 10:51:05**

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E037D92C-2F6A-4B91-B9C7-F8A20B33EADC)', Time: '2020-08-13T21:06:30', User OID: 'PatientReportedOutcome (US3312046)', ODM File OID: '80a78d38-0d05-40fa-8071-67243bace9e1'	System	14 Aug 2020 02:07:07
User entered 'None (0)'	System	14 Aug 2020 02:07:07

**US3312046**

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

**Form: General\_Day(2)**

**Generated On: 26 Nov 2020 10:51:05**

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E037D92C-2F6A-4B91-B9C7-F8A20B33EADC)', Time: '2020-08-13T21:06:40', User OID: 'PatientReportedOutcome (US3312046)', ODM File OID: '80a78d38-0d05-40fa-8071-67243bace9e1'	System	14 Aug 2020 02:07:07
User entered 'None (0)'	System	14 Aug 2020 02:07:07



**US3312046**

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

**Form: General\_Day(2)**

**Generated On: 26 Nov 2020 10:51:05**

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E037D92C-2F6A-4B91-B9C7-F8A20B33EADC)', Time: '2020-08-13T21:06:45', User OID: 'PatientReportedOutcome (US3312046)', ODM File OID: '80a78d38-0d05-40fa-8071-67243bace9e1'	System	14 Aug 2020 02:07:07
User entered 'None (0)'	System	14 Aug 2020 02:07:07

**US3312046**

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

**Form: General\_Day(2)**

**Generated On: 26 Nov 2020 10:51:05**

**CHILLS**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E037D92C-2F6A-4B91-B9C7-F8A20B33EADC)', Time: '2020-08-13T21:06:47', User OID: 'PatientReportedOutcome (US3312046)', ODM File OID: '80a78d38-0d05-40fa-8071-67243bace9e1'	System	14 Aug 2020 02:07:07
User entered 'None (0)'	System	14 Aug 2020 02:07:07

**US3312046**

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

**Form: General\_Day(2)**

**Generated On: 26 Nov 2020 10:51:05**

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 (E037D92C-2F6A-4B91-B9C7-F8A20B33EADC)', Time: '2020-08-13T21:07:00', User OID: 'PatientReportedOutcome (US3312046)', ODM File OID: '80a78d38-0d05-40fa-8071-67243bace9e1'	System	14 Aug 2020 02:07:07
User entered 'No (N)'	System	14 Aug 2020 02:07:07

**US3312046**

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

**Form: General\_Day(2)**

**Generated On: 26 Nov 2020 10:51:05**

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E037D92C-2F6A-4B91-B9C7-F8A20B33EADC)', Time: '2020-08-13T21:07:05', User OID: 'PatientReportedOutcome (US3312046)', ODM File OID: '80a78d38-0d05-40fa-8071-67243bace9e1'	System	14 Aug 2020 02:07:07
User entered '13 Aug 2020 21:07'	System	14 Aug 2020 02:07:07

**US3312046**

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

**Form: General\_Day(2)**

**Generated On: 26 Nov 2020 10:51:05**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '13 Aug 2020 12:00'	System	12 Aug 2020 17:29:06

**US3312046**

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

**Form: General\_Day(2)**

**Generated On: 26 Nov 2020 10:51:05**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '14 Aug 2020 11:59'	System	12 Aug 2020 17:29:06

**US3312046**

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

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

**Generated On: 26 Nov 2020 10:51:05**

**TIMEPOINT**

Audit	User	Time (GMT)
Data entry locked.	System	12 Aug 2020 17:29:06
User entered 'Day 3'	System	12 Aug 2020 17:29:06

**US3312046**

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

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

**Generated On: 26 Nov 2020 10:51:05**

**HEADACHE**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E037D92C-2F6A-4B91-B9C7-F8A20B33EADC)', Time: '2020-08-14T21:06:08', User OID: 'PatientReportedOutcome (US3312046)', ODM File OID: '1eef5ed0-2c3e-4354-93cd-e01e2ffc3d56'	System	15 Aug 2020 02:06:50
User entered 'None (0)'	System	15 Aug 2020 02:06:50



**US3312046**

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

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

**Generated On: 26 Nov 2020 10:51:05**

**FATIGUE**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E037D92C-2F6A-4B91-B9C7-F8A20B33EADC)', Time: '2020-08-14T21:06:11', User OID: 'PatientReportedOutcome (US3312046)', ODM File OID: '1eef5ed0-2c3e-4354-93cd-e01e2ffc3d56'	System	15 Aug 2020 02:06:50
User entered 'None (0)'	System	15 Aug 2020 02:06:50

**US3312046**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(3)**

**Generated On: 26 Nov 2020 10:51:05**

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E037D92C-2F6A-4B91-B9C7-F8A20B33EADC)', Time: '2020-08-14T21:06:16', User OID: 'PatientReportedOutcome (US3312046)', ODM File OID: '1eef5ed0-2c3e-4354-93cd-e01e2ffc3d56'	System	15 Aug 2020 02:06:50
User entered 'None (0)'	System	15 Aug 2020 02:06:50

**US3312046**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(3)**

**Generated On: 26 Nov 2020 10:51:05**

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E037D92C-2F6A-4B91-B9C7-F8A20B33EADC)', Time: '2020-08-14T21:06:21', User OID: 'PatientReportedOutcome (US3312046)', ODM File OID: '1eef5ed0-2c3e-4354-93cd-e01e2ffc3d56'	System	15 Aug 2020 02:06:50
User entered 'None (0)'	System	15 Aug 2020 02:06:50

**US3312046**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(3)**

**Generated On: 26 Nov 2020 10:51:05**

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E037D92C-2F6A-4B91-B9C7-F8A20B33EADC)', Time: '2020-08-14T21:06:25', User OID: 'PatientReportedOutcome (US3312046)', ODM File OID: '1eef5ed0-2c3e-4354-93cd-e01e2ffc3d56'	System	15 Aug 2020 02:06:50
User entered 'None (0)'	System	15 Aug 2020 02:06:50

**US3312046**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(3)**

**Generated On: 26 Nov 2020 10:51:05**

**CHILLS**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E037D92C-2F6A-4B91-B9C7-F8A20B33EADC)', Time: '2020-08-14T21:06:29', User OID: 'PatientReportedOutcome (US3312046)', ODM File OID: '1eef5ed0-2c3e-4354-93cd-e01e2ffc3d56'	System	15 Aug 2020 02:06:50
User entered 'None (0)'	System	15 Aug 2020 02:06:50

**US3312046**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(3)**

**Generated On: 26 Nov 2020 10:51:05**

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 (E037D92C-2F6A-4B91-B9C7-F8A20B33EADC)', Time: '2020-08-14T21:06:35', User OID: 'PatientReportedOutcome (US3312046)', ODM File OID: '1eef5ed0-2c3e-4354-93cd-e01e2ffc3d56'	System	15 Aug 2020 02:06:50
User entered 'No (N)'	System	15 Aug 2020 02:06:50

**US3312046**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(3)**

**Generated On: 26 Nov 2020 10:51:05**

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E037D92C-2F6A-4B91-B9C7-F8A20B33EADC)', Time: '2020-08-14T21:06:48', User OID: 'PatientReportedOutcome (US3312046)', ODM File OID: '1eef5ed0-2c3e-4354-93cd-e01e2ffc3d56'	System	15 Aug 2020 02:06:50
User entered '14 Aug 2020 21:06'	System	15 Aug 2020 02:06:50

**US3312046**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(3)**

**Generated On: 26 Nov 2020 10:51:05**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '14 Aug 2020 12:00'	System	12 Aug 2020 17:29:06



**US3312046**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(3)**

**Generated On: 26 Nov 2020 10:51:05**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '15 Aug 2020 11:59'	System	12 Aug 2020 17:29:06

**US3312046**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(4)**

**Generated On: 26 Nov 2020 10:51:05**

**TIMEPOINT**

Audit	User	Time (GMT)
Data entry locked.	System	12 Aug 2020 17:29:06
User entered 'Day 4'	System	12 Aug 2020 17:29:06

**US3312046**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(4)**

**Generated On: 26 Nov 2020 10:51:05**

**HEADACHE**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E037D92C-2F6A-4B91-B9C7-F8A20B33EADC)', Time: '2020-08-15T19:36:33', User OID: 'PatientReportedOutcome (US3312046)', ODM File OID: 'adbcb09-2a14-4be2-9557-fec54af08361'	System	16 Aug 2020 00:37:14
User entered 'None (0)'	System	16 Aug 2020 00:37:14

**US3312046**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(4)**

**Generated On: 26 Nov 2020 10:51:05**

**FATIGUE**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E037D92C-2F6A-4B91-B9C7-F8A20B33EADC)', Time: '2020-08-15T19:36:36', User OID: 'PatientReportedOutcome (US3312046)', ODM File OID: 'adbcb09-2a14-4be2-9557-fec54af08361'	System	16 Aug 2020 00:37:14
User entered 'None (0)'	System	16 Aug 2020 00:37:14

**US3312046**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(4)**

**Generated On: 26 Nov 2020 10:51:05**

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E037D92C-2F6A-4B91-B9C7-F8A20B33EADC)', Time: '2020-08-15T19:36:40', User OID: 'PatientReportedOutcome (US3312046)', ODM File OID: 'adbcb09-2a14-4be2-9557-fec54af08361'	System	16 Aug 2020 00:37:14
User entered 'None (0)'	System	16 Aug 2020 00:37:14

**US3312046**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(4)**

**Generated On: 26 Nov 2020 10:51:05**

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E037D92C-2F6A-4B91-B9C7-F8A20B33EADC)', Time: '2020-08-15T19:36:45', User OID: 'PatientReportedOutcome (US3312046)', ODM File OID: 'adbcb09-2a14-4be2-9557-fec54af08361'	System	16 Aug 2020 00:37:14
User entered 'None (0)'	System	16 Aug 2020 00:37:14

**US3312046**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(4)**

**Generated On: 26 Nov 2020 10:51:05**

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E037D92C-2F6A-4B91-B9C7-F8A20B33EADC)', Time: '2020-08-15T19:36:48', User OID: 'PatientReportedOutcome (US3312046)', ODM File OID: 'adbcb09-2a14-4be2-9557-fec54af08361'	System	16 Aug 2020 00:37:14
User entered 'None (0)'	System	16 Aug 2020 00:37:14

**US3312046**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(4)**

**Generated On: 26 Nov 2020 10:51:05**

**CHILLS**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E037D92C-2F6A-4B91-B9C7-F8A20B33EADC)', Time: '2020-08-15T19:36:51', User OID: 'PatientReportedOutcome (US3312046)', ODM File OID: 'adbcb09-2a14-4be2-9557-fec54af08361'	System	16 Aug 2020 00:37:14
User entered 'None (0)'	System	16 Aug 2020 00:37:14



US3312046

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 26 Nov 2020 10:51:05

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 (E037D92C-2F6A-4B91-B9C7-F8A20B33EADC)', Time: '2020-08-15T19:36:58', User OID: 'PatientReportedOutcome (US3312046)', ODM File OID: 'adbcb09-2a14-4be2-9557-fec54af08361'	System	16 Aug 2020 00:37:14
User entered 'No (N)'	System	16 Aug 2020 00:37:14

**US3312046**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(4)**

**Generated On: 26 Nov 2020 10:51:05**

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E037D92C-2F6A-4B91-B9C7-F8A20B33EADC)', Time: '2020-08-15T19:37:12', User OID: 'PatientReportedOutcome (US3312046)', ODM File OID: 'adbcb09-2a14-4be2-9557-fec54af08361'	System	16 Aug 2020 00:37:14
User entered '15 Aug 2020 19:37'	System	16 Aug 2020 00:37:14

**US3312046**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(4)**

**Generated On: 26 Nov 2020 10:51:05**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '15 Aug 2020 12:00'	System	12 Aug 2020 17:29:06

**US3312046**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(4)**

**Generated On: 26 Nov 2020 10:51:05**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '16 Aug 2020 11:59'	System	12 Aug 2020 17:29:06

**US3312046**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(5)**

**Generated On: 26 Nov 2020 10:51:05**

**TIMEPOINT**

Audit	User	Time (GMT)
Data entry locked.	System	12 Aug 2020 17:29:06
User entered 'Day 5'	System	12 Aug 2020 17:29:06

**US3312046**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(5)**

**Generated On: 26 Nov 2020 10:51:05**

**HEADACHE**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E037D92C-2F6A-4B91-B9C7-F8A20B33EADC)', Time: '2020-08-16T20:25:00', User OID: 'PatientReportedOutcome (US3312046)', ODM File OID: '4ea2f786-0773-4c33-aff7-3d867768832a'	System	17 Aug 2020 01:25:53
User entered 'None (0)'	System	17 Aug 2020 01:25:53

**US3312046**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(5)**

**Generated On: 26 Nov 2020 10:51:05**

**FATIGUE**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E037D92C-2F6A-4B91-B9C7-F8A20B33EADC)', Time: '2020-08-16T20:25:03', User OID: 'PatientReportedOutcome (US3312046)', ODM File OID: '4ea2f786-0773-4c33-aff7-3d867768832a'	System	17 Aug 2020 01:25:53
User entered 'None (0)'	System	17 Aug 2020 01:25:53

**US3312046**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(5)**

**Generated On: 26 Nov 2020 10:51:05**

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E037D92C-2F6A-4B91-B9C7-F8A20B33EADC)', Time: '2020-08-16T20:25:06', User OID: 'PatientReportedOutcome (US3312046)', ODM File OID: '4ea2f786-0773-4c33-aff7-3d867768832a'	System	17 Aug 2020 01:25:53
User entered 'None (0)'	System	17 Aug 2020 01:25:53



**US3312046**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(5)**

**Generated On: 26 Nov 2020 10:51:05**

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E037D92C-2F6A-4B91-B9C7-F8A20B33EADC)', Time: '2020-08-16T20:25:13', User OID: 'PatientReportedOutcome (US3312046)', ODM File OID: '4ea2f786-0773-4c33-aff7-3d867768832a'	System	17 Aug 2020 01:25:53
User entered 'None (0)'	System	17 Aug 2020 01:25:53

**US3312046**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(5)**

**Generated On: 26 Nov 2020 10:51:05**

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E037D92C-2F6A-4B91-B9C7-F8A20B33EADC)', Time: '2020-08-16T20:25:29', User OID: 'PatientReportedOutcome (US3312046)', ODM File OID: '4ea2f786-0773-4c33-aff7-3d867768832a'	System	17 Aug 2020 01:25:53
User entered 'None (0)'	System	17 Aug 2020 01:25:53

**US3312046**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(5)**

**Generated On: 26 Nov 2020 10:51:05**

**CHILLS**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E037D92C-2F6A-4B91-B9C7-F8A20B33EADC)', Time: '2020-08-16T20:25:32', User OID: 'PatientReportedOutcome (US3312046)', ODM File OID: '4ea2f786-0773-4c33-aff7-3d867768832a'	System	17 Aug 2020 01:25:53
User entered 'None (0)'	System	17 Aug 2020 01:25:53

**US3312046**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(5)**

**Generated On: 26 Nov 2020 10:51:05**

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 (E037D92C-2F6A-4B91-B9C7-F8A20B33EADC)', Time: '2020-08-16T20:25:40', User OID: 'PatientReportedOutcome (US3312046)', ODM File OID: '4ea2f786-0773-4c33-aff7-3d867768832a'	System	17 Aug 2020 01:25:53
User entered 'No (N)'	System	17 Aug 2020 01:25:53

**US3312046**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(5)**

**Generated On: 26 Nov 2020 10:51:05**

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E037D92C-2F6A-4B91-B9C7-F8A20B33EADC)', Time: '2020-08-16T20:25:52', User OID: 'PatientReportedOutcome (US3312046)', ODM File OID: '4ea2f786-0773-4c33-aff7-3d867768832a'	System	17 Aug 2020 01:25:53
User entered '16 Aug 2020 20:25'	System	17 Aug 2020 01:25:53

**US3312046**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(5)**

**Generated On: 26 Nov 2020 10:51:05**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '16 Aug 2020 12:00'	System	12 Aug 2020 17:29:06

**US3312046**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(5)**

**Generated On: 26 Nov 2020 10:51:05**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '17 Aug 2020 11:59'	System	12 Aug 2020 17:29:06

**US3312046**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(6)**

**Generated On: 26 Nov 2020 10:51:05**

**TIMEPOINT**

Audit	User	Time (GMT)
Data entry locked.	System	12 Aug 2020 17:29:06
User entered 'Day 6'	System	12 Aug 2020 17:29:06



**US3312046**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(6)**

**Generated On: 26 Nov 2020 10:51:05**

**HEADACHE**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E037D92C-2F6A-4B91-B9C7-F8A20B33EADC)', Time: '2020-08-17T21:54:12', User OID: 'PatientReportedOutcome (US3312046)', ODM File OID: 'fc3128a8-0bfd-4174-81dc-322be97bba22'	System	18 Aug 2020 02:54:55
User entered 'None (0)'	System	18 Aug 2020 02:54:55

**US3312046**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(6)**

**Generated On: 26 Nov 2020 10:51:05**

**FATIGUE**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E037D92C-2F6A-4B91-B9C7-F8A20B33EADC)', Time: '2020-08-17T21:54:15', User OID: 'PatientReportedOutcome (US3312046)', ODM File OID: 'fc3128a8-0bfd-4174-81dc-322be97bba22'	System	18 Aug 2020 02:54:55
User entered 'None (0)'	System	18 Aug 2020 02:54:55

**US3312046**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(6)**

**Generated On: 26 Nov 2020 10:51:05**

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E037D92C-2F6A-4B91-B9C7-F8A20B33EADC)', Time: '2020-08-17T21:54:19', User OID: 'PatientReportedOutcome (US3312046)', ODM File OID: 'fc3128a8-0bfd-4174-81dc-322be97bba22'	System	18 Aug 2020 02:54:55
User entered 'None (0)'	System	18 Aug 2020 02:54:55

**US3312046**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(6)**

**Generated On: 26 Nov 2020 10:51:05**

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E037D92C-2F6A-4B91-B9C7-F8A20B33EADC)', Time: '2020-08-17T21:54:25', User OID: 'PatientReportedOutcome (US3312046)', ODM File OID: 'fc3128a8-0bfd-4174-81dc-322be97bba22'	System	18 Aug 2020 02:54:55
User entered 'None (0)'	System	18 Aug 2020 02:54:55

**US3312046**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(6)**

**Generated On: 26 Nov 2020 10:51:05**

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E037D92C-2F6A-4B91-B9C7-F8A20B33EADC)', Time: '2020-08-17T21:54:29', User OID: 'PatientReportedOutcome (US3312046)', ODM File OID: 'fc3128a8-0bfd-4174-81dc-322be97bba22'	System	18 Aug 2020 02:54:55
User entered 'None (0)'	System	18 Aug 2020 02:54:55

**US3312046**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(6)**

**Generated On: 26 Nov 2020 10:51:05**

**CHILLS**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E037D92C-2F6A-4B91-B9C7-F8A20B33EADC)', Time: '2020-08-17T21:54:33', User OID: 'PatientReportedOutcome (US3312046)', ODM File OID: 'fc3128a8-0bfd-4174-81dc-322be97bba22'	System	18 Aug 2020 02:54:55
User entered 'None (0)'	System	18 Aug 2020 02:54:55

**US3312046**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(6)**

**Generated On: 26 Nov 2020 10:51:05**

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 (E037D92C-2F6A-4B91-B9C7-F8A20B33EADC)', Time: '2020-08-17T21:54:41', User OID: 'PatientReportedOutcome (US3312046)', ODM File OID: 'fc3128a8-0bfd-4174-81dc-322be97bba22'	System	18 Aug 2020 02:54:55
User entered 'No (N)'	System	18 Aug 2020 02:54:55

**US3312046**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(6)**

**Generated On: 26 Nov 2020 10:51:05**

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E037D92C-2F6A-4B91-B9C7-F8A20B33EADC)', Time: '2020-08-17T21:54:53', User OID: 'PatientReportedOutcome (US3312046)', ODM File OID: 'fc3128a8-0bfd-4174-81dc-322be97bba22'	System	18 Aug 2020 02:54:55
User entered '17 Aug 2020 21:54'	System	18 Aug 2020 02:54:55



**US3312046**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(6)**

**Generated On: 26 Nov 2020 10:51:05**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '17 Aug 2020 12:00'	System	12 Aug 2020 17:29:06

**US3312046**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(6)**

**Generated On: 26 Nov 2020 10:51:05**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '18 Aug 2020 11:59'	System	12 Aug 2020 17:29:06

**US3312046**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(7)**

**Generated On: 26 Nov 2020 10:51:05**

**TIMEPOINT**

Audit	User	Time (GMT)
Data entry locked.	System	12 Aug 2020 17:29:06
User entered 'Day 7'	System	12 Aug 2020 17:29:06

**US3312046**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(7)**

**Generated On: 26 Nov 2020 10:51:05**

**HEADACHE**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E037D92C-2F6A-4B91-B9C7-F8A20B33EADC)', Time: '2020-08-18T21:28:23', User OID: 'PatientReportedOutcome (US3312046)', ODM File OID: '43037fa6-5c6f-41d1-b411-46e1253f1247'	System	19 Aug 2020 02:29:15
User entered 'None (0)'	System	19 Aug 2020 02:29:15

**US3312046**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(7)**

**Generated On: 26 Nov 2020 10:51:05**

**FATIGUE**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E037D92C-2F6A-4B91-B9C7-F8A20B33EADC)', Time: '2020-08-18T21:28:26', User OID: 'PatientReportedOutcome (US3312046)', ODM File OID: '43037fa6-5c6f-41d1-b411-46e1253f1247'	System	19 Aug 2020 02:29:15
User entered 'None (0)'	System	19 Aug 2020 02:29:15

**US3312046**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(7)**

**Generated On: 26 Nov 2020 10:51:05**

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E037D92C-2F6A-4B91-B9C7-F8A20B33EADC)', Time: '2020-08-18T21:28:29', User OID: 'PatientReportedOutcome (US3312046)', ODM File OID: '43037fa6-5c6f-41d1-b411-46e1253f1247'	System	19 Aug 2020 02:29:15
User entered 'None (0)'	System	19 Aug 2020 02:29:15

**US3312046**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(7)**

**Generated On: 26 Nov 2020 10:51:05**

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E037D92C-2F6A-4B91-B9C7-F8A20B33EADC)', Time: '2020-08-18T21:28:33', User OID: 'PatientReportedOutcome (US3312046)', ODM File OID: '43037fa6-5c6f-41d1-b411-46e1253f1247'	System	19 Aug 2020 02:29:15
User entered 'None (0)'	System	19 Aug 2020 02:29:15

**US3312046**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(7)**

**Generated On: 26 Nov 2020 10:51:05**

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E037D92C-2F6A-4B91-B9C7-F8A20B33EADC)', Time: '2020-08-18T21:28:37', User OID: 'PatientReportedOutcome (US3312046)', ODM File OID: '43037fa6-5c6f-41d1-b411-46e1253f1247'	System	19 Aug 2020 02:29:15
User entered 'None (0)'	System	19 Aug 2020 02:29:15



**US3312046**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(7)**

**Generated On: 26 Nov 2020 10:51:05**

**CHILLS**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E037D92C-2F6A-4B91-B9C7-F8A20B33EADC)', Time: '2020-08-18T21:28:40', User OID: 'PatientReportedOutcome (US3312046)', ODM File OID: '43037fa6-5c6f-41d1-b411-46e1253f1247'	System	19 Aug 2020 02:29:15
User entered 'None (0)'	System	19 Aug 2020 02:29:15

**US3312046**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(7)**

**Generated On: 26 Nov 2020 10:51:05**

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 (E037D92C-2F6A-4B91-B9C7-F8A20B33EADC)', Time: '2020-08-18T21:28:57', User OID: 'PatientReportedOutcome (US3312046)', ODM File OID: '43037fa6-5c6f-41d1-b411-46e1253f1247'	System	19 Aug 2020 02:29:15
User entered 'No (N)'	System	19 Aug 2020 02:29:15

**US3312046**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(7)**

**Generated On: 26 Nov 2020 10:51:05**

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E037D92C-2F6A-4B91-B9C7-F8A20B33EADC)', Time: '2020-08-18T21:29:12', User OID: 'PatientReportedOutcome (US3312046)', ODM File OID: '43037fa6-5c6f-41d1-b411-46e1253f1247'	System	19 Aug 2020 02:29:15
User entered '18 Aug 2020 21:29'	System	19 Aug 2020 02:29:15

**US3312046**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(7)**

**Generated On: 26 Nov 2020 10:51:05**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '18 Aug 2020 12:00'	System	12 Aug 2020 17:29:06

**US3312046**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(7)**

**Generated On: 26 Nov 2020 10:51:05**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '19 Aug 2020 11:59'	System	12 Aug 2020 17:29:06

US3312046

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 26 Nov 2020 10:51:05

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
User closed query 'Was Contact Attempted? = Yes and 'Date of Contact or Contact Attempt' or ' Please select one status for the follow-up contact' is missing. Please review and reconcile.' (Site from System).	System	19 Aug 2020 19:48:35
User opened query 'Was Contact Attempted? = Yes and 'Date of Contact or Contact Attempt' or ' Please select one status for the follow-up contact' is missing. Please review and reconcile.' (Site from System).	System	19 Aug 2020 19:48:19
User entered 'Yes (Y)'	Kelly Moen (b) (4) (b) (4)	19 Aug 2020 19:48:19

**US3312046**

**Folder: Safety Call Day 8 (1)**

**Form: Safety Call**

**Generated On: 26 Nov 2020 10:51:05**

[Date of Contact or Contact Attempt \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User entered '19 Aug 2020' reason for change: Data Entry Error	Kelly Moen (b) (4)	19 Aug 2020 19:48:35
User entered empty.	Kelly Moen (b) (4)	19 Aug 2020 19:48:19

**US3312046**

**Folder: Safety Call Day 8 (1)**

**Form: Safety Call**

**Generated On: 26 Nov 2020 10:51:05**

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
User entered 'Contact Made (CONTACT MADE)'	Kelly Moen (b) (4) (b) (4)	19 Aug 2020 19:48:19



**US3312046**

**Folder: Safety Call Day 8 (1)**

**Form: Safety Call**

**Generated On: 26 Nov 2020 10:51:05**

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
User entered empty.	Kelly Moen (b) (4) (b) (4)	19 Aug 2020 19:48:19

US3312046

Folder: Safety Call Day 8 (1)

Form: Continuing

Generated On: 26 Nov 2020 10:51:05

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Kelly Moen (b) (4) (b) (4)	19 Aug 2020 19:48:25

**US3312046**

**Folder: Safety Call Day 8 (1)**

**Form: Continuing**

**Generated On: 26 Nov 2020 10:51:05**

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered 'I'	System	19 Aug 2020 19:48:25

**US3312046**

**Folder: Safety Call Day 15 (1)**

**Form: Safety Call**

**Generated On: 26 Nov 2020 10:51:05**

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Karol Moore (b) (4) (b) (4)	26 Aug 2020 15:21:10

**US3312046**

**Folder: Safety Call Day 15 (1)**

**Form: Safety Call**

**Generated On: 26 Nov 2020 10:51:05**

**Date of Contact or Contact Attempt** (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered '26 Aug 2020'	Karol Moore (b) (4) (b) (4)	26 Aug 2020 15:21:10

**US3312046**

**Folder: Safety Call Day 15 (1)**

**Form: Safety Call**

**Generated On: 26 Nov 2020 10:51:05**

[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)	26 Aug 2020 15:21:10

**US3312046**

**Folder: Safety Call Day 15 (1)**

**Form: Safety Call**

**Generated On: 26 Nov 2020 10:51:05**

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
User entered empty.	Karol Moore (b) (4) (b) (4)	26 Aug 2020 15:21:10

US3312046

Folder: Safety Call Day 15 (1)

Form: Continuing

Generated On: 26 Nov 2020 10:51:05

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Karol Moore (b) (4) (b) (4)	26 Aug 2020 15:21:13



**US3312046**

**Folder: Safety Call Day 15 (1)**

**Form: Continuing**

**Generated On: 26 Nov 2020 10:51:05**

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered 'I'	System	26 Aug 2020 15:21:13

**US3312046**

**Folder: Safety Call Day 22 (1)**

**Form: Safety Call**

**Generated On: 26 Nov 2020 10:51:05**

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Kelly Moen (b) (4) (b) (4)	02 Sep 2020 21:27:01

**US3312046**

**Folder: Safety Call Day 22 (1)**

**Form: Safety Call**

**Generated On: 26 Nov 2020 10:51:05**

**Date of Contact or Contact Attempt** (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered '2 Sep 2020'	Kelly Moen (b) (4) (b) (4)	02 Sep 2020 21:27:01

**US3312046**

**Folder: Safety Call Day 22 (1)**

**Form: Safety Call**

**Generated On: 26 Nov 2020 10:51:05**

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
User entered 'Contact Made (CONTACT MADE)'	Kelly Moen (b) (4) (b) (4)	02 Sep 2020 21:27:01

**US3312046**

**Folder: Safety Call Day 22 (1)**

**Form: Safety Call**

**Generated On: 26 Nov 2020 10:51:05**

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
User entered empty.	Kelly Moen (b) (4) (b) (4)	02 Sep 2020 21:27:01

US3312046

Folder: Safety Call Day 22 (1)

Form: Continuing

Generated On: 26 Nov 2020 10:51:05

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Kelly Moen (b) (4) (b) (4)	02 Sep 2020 21:27:06

**US3312046**

**Folder: Safety Call Day 22 (1)**

**Form: Continuing**

**Generated On: 26 Nov 2020 10:51:05**

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered 'I'	System	02 Sep 2020 21:27:06

US3312046

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 26 Nov 2020 10:51:05

[Was this visit performed?](#)

Audit	User	Time (GMT)
User closed query 'Per GCL Lab Reconciliation: Saliva: Sample dated 19,21OCT2020 is reported under Illness Visits in PPD Central lab, however the same is missing in EDC. Please review if the sample has been collected then update the details under appropriate visit. Else clarify, thank you. ' (Site from DM).	(b) (4), (b) (6)	12 Nov 2020 12:00:25
Query 'Per GCL Lab Reconciliation: Saliva: Sample dated 19,21OCT2020 is reported under Illness Visits in PPD Central lab, however the same is missing in EDC. Please review if the sample has been collected then update the details under appropriate visit. Else clarify, thank you. ' answered with 'UPDAETD' (Site from DM).	Karol Moore (b) (4) (b) (4)	09 Nov 2020 16:02:58
User opened query 'Per GCL Lab Reconciliation: Saliva: Sample dated 19,21OCT2020 is reported under Illness Visits in PPD Central lab, however the same is missing in EDC. Please review if the sample has been collected then update the details under appropriate visit. Else clarify, thank you. ' (Site from DM).	(b) (4), (b) (6)	05 Nov 2020 09:45:25
Query 'Per GCL Lab Reconciliation: Saliva: Sample dated 19OCT2020 is reported under Illness Visits in PPD Central lab, however the same is missing in EDC. Please review if the sample has been collected then update the details under appropriate visit. Else clarify, thank you. ' canceled (Site from DM).	(b) (4), (b) (6)	05 Nov 2020 09:45:14
User opened query 'Per GCL Lab Reconciliation: Saliva: Sample dated 19OCT2020 is reported under Illness Visits in PPD Central lab, however the same is missing in EDC. Please review if the sample has been collected then update the details under appropriate visit. Else clarify, thank you. ' (Site from DM).	(b) (4), (b) (6)	05 Nov 2020 09:45:12
User entered 'Yes (Y)'	Christa Estrada (b) (4) (b) (4)	09 Sep 2020 18:56:51



US3312046

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 26 Nov 2020 10:51:05

Visit date (dd MMM yyyy)

Audit	User	Time (GMT)
User closed query ' Per GCL Lab Reconciliation: SARS-CoV-2 serum sample: As per the CCG v 2, please add illness folder using ADD EVENT DROP Down. Please review and update the EDC as the SARS-CoV-2 serum sample dated 16 OCT 2020 is reported under Illness Visit Day 1 in PPD Central lab. Else clarify, thank you.' (Site from DM).	(b) (4), (b) (6)	20 Nov 2020 09:28:26
Query ' Per GCL Lab Reconciliation: SARS-CoV-2 serum sample: As per the CCG v 2, please add illness folder using ADD EVENT DROP Down. Please review and update the EDC as the SARS-CoV-2 serum sample dated 16 OCT 2020 is reported under Illness Visit Day 1 in PPD Central lab. Else clarify, thank you.' answered with 'UPDATED' (Site from DM).	Karol Moore (b) (4) (b) (4)	09 Nov 2020 16:03:07
User opened query ' Per GCL Lab Reconciliation: SARS-CoV-2 serum sample: As per the CCG v 2, please add illness folder using ADD EVENT DROP Down. Please review and update the EDC as the SARS-CoV-2 serum sample dated 16 OCT 2020 is reported under Illness Visit Day 1 in PPD Central lab. Else clarify, thank you.' (Site from DM).	(b) (4), (b) (6)	09 Nov 2020 12:51:33
User entered '9 Sep 2020'	Christa Estrada (b) (4) (b) (4)	09 Sep 2020 18:56:51

US3312046

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 26 Nov 2020 10:51:05

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)	09 Sep 2020 18:56:51

**US3312046**

**Folder: Visit 2 Day 29 (1)**

**Form: Visit Date**

**Generated On: 26 Nov 2020 10:51:05**

[Folder OID](#)

Audit	User	Time (GMT)
User entered 'VISIT2'	System	09 Sep 2020 18:56:51

US3312046

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 10:51:05

[Timepoint](#)

Audit	User	Time (GMT)
User accepted default value 'Pre-Dose (PREDOSE)'	Christa Estrada (b) (4) (b) (4)	18 Sep 2020 19:36:30

US3312046

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 10:51:05

Were vital signs assessed?

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Christa Estrada (b) (4) (b) (4)	18 Sep 2020 19:36:30

**US3312046**

**Folder: Visit 2 Day 29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 26 Nov 2020 10:51:05**

**Date of assessment** (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered '09 Sep 2020'	Christa Estrada (b) (4) (b) (4)	18 Sep 2020 19:36:30

**US3312046**

**Folder: Visit 2 Day 29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 26 Nov 2020 10:51:05**

**Time of assessment (00:00-23:59)**

Audit	User	Time (GMT)
User entered '13:02'	Christa Estrada (b) (4) (b) (4)	18 Sep 2020 19:36:30

**US3312046**

**Folder: Visit 2 Day 29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 26 Nov 2020 10:51:05**

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered '09 Sep 2020 13:02'	System	18 Sep 2020 19:36:30



US3312046

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 10:51:05

Temperature (xxx.x)

Audit	User	Time (GMT)
User entered '97.8' F	Christa Estrada (b) (4) (b) (4)	18 Sep 2020 19:36:30

US3312046

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 10:51:05

[Route of measurement](#)

Audit	User	Time (GMT)
User entered 'Oral (Oral)'	Christa Estrada (b) (4) (b) (4)	18 Sep 2020 19:36:30

**US3312046**

**Folder: Visit 2 Day 29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 26 Nov 2020 10:51:05**

[If Other, specify](#)

Audit	User	Time (GMT)
User entered empty.	Christa Estrada (b) (4) (b) (4)	18 Sep 2020 19:36:30

**US3312046**

**Folder: Visit 2 Day 29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 26 Nov 2020 10:51:05**

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
User entered '61'	Christa Estrada (b) (4) (b) (4)	18 Sep 2020 19:36:30

**US3312046**

**Folder: Visit 2 Day 29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 26 Nov 2020 10:51:05**

[Pulse units](#)

Audit	User	Time (GMT)
User entered 'bpm'	System	18 Sep 2020 19:36:30

US3312046

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 10:51:05

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
User entered '14'	Christa Estrada (b) (4) (b) (4)	18 Sep 2020 19:36:30

**US3312046**

**Folder: Visit 2 Day 29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 26 Nov 2020 10:51:05**

[Respiratory Rate units](#)

Audit	User	Time (GMT)
User entered 'breaths/min'	System	18 Sep 2020 19:36:30

US3312046

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 10:51:05

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
User entered '138'	Christa Estrada (b) (4) (b) (4)	18 Sep 2020 19:36:30



**US3312046**

**Folder: Visit 2 Day 29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 26 Nov 2020 10:51:05**

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	18 Sep 2020 19:36:30

US3312046

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 10:51:05

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
User entered '86'	Christa Estrada (b) (4) (b) (4)	18 Sep 2020 19:36:30

**US3312046**

**Folder: Visit 2 Day 29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 26 Nov 2020 10:51:05**

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	18 Sep 2020 19:36:30

US3312046

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 10:51:05

[Timepoint](#)

Audit	User	Time (GMT)
User accepted default value 'Post-Dose (POSTDOSE)'	Christa Estrada (b) (4) (b) (4)	18 Sep 2020 19:36:30

US3312046

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 10:51:05

Were vital signs assessed?

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Christa Estrada (b) (4) (b) (4)	18 Sep 2020 19:36:30

US3312046

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 10:51:05

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered '09 Sep 2020'	Christa Estrada (b) (4) (b) (4)	18 Sep 2020 19:36:30

**US3312046**

**Folder: Visit 2 Day 29 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 26 Nov 2020 10:51:05**

**Time of assessment (00:00-23:59)**

Audit	User	Time (GMT)
User entered '14:21'	Christa Estrada (b) (4) (b) (4)	18 Sep 2020 19:36:30

**US3312046**

**Folder: Visit 2 Day 29 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 26 Nov 2020 10:51:05**

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered '09 Sep 2020 14:21'	System	18 Sep 2020 19:36:30



US3312046

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 10:51:05

Temperature (xxx.x)

Audit	User	Time (GMT)
User entered '98.0' F	Christa Estrada (b) (4) (b) (4)	18 Sep 2020 19:36:30

US3312046

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 10:51:05

[Route of measurement](#)

Audit	User	Time (GMT)
User entered 'Oral (Oral)'	Christa Estrada (b) (4) (b) (4)	18 Sep 2020 19:36:30

US3312046

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 10:51:05

[If Other, specify](#)

Audit	User	Time (GMT)
User entered empty.	Christa Estrada (b) (4) (b) (4)	18 Sep 2020 19:36:30

**US3312046**

**Folder: Visit 2 Day 29 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 26 Nov 2020 10:51:05**

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
User entered '60'	Christa Estrada (b) (4) (b) (4)	18 Sep 2020 19:36:30

**US3312046**

**Folder: Visit 2 Day 29 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 26 Nov 2020 10:51:05**

[Pulse units](#)

Audit	User	Time (GMT)
User entered 'bpm'	System	18 Sep 2020 19:36:30

US3312046

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 10:51:05

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
User entered '16'	Christa Estrada (b) (4) (b) (4)	18 Sep 2020 19:36:30

**US3312046**

**Folder: Visit 2 Day 29 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 26 Nov 2020 10:51:05**

[Respiratory Rate units](#)

Audit	User	Time (GMT)
User entered 'breaths/min'	System	18 Sep 2020 19:36:30

US3312046

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 10:51:05

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
User entered '140'	Christa Estrada (b) (4) (b) (4)	18 Sep 2020 19:36:30



**US3312046**

**Folder: Visit 2 Day 29 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 26 Nov 2020 10:51:05**

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	18 Sep 2020 19:36:30

US3312046

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 10:51:05

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
User entered '83'	Christa Estrada (b) (4) (b) (4)	18 Sep 2020 19:36:30

**US3312046**

**Folder: Visit 2 Day 29 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 26 Nov 2020 10:51:05**

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	18 Sep 2020 19:36:30

US3312046

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Generated On: 26 Nov 2020 10:51:05

Was the physical examination performed?

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Christa Estrada (b) (4) (b) (4)	18 Sep 2020 19:36:41

US3312046

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Generated On: 26 Nov 2020 10:51:05

Date of examination (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered '09 Sep 2020'	Christa Estrada (b) (4) (b) (4)	18 Sep 2020 19:36:41

US3312046

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 26 Nov 2020 10:51:05

[Was study treatment given?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Christa Estrada (b) (4) (b) (4)	09 Sep 2020 18:57:30

US3312046

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 26 Nov 2020 10:51:05

If No, reason not given

Audit	User	Time (GMT)
User entered empty.	Christa Estrada (b) (4) (b) (4)	09 Sep 2020 18:57:30

**US3312046**

**Folder: Visit 2 Day 29 (1)**

**Form: Exposure**

**Generated On: 26 Nov 2020 10:51:05**

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)	09 Sep 2020 18:57:30



**US3312046**

**Folder: Visit 2 Day 29 (1)**

**Form: Exposure**

**Generated On: 26 Nov 2020 10:51:05**

[What was the study treatment?](#)

Audit	User	Time (GMT)
User entered 'MRNA-1273 OR PLACEBO'	System	09 Sep 2020 18:57:30

US3312046

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 26 Nov 2020 10:51:05

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
User entered '9 Sep 2020'	Christa Estrada (b) (4) (b) (4)	09 Sep 2020 18:57:30

US3312046

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 26 Nov 2020 10:51:05

[What was the treatment time? \(00:00-23:59\)](#)

Audit	User	Time (GMT)
User entered '13:50'	Christa Estrada (b) (4) (b) (4)	09 Sep 2020 18:57:30

**US3312046**

**Folder: Visit 2 Day 29 (1)**

**Form: Exposure**

**Generated On: 26 Nov 2020 10:51:05**

[Treatment Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered '9 Sep 2020 13:50'	System	09 Sep 2020 18:57:30

US3312046

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 26 Nov 2020 10:51:05

Which arm was used to give treatment?

Audit	User	Time (GMT)
User entered 'Left Arm (LEFT ARM)'	Christa Estrada (b) (4) (b) (4)	09 Sep 2020 18:57:30

**US3312046**

**Folder: Visit 2 Day 29 (1)**

**Form: Exposure**

**Generated On: 26 Nov 2020 10:51:05**

[What was the frequency of the study treatment dosing?](#)

Audit	User	Time (GMT)
User entered 'ONCE'	System	09 Sep 2020 18:57:30

US3312046

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 26 Nov 2020 10:51:05

What was the route of administration for the study treatment?

Audit	User	Time (GMT)
User entered 'INTRAMUSCULAR'	System	09 Sep 2020 18:57:30

US3312046

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 10:51:05

[Was the sample collected?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Christa Estrada (b) (4) (b) (4)	18 Sep 2020 19:36:50



US3312046

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 10:51:05

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered '09 Sep 2020'	Christa Estrada (b) (4) (b) (4)	18 Sep 2020 19:36:50

**US3312046**

**Folder: Visit 2 Day 29 (1)**

**Form: Immunogenicity Assessment**

**Generated On: 26 Nov 2020 10:51:05**

[Collection time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
User entered '13:16'	Christa Estrada (b) (4) (b) (4)	18 Sep 2020 19:36:50

**US3312046**

**Folder: Visit 2 Day 29 (1)**

**Form: Immunogenicity Assessment**

**Generated On: 26 Nov 2020 10:51:05**

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered '09 Sep 2020 13:16'	System	18 Sep 2020 19:36:50

US3312046

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 26 Nov 2020 10:51:05

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered '09 Sep 2020'	Christa Estrada (b) (4) (b) (4)	18 Sep 2020 19:37:03

**US3312046**

**Folder: Visit 2 Day 29 (1)**

**Form: Central Laboratory - Nasopharyngeal Swab (1)**

**Generated On: 26 Nov 2020 10:51:05**

[Lab Test](#)

Audit	User	Time (GMT)
User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)'	Christa Estrada (b) (4) (b) (4)	18 Sep 2020 19:37:03

**US3312046**

**Folder: Visit 2 Day 29 (1)**

**Form: Central Laboratory - Nasopharyngeal Swab (1)**

**Generated On: 26 Nov 2020 10:51:05**

[Was the sample collected?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Christa Estrada (b) (4) (b) (4)	18 Sep 2020 19:37:03

**US3312046**

**Folder: Visit 2 Day 29 (1)**

**Form: Central Laboratory - Nasopharyngeal Swab (1)**

**Generated On: 26 Nov 2020 10:51:05**

**Collection time (00:00 - 23:59)**

Audit	User	Time (GMT)
User entered '13:10'	Christa Estrada (b) (4) (b) (4)	18 Sep 2020 19:37:03

**US3312046**

**Folder: Visit 2 Day 29 (1)**

**Form: Central Laboratory - Nasopharyngeal Swab (1)**

**Generated On: 26 Nov 2020 10:51:05**

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered '09 Sep 2020 13:10'	System	18 Sep 2020 19:37:03



**US3312046**

**Folder: Visit 2 Day 29 (1)**

**Form: Central Laboratory - Nasopharyngeal Swab (2)**

**Generated On: 26 Nov 2020 10:51:05**

[Lab Test](#)

Audit	User	Time (GMT)
User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)'	Christa Estrada (b) (4) (b) (4)	18 Sep 2020 19:37:03

**US3312046**

**Folder: Visit 2 Day 29 (1)**

**Form: Central Laboratory - Nasopharyngeal Swab (2)**

**Generated On: 26 Nov 2020 10:51:05**

[Was the sample collected?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Christa Estrada (b) (4) (b) (4)	18 Sep 2020 19:37:03

**US3312046**

**Folder: Visit 2 Day 29 (1)**

**Form: Central Laboratory - Nasopharyngeal Swab (2)**

**Generated On: 26 Nov 2020 10:51:05**

**Collection time (00:00 - 23:59)**

Audit	User	Time (GMT)
User entered empty.	Christa Estrada (b) (4) (b) (4)	18 Sep 2020 19:37:03

**US3312046**

**Folder: Visit 2 Day 29 (1)**

**Form: Central Laboratory - Nasopharyngeal Swab (2)**

**Generated On: 26 Nov 2020 10:51:05**

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	18 Sep 2020 19:37:03

US3312046

Folder: Visit 2 Day 29 (1)

Form: Continuing

Generated On: 26 Nov 2020 10:51:05

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Christa Estrada (b) (4) (b) (4)	09 Sep 2020 18:57:39

**US3312046**

**Folder: Visit 2 Day 29 (1)**

**Form: Continuing**

**Generated On: 26 Nov 2020 10:51:05**

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered '1'	System	09 Sep 2020 18:57:39

**US3312046**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(1/1)**

**Generated On: 26 Nov 2020 10:51:05**

**TIMEPOINT**

Audit	User	Time (GMT)
Data entry locked.	System	09 Sep 2020 18:57:30
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	09 Sep 2020 18:57:30

**US3312046**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(1/1)**

**Generated On: 26 Nov 2020 10:51:05**

**Was TEMPERATURE taken?**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E037D92C-2F6A-4B91-B9C7-F8A20B33EADC)', Time: '2020-09-09T14:21:25', User OID: 'PatientReportedOutcome (US3312046)', ODM File OID: '44eaa73c-8dc8-4ab6-adda-2d7363b3e667'	System	09 Sep 2020 19:21:49
User entered 'Yes (Y)'	System	09 Sep 2020 19:21:49



**US3312046**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(1/1)**

**Generated On: 26 Nov 2020 10:51:05**

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E037D92C-2F6A-4B91-B9C7-F8A20B33EADC)', Time: '2020-09-09T14:21:31', User OID: 'PatientReportedOutcome (US3312046)', ODM File OID: '44eaa73c-8dc8-4ab6-adda-2d7363b3e667'	System	09 Sep 2020 19:21:49
User entered '98.0'	System	09 Sep 2020 19:21:49

**US3312046**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(1/1)**

**Generated On: 26 Nov 2020 10:51:05**

**Was any MEDICATION TAKEN today for pain or fever?**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E037D92C-2F6A-4B91-B9C7-F8A20B33EADC)', Time: '2020-09-09T14:21:37', User OID: 'PatientReportedOutcome (US3312046)', ODM File OID: '44eaa73c-8dc8-4ab6-adda-2d7363b3e667'	System	09 Sep 2020 19:21:49
User entered 'No (N)'	System	09 Sep 2020 19:21:49

**US3312046**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(1/1)**

**Generated On: 26 Nov 2020 10:51:05**

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E037D92C-2F6A-4B91-B9C7-F8A20B33EADC)', Time: '2020-09-09T14:21:44', User OID: 'PatientReportedOutcome (US3312046)', ODM File OID: '44eaa73c-8dc8-4ab6-adda-2d7363b3e667'	System	09 Sep 2020 19:21:49
User entered '09 Sep 2020 14:21'	System	09 Sep 2020 19:21:49

**US3312046**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(1/1)**

**Generated On: 26 Nov 2020 10:51:05**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '09 Sep 2020 14:10'	System	09 Sep 2020 18:57:30

**US3312046**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(1/1)**

**Generated On: 26 Nov 2020 10:51:05**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '09 Sep 2020 16:40'	System	09 Sep 2020 18:57:30

**US3312046**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(1/2)**

**Generated On: 26 Nov 2020 10:51:05**

**TIMEPOINT**

Audit	User	Time (GMT)
Data entry locked.	System	09 Sep 2020 18:57:30
User entered 'Day 1, after vaccination (at home)'	System	09 Sep 2020 18:57:30

**US3312046**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(1/2)**

**Generated On: 26 Nov 2020 10:51:05**

**Was TEMPERATURE taken?**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E037D92C-2F6A-4B91-B9C7-F8A20B33EADC)', Time: '2020-09-09T19:45:36', User OID: 'PatientReportedOutcome (US3312046)', ODM File OID: 'a93bc34b-056c-4bc5-b7f1-e77060517972'	System	10 Sep 2020 00:45:58
User entered 'Yes (Y)'	System	10 Sep 2020 00:45:58

**US3312046**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(1/2)**

**Generated On: 26 Nov 2020 10:51:05**

Please record your **TEMPERATURE in °F**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E037D92C-2F6A-4B91-B9C7-F8A20B33EADC)', Time: '2020-09-09T19:45:46', User OID: 'PatientReportedOutcome (US3312046)', ODM File OID: 'a93bc34b-056c-4bc5-b7f1-e77060517972'	System	10 Sep 2020 00:45:58
User entered '98.0'	System	10 Sep 2020 00:45:58



US3312046

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/2)

Generated On: 26 Nov 2020 10:51:05

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E037D92C-2F6A-4B91-B9C7-F8A20B33EADC)', Time: '2020-09-09T19:45:52', User OID: 'PatientReportedOutcome (US3312046)', ODM File OID: 'a93bc34b-056c-4bc5-b7f1-e77060517972'	System	10 Sep 2020 00:45:58
User entered 'No (N)'	System	10 Sep 2020 00:45:58

**US3312046**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(1/2)**

**Generated On: 26 Nov 2020 10:51:05**

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E037D92C-2F6A-4B91-B9C7-F8A20B33EADC)', Time: '2020-09-09T19:45:56', User OID: 'PatientReportedOutcome (US3312046)', ODM File OID: 'a93bc34b-056c-4bc5-b7f1-e77060517972'	System	10 Sep 2020 00:45:58
User entered '09 Sep 2020 19:45'	System	10 Sep 2020 00:45:58

**US3312046**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(1/2)**

**Generated On: 26 Nov 2020 10:51:05**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '09 Sep 2020 17:35'	System	09 Sep 2020 18:57:30

**US3312046**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(1/2)**

**Generated On: 26 Nov 2020 10:51:05**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '10 Sep 2020 11:59'	System	09 Sep 2020 18:57:30

**US3312046**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(2)**

**Generated On: 26 Nov 2020 10:51:05**

**TIMEPOINT**

Audit	User	Time (GMT)
Data entry locked.	System	09 Sep 2020 18:57:30
User entered 'Day 2'	System	09 Sep 2020 18:57:30

**US3312046**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(2)**

**Generated On: 26 Nov 2020 10:51:05**

**Was TEMPERATURE taken?**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E037D92C-2F6A-4B91-B9C7-F8A20B33EADC)', Time: '2020-09-10T19:02:12', User OID: 'PatientReportedOutcome (US3312046)', ODM File OID: '71179eba-e25d-4377-8410-077cc6bdf871'	System	11 Sep 2020 00:03:01
User entered 'Yes (Y)'	System	11 Sep 2020 00:03:01

**US3312046**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(2)**

**Generated On: 26 Nov 2020 10:51:05**

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E037D92C-2F6A-4B91-B9C7-F8A20B33EADC)', Time: '2020-09-10T19:02:21', User OID: 'PatientReportedOutcome (US3312046)', ODM File OID: '71179eba-e25d-4377-8410-077cc6bdf871'	System	11 Sep 2020 00:03:01
User entered '96.9'	System	11 Sep 2020 00:03:01

**US3312046**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(2)**

**Generated On: 26 Nov 2020 10:51:05**

**Was any MEDICATION TAKEN today for pain or fever?**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E037D92C-2F6A-4B91-B9C7-F8A20B33EADC)', Time: '2020-09-10T19:02:31', User OID: 'PatientReportedOutcome (US3312046)', ODM File OID: '71179eba-e25d-4377-8410-077cc6bdf871'	System	11 Sep 2020 00:03:01
User entered 'No (N)'	System	11 Sep 2020 00:03:01



**US3312046**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(2)**

**Generated On: 26 Nov 2020 10:51:05**

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E037D92C-2F6A-4B91-B9C7-F8A20B33EADC)', Time: '2020-09-10T19:02:57', User OID: 'PatientReportedOutcome (US3312046)', ODM File OID: '71179eba-e25d-4377-8410-077cc6bdf871'	System	11 Sep 2020 00:03:01
User entered '10 Sep 2020 19:02'	System	11 Sep 2020 00:03:01

**US3312046**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(2)**

**Generated On: 26 Nov 2020 10:51:05**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '10 Sep 2020 12:00'	System	09 Sep 2020 18:57:30

**US3312046**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(2)**

**Generated On: 26 Nov 2020 10:51:05**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '11 Sep 2020 11:59'	System	09 Sep 2020 18:57:30

**US3312046**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(3)**

**Generated On: 26 Nov 2020 10:51:05**

**TIMEPOINT**

Audit	User	Time (GMT)
Data entry locked.	System	09 Sep 2020 18:57:30
User entered 'Day 3'	System	09 Sep 2020 18:57:30

**US3312046**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(3)**

**Generated On: 26 Nov 2020 10:51:05**

**Was TEMPERATURE taken?**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E037D92C-2F6A-4B91-B9C7-F8A20B33EADC)', Time: '2020-09-11T18:23:44', User OID: 'PatientReportedOutcome (US3312046)', ODM File OID: 'af164a77-6aeb-4006-a1e3-4061cfb8b949'	System	11 Sep 2020 23:24:25
User entered 'Yes (Y)'	System	11 Sep 2020 23:24:25

**US3312046**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(3)**

**Generated On: 26 Nov 2020 10:51:05**

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E037D92C-2F6A-4B91-B9C7-F8A20B33EADC)', Time: '2020-09-11T18:23:52', User OID: 'PatientReportedOutcome (US3312046)', ODM File OID: 'af164a77-6aeb-4006-a1e3-4061cfb8b949'	System	11 Sep 2020 23:24:25
User entered '97.1'	System	11 Sep 2020 23:24:25

**US3312046**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(3)**

**Generated On: 26 Nov 2020 10:51:05**

**Was any MEDICATION TAKEN today for pain or fever?**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E037D92C-2F6A-4B91-B9C7-F8A20B33EADC)', Time: '2020-09-11T18:23:58', User OID: 'PatientReportedOutcome (US3312046)', ODM File OID: 'af164a77-6aeb-4006-a1e3-4061cfb8b949'	System	11 Sep 2020 23:24:25
User entered 'Yes (Y)'	System	11 Sep 2020 23:24:25

US3312046

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(3)

Generated On: 26 Nov 2020 10:51:05

To **TREAT** pain or fever that has already occurred

Audit	User	Time (GMT)
User closed query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' (Site from System). Query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' answered with 'CONTACT COMFRIMED. MEDICATION DETAILS ADDED TO concomitant medication pages. (Site from System).	(b) (4), (b) (6)	16 Oct 2020 14:48:34
User opened query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' (Site from System). External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E037D92C-2F6A-4B91-B9C7-F8A20B33EADC)', Time: '2020-09-11T18:24:13', User OID: 'PatientReportedOutcome (US3312046)', ODM File OID: 'af164a77-6aeb-4006-a1e3-4061cfb8b949'	System	11 Sep 2020 23:24:25
User entered '1'	System	11 Sep 2020 23:24:25



**US3312046**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(3)**

**Generated On: 26 Nov 2020 10:51:05**

To **PREVENT** pain or fever from occurring

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E037D92C-2F6A-4B91-B9C7-F8A20B33EADC)', Time: '2020-09-11T18:24:13', User OID: 'PatientReportedOutcome (US3312046)', ODM File OID: 'af164a77-6aeb-4006-a1e3-4061cfb8b949'	System	11 Sep 2020 23:24:25
User entered '0'	System	11 Sep 2020 23:24:25

**US3312046**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(3)**

**Generated On: 26 Nov 2020 10:51:05**

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E037D92C-2F6A-4B91-B9C7-F8A20B33EADC)', Time: '2020-09-11T18:24:19', User OID: 'PatientReportedOutcome (US3312046)', ODM File OID: 'af164a77-6aeb-4006-a1e3-4061cfb8b949'	System	11 Sep 2020 23:24:25
User entered '11 Sep 2020 18:24'	System	11 Sep 2020 23:24:25

**US3312046**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(3)**

**Generated On: 26 Nov 2020 10:51:05**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '11 Sep 2020 12:00'	System	09 Sep 2020 18:57:30

**US3312046**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(3)**

**Generated On: 26 Nov 2020 10:51:05**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '12 Sep 2020 11:59'	System	09 Sep 2020 18:57:30

**US3312046**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(4)**

**Generated On: 26 Nov 2020 10:51:05**

**TIMEPOINT**

Audit	User	Time (GMT)
Data entry locked.	System	09 Sep 2020 18:57:30
User entered 'Day 4'	System	09 Sep 2020 18:57:30

**US3312046**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(4)**

**Generated On: 26 Nov 2020 10:51:05**

**Was TEMPERATURE taken?**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E037D92C-2F6A-4B91-B9C7-F8A20B33EADC)', Time: '2020-09-12T19:10:29', User OID: 'PatientReportedOutcome (US3312046)', ODM File OID: '0581d70a-e2d5-464d-9fbe-992a0b4b5ade'	System	13 Sep 2020 00:11:15
User entered 'Yes (Y)'	System	13 Sep 2020 00:11:15

**US3312046**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(4)**

**Generated On: 26 Nov 2020 10:51:05**

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E037D92C-2F6A-4B91-B9C7-F8A20B33EADC)', Time: '2020-09-12T19:10:38', User OID: 'PatientReportedOutcome (US3312046)', ODM File OID: '0581d70a-e2d5-464d-9fbe-992a0b4b5ade'	System	13 Sep 2020 00:11:15
User entered '96.8'	System	13 Sep 2020 00:11:15

US3312046

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(4)

Generated On: 26 Nov 2020 10:51:05

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E037D92C-2F6A-4B91-B9C7-F8A20B33EADC)', Time: '2020-09-12T19:10:45', User OID: 'PatientReportedOutcome (US3312046)', ODM File OID: '0581d70a-e2d5-464d-9fbe-992a0b4b5ade'	System	13 Sep 2020 00:11:15
User entered 'Yes (Y)'	System	13 Sep 2020 00:11:15



US3312046

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(4)

Generated On: 26 Nov 2020 10:51:05

To **TREAT** pain or fever that has already occurred

Audit	User	Time (GMT)
User closed query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' (Site from System). Query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' answered with 'CONTACT COMFRIMED. MEDICATION DETAILS ADDED TO concomitant medication pages. (Site from System).	(b) (4), (b) (6)	16 Oct 2020 14:48:38
User opened query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' (Site from System).	System	13 Sep 2020 00:11:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E037D92C-2F6A-4B91-B9C7-F8A20B33EADC)', Time: '2020-09-12T19:10:57', User OID: 'PatientReportedOutcome (US3312046)', ODM File OID: '0581d70a-e2d5-464d-9fbe-992a0b4b5ade'	System	13 Sep 2020 00:11:15
User entered '1'	System	13 Sep 2020 00:11:15

**US3312046**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(4)**

**Generated On: 26 Nov 2020 10:51:05**

To **PREVENT** pain or fever from occurring

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E037D92C-2F6A-4B91-B9C7-F8A20B33EADC)', Time: '2020-09-12T19:10:57', User OID: 'PatientReportedOutcome (US3312046)', ODM File OID: '0581d70a-e2d5-464d-9fbe-992a0b4b5ade'	System	13 Sep 2020 00:11:15
User entered '0'	System	13 Sep 2020 00:11:15

**US3312046**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(4)**

**Generated On: 26 Nov 2020 10:51:05**

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E037D92C-2F6A-4B91-B9C7-F8A20B33EADC)', Time: '2020-09-12T19:11:01', User OID: 'PatientReportedOutcome (US3312046)', ODM File OID: '0581d70a-e2d5-464d-9fbe-992a0b4b5ade'	System	13 Sep 2020 00:11:15
User entered '12 Sep 2020 19:11'	System	13 Sep 2020 00:11:15

**US3312046**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(4)**

**Generated On: 26 Nov 2020 10:51:05**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '12 Sep 2020 12:00'	System	09 Sep 2020 18:57:30

**US3312046**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(4)**

**Generated On: 26 Nov 2020 10:51:05**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '13 Sep 2020 11:59'	System	09 Sep 2020 18:57:30

**US3312046**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(5)**

**Generated On: 26 Nov 2020 10:51:05**

**TIMEPOINT**

Audit	User	Time (GMT)
Data entry locked.	System	09 Sep 2020 18:57:30
User entered 'Day 5'	System	09 Sep 2020 18:57:30

**US3312046**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(5)**

**Generated On: 26 Nov 2020 10:51:05**

**Was TEMPERATURE taken?**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E037D92C-2F6A-4B91-B9C7-F8A20B33EADC)', Time: '2020-09-13T18:41:38', User OID: 'PatientReportedOutcome (US3312046)', ODM File OID: '3bcfb43f-3811-4fd4-af3d-7fc168c499d1'	System	13 Sep 2020 23:42:06
User entered 'Yes (Y)'	System	13 Sep 2020 23:42:06

**US3312046**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(5)**

**Generated On: 26 Nov 2020 10:51:05**

Please record your **TEMPERATURE in °F**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E037D92C-2F6A-4B91-B9C7-F8A20B33EADC)', Time: '2020-09-13T18:41:47', User OID: 'PatientReportedOutcome (US3312046)', ODM File OID: '3bcfb43f-3811-4fd4-af3d-7fc168c499d1'	System	13 Sep 2020 23:42:06
User entered '96.8'	System	13 Sep 2020 23:42:06



**US3312046**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(5)**

**Generated On: 26 Nov 2020 10:51:05**

**Was any MEDICATION TAKEN today for pain or fever?**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E037D92C-2F6A-4B91-B9C7-F8A20B33EADC)', Time: '2020-09-13T18:41:53', User OID: 'PatientReportedOutcome (US3312046)', ODM File OID: '3bcfb43f-3811-4fd4-af3d-7fc168c499d1'	System	13 Sep 2020 23:42:06
User entered 'No (N)'	System	13 Sep 2020 23:42:06

**US3312046**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(5)**

**Generated On: 26 Nov 2020 10:51:05**

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E037D92C-2F6A-4B91-B9C7-F8A20B33EADC)', Time: '2020-09-13T18:42:02', User OID: 'PatientReportedOutcome (US3312046)', ODM File OID: '3bcfb43f-3811-4fd4-af3d-7fc168c499d1'	System	13 Sep 2020 23:42:06
User entered '13 Sep 2020 18:42'	System	13 Sep 2020 23:42:06

**US3312046**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(5)**

**Generated On: 26 Nov 2020 10:51:05**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '13 Sep 2020 12:00'	System	09 Sep 2020 18:57:30

**US3312046**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(5)**

**Generated On: 26 Nov 2020 10:51:05**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '14 Sep 2020 11:59'	System	09 Sep 2020 18:57:30

**US3312046**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(6)**

**Generated On: 26 Nov 2020 10:51:05**

**TIMEPOINT**

Audit	User	Time (GMT)
Data entry locked.	System	09 Sep 2020 18:57:30
User entered 'Day 6'	System	09 Sep 2020 18:57:30

**US3312046**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(6)**

**Generated On: 26 Nov 2020 10:51:05**

**Was TEMPERATURE taken?**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E037D92C-2F6A-4B91-B9C7-F8A20B33EADC)', Time: '2020-09-14T19:05:58', User OID: 'PatientReportedOutcome (US3312046)', ODM File OID: 'd61aeb71-11c5-49b8-857a-e701db6c7c59'	System	15 Sep 2020 00:06:18
User entered 'Yes (Y)'	System	15 Sep 2020 00:06:18

**US3312046**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(6)**

**Generated On: 26 Nov 2020 10:51:05**

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E037D92C-2F6A-4B91-B9C7-F8A20B33EADC)', Time: '2020-09-14T19:06:06', User OID: 'PatientReportedOutcome (US3312046)', ODM File OID: 'd61aeb71-11c5-49b8-857a-e701db6c7c59'	System	15 Sep 2020 00:06:18
User entered '96.4'	System	15 Sep 2020 00:06:18

US3312046

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(6)

Generated On: 26 Nov 2020 10:51:05

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E037D92C-2F6A-4B91-B9C7-F8A20B33EADC)', Time: '2020-09-14T19:06:12', User OID: 'PatientReportedOutcome (US3312046)', ODM File OID: 'd61aeb71-11c5-49b8-857a-e701db6c7c59'	System	15 Sep 2020 00:06:18
User entered 'No (N)'	System	15 Sep 2020 00:06:18



**US3312046**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(6)**

**Generated On: 26 Nov 2020 10:51:05**

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E037D92C-2F6A-4B91-B9C7-F8A20B33EADC)', Time: '2020-09-14T19:06:16', User OID: 'PatientReportedOutcome (US3312046)', ODM File OID: 'd61aeb71-11c5-49b8-857a-e701db6c7c59'	System	15 Sep 2020 00:06:18
User entered '14 Sep 2020 19:06'	System	15 Sep 2020 00:06:18

**US3312046**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(6)**

**Generated On: 26 Nov 2020 10:51:05**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '14 Sep 2020 12:00'	System	09 Sep 2020 18:57:30

**US3312046**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(6)**

**Generated On: 26 Nov 2020 10:51:05**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '15 Sep 2020 11:59'	System	09 Sep 2020 18:57:30

**US3312046**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(7)**

**Generated On: 26 Nov 2020 10:51:05**

**TIMEPOINT**

Audit	User	Time (GMT)
Data entry locked.	System	09 Sep 2020 18:57:30
User entered 'Day 7'	System	09 Sep 2020 18:57:30

**US3312046**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(7)**

**Generated On: 26 Nov 2020 10:51:05**

**Was TEMPERATURE taken?**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E037D92C-2F6A-4B91-B9C7-F8A20B33EADC)', Time: '2020-09-15T20:33:45', User OID: 'PatientReportedOutcome (US3312046)', ODM File OID: 'ff4fc6d3-82db-431e-9db7-644315643d43'	System	16 Sep 2020 01:34:08
User entered 'Yes (Y)'	System	16 Sep 2020 01:34:08

**US3312046**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(7)**

**Generated On: 26 Nov 2020 10:51:05**

Please record your **TEMPERATURE in °F**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E037D92C-2F6A-4B91-B9C7-F8A20B33EADC)', Time: '2020-09-15T20:33:54', User OID: 'PatientReportedOutcome (US3312046)', ODM File OID: 'ff4fc6d3-82db-431e-9db7-644315643d43'	System	16 Sep 2020 01:34:08
User entered '98.6'	System	16 Sep 2020 01:34:08

US3312046

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(7)

Generated On: 26 Nov 2020 10:51:05

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E037D92C-2F6A-4B91-B9C7-F8A20B33EADC)', Time: '2020-09-15T20:33:59', User OID: 'PatientReportedOutcome (US3312046)', ODM File OID: 'ff4fc6d3-82db-431e-9db7-644315643d43'	System	16 Sep 2020 01:34:08
User entered 'No (N)'	System	16 Sep 2020 01:34:08

**US3312046**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(7)**

**Generated On: 26 Nov 2020 10:51:05**

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E037D92C-2F6A-4B91-B9C7-F8A20B33EADC)', Time: '2020-09-15T20:34:04', User OID: 'PatientReportedOutcome (US3312046)', ODM File OID: 'ff4fc6d3-82db-431e-9db7-644315643d43'	System	16 Sep 2020 01:34:08
User entered '15 Sep 2020 20:34'	System	16 Sep 2020 01:34:08



**US3312046**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(7)**

**Generated On: 26 Nov 2020 10:51:05**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '15 Sep 2020 12:00'	System	09 Sep 2020 18:57:30

**US3312046**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(7)**

**Generated On: 26 Nov 2020 10:51:05**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '16 Sep 2020 11:59'	System	09 Sep 2020 18:57:30

**US3312046**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(1/1)**

**Generated On: 26 Nov 2020 10:51:05**

**TIMEPOINT**

Audit	User	Time (GMT)
Data entry locked.	System	09 Sep 2020 18:57:30
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	09 Sep 2020 18:57:30

**US3312046**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(1/1)**

**Generated On: 26 Nov 2020 10:51:05**

[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 (E037D92C-2F6A-4B91-B9C7-F8A20B33EADC)', Time: '2020-09-09T14:21:52', User OID: 'PatientReportedOutcome (US3312046)', ODM File OID: '33543bec-ecc7-43d5-9901-23e0f051d738' User entered 'None (1)'	System	09 Sep 2020 19:22:13
	System	09 Sep 2020 19:22:13

**US3312046**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(1/1)**

**Generated On: 26 Nov 2020 10:51:05**

Is there any **REDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E037D92C-2F6A-4B91-B9C7-F8A20B33EADC)', Time: '2020-09-09T14:21:58', User OID: 'PatientReportedOutcome (US3312046)', ODM File OID: '33543bec-ecc7-43d5-9901-23e0f051d738'	System	09 Sep 2020 19:22:13
User entered 'No (N)'	System	09 Sep 2020 19:22:13

**US3312046**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(1/1)**

**Generated On: 26 Nov 2020 10:51:05**

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E037D92C-2F6A-4B91-B9C7-F8A20B33EADC)', Time: '2020-09-09T14:22:02', User OID: 'PatientReportedOutcome (US3312046)', ODM File OID: '33543bec-ecc7-43d5-9901-23e0f051d738'	System	09 Sep 2020 19:22:13
User entered 'No (N)'	System	09 Sep 2020 19:22:13

US3312046

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/1)

Generated On: 26 Nov 2020 10:51:05

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 (E037D92C-2F6A-4B91-B9C7-F8A20B33EADC)', Time: '2020-09-09T14:22:05', User OID: 'PatientReportedOutcome (US3312046)', ODM File OID: '33543bec-ecc7-43d5-9901-23e0f051d738'	System	09 Sep 2020 19:22:13
User entered 'None (1)'	System	09 Sep 2020 19:22:13

**US3312046**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(1/1)**

**Generated On: 26 Nov 2020 10:51:05**

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E037D92C-2F6A-4B91-B9C7-F8A20B33EADC)', Time: '2020-09-09T14:22:10', User OID: 'PatientReportedOutcome (US3312046)', ODM File OID: '33543bec-ecc7-43d5-9901-23e0f051d738' User entered '09 Sep 2020 14:22'	System	09 Sep 2020 19:22:13
	System	09 Sep 2020 19:22:13



**US3312046**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(1/1)**

**Generated On: 26 Nov 2020 10:51:05**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '09 Sep 2020 14:10'	System	09 Sep 2020 18:57:30

**US3312046**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(1/1)**

**Generated On: 26 Nov 2020 10:51:05**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '09 Sep 2020 16:40'	System	09 Sep 2020 18:57:30

**US3312046**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(1/2)**

**Generated On: 26 Nov 2020 10:51:05**

**TIMEPOINT**

Audit	User	Time (GMT)
Data entry locked.	System	09 Sep 2020 18:57:30
User entered 'Day 1, after vaccination (at home)'	System	09 Sep 2020 18:57:30

**US3312046**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(1/2)**

**Generated On: 26 Nov 2020 10:51:05**

[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 (E037D92C-2F6A-4B91-B9C7-F8A20B33EADC)', Time: '2020-09-09T19:46:02', User OID: 'PatientReportedOutcome (US3312046)', ODM File OID: '6db44fba-41f8-452f-91db-df44e3e32953'	System	10 Sep 2020 00:46:26
User entered 'None (1)'	System	10 Sep 2020 00:46:26

**US3312046**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(1/2)**

**Generated On: 26 Nov 2020 10:51:05**

Is there any **REDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E037D92C-2F6A-4B91-B9C7-F8A20B33EADC)', Time: '2020-09-09T19:46:05', User OID: 'PatientReportedOutcome (US3312046)', ODM File OID: '6db44fba-41f8-452f-91db-df44e3e32953'	System	10 Sep 2020 00:46:26
User entered 'No (N)'	System	10 Sep 2020 00:46:26

**US3312046**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(1/2)**

**Generated On: 26 Nov 2020 10:51:05**

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E037D92C-2F6A-4B91-B9C7-F8A20B33EADC)', Time: '2020-09-09T19:46:11', User OID: 'PatientReportedOutcome (US3312046)', ODM File OID: '6db44fba-41f8-452f-91db-df44e3e32953'	System	10 Sep 2020 00:46:26
User entered 'No (N)'	System	10 Sep 2020 00:46:26

US3312046

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/2)

Generated On: 26 Nov 2020 10:51:05

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 (E037D92C-2F6A-4B91-B9C7-F8A20B33EADC)', Time: '2020-09-09T19:46:17', User OID: 'PatientReportedOutcome (US3312046)', ODM File OID: '6db44fba-41f8-452f-91db-df44e3e32953'	System	10 Sep 2020 00:46:26
User entered 'None (1)'	System	10 Sep 2020 00:46:26

**US3312046**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(1/2)**

**Generated On: 26 Nov 2020 10:51:05**

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E037D92C-2F6A-4B91-B9C7-F8A20B33EADC)', Time: '2020-09-09T19:46:21', User OID: 'PatientReportedOutcome (US3312046)', ODM File OID: '6db44fba-41f8-452f-91db-df44e3e32953'	System	10 Sep 2020 00:46:26
User entered '09 Sep 2020 19:46'	System	10 Sep 2020 00:46:26



**US3312046**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(1/2)**

**Generated On: 26 Nov 2020 10:51:05**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '09 Sep 2020 17:35'	System	09 Sep 2020 18:57:30

**US3312046**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(1/2)**

**Generated On: 26 Nov 2020 10:51:05**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '10 Sep 2020 11:59'	System	09 Sep 2020 18:57:30

**US3312046**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(2)**

**Generated On: 26 Nov 2020 10:51:05**

**TIMEPOINT**

Audit	User	Time (GMT)
Data entry locked.	System	09 Sep 2020 18:57:30
User entered 'Day 2'	System	09 Sep 2020 18:57:30

**US3312046**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(2)**

**Generated On: 26 Nov 2020 10:51:05**

[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 (E037D92C-2F6A-4B91-B9C7-F8A20B33EADC)', Time: '2020-09-10T19:03:29', User OID: 'PatientReportedOutcome (US3312046)', ODM File OID: '9b922c70-b656-4261-85cf-4d4a16c668a9'	System	11 Sep 2020 00:07:52
User entered 'Does not interfere with activity (2)'	System	11 Sep 2020 00:07:52

**US3312046**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(2)**

**Generated On: 26 Nov 2020 10:51:05**

Is there any **REDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E037D92C-2F6A-4B91-B9C7-F8A20B33EADC)', Time: '2020-09-10T19:03:33', User OID: 'PatientReportedOutcome (US3312046)', ODM File OID: '9b922c70-b656-4261-85cf-4d4a16c668a9'	System	11 Sep 2020 00:07:52
User entered 'No (N)'	System	11 Sep 2020 00:07:52

**US3312046**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(2)**

**Generated On: 26 Nov 2020 10:51:05**

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E037D92C-2F6A-4B91-B9C7-F8A20B33EADC)', Time: '2020-09-10T19:03:45', User OID: 'PatientReportedOutcome (US3312046)', ODM File OID: '9b922c70-b656-4261-85cf-4d4a16c668a9'	System	11 Sep 2020 00:07:52
User entered 'Yes (Y)'	System	11 Sep 2020 00:07:52

US3312046

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(2)

Generated On: 26 Nov 2020 10:51:05

Please record - **SWELLING/HARDNESS AT INJECTION SITE (in mm)**

Measure the largest size across any injection site swelling/hardness with the ruler provided.

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E037D92C-2F6A-4B91-B9C7-F8A20B33EADC)', Time: '2020-09-10T19:07:29', User OID: 'PatientReportedOutcome (US3312046)', ODM File OID: '9b922c70-b656-4261-85cf-4d4a16c668a9' User entered '7'	System	11 Sep 2020 00:07:52
	System	11 Sep 2020 00:07:52

US3312046

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(2)

Generated On: 26 Nov 2020 10:51:05

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 (E037D92C-2F6A-4B91-B9C7-F8A20B33EADC)', Time: '2020-09-10T19:07:37', User OID: 'PatientReportedOutcome (US3312046)', ODM File OID: '9b922c70-b656-4261-85cf-4d4a16c668a9' User entered 'None (1)'	System	11 Sep 2020 00:07:52
	System	11 Sep 2020 00:07:52



**US3312046**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(2)**

**Generated On: 26 Nov 2020 10:51:05**

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E037D92C-2F6A-4B91-B9C7-F8A20B33EADC)', Time: '2020-09-10T19:07:50', User OID: 'PatientReportedOutcome (US3312046)', ODM File OID: '9b922c70-b656-4261-85cf-4d4a16c668a9' User entered '10 Sep 2020 19:07'	System	11 Sep 2020 00:07:52
	System	11 Sep 2020 00:07:52

**US3312046**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(2)**

**Generated On: 26 Nov 2020 10:51:05**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '10 Sep 2020 12:00'	System	09 Sep 2020 18:57:30

**US3312046**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(2)**

**Generated On: 26 Nov 2020 10:51:05**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '11 Sep 2020 11:59'	System	09 Sep 2020 18:57:30

**US3312046**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(3)**

**Generated On: 26 Nov 2020 10:51:05**

**TIMEPOINT**

Audit	User	Time (GMT)
Data entry locked.	System	09 Sep 2020 18:57:30
User entered 'Day 3'	System	09 Sep 2020 18:57:30

**US3312046**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(3)**

**Generated On: 26 Nov 2020 10:51:05**

[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 (E037D92C-2F6A-4B91-B9C7-F8A20B33EADC)', Time: '2020-09-11T18:24:44', User OID: 'PatientReportedOutcome (US3312046)', ODM File OID: 'adf2a39c-9bf5-4630-b5a1-ae0d268fb77c'	System	11 Sep 2020 23:25:21
User entered 'Does not interfere with activity (2)'	System	11 Sep 2020 23:25:21

**US3312046**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(3)**

**Generated On: 26 Nov 2020 10:51:05**

Is there any **REDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E037D92C-2F6A-4B91-B9C7-F8A20B33EADC)', Time: '2020-09-11T18:24:49', User OID: 'PatientReportedOutcome (US3312046)', ODM File OID: 'adf2a39c-9bf5-4630-b5a1-ae0d268fb77c'	System	11 Sep 2020 23:25:21
User entered 'No (N)'	System	11 Sep 2020 23:25:21

**US3312046**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(3)**

**Generated On: 26 Nov 2020 10:51:05**

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E037D92C-2F6A-4B91-B9C7-F8A20B33EADC)', Time: '2020-09-11T18:24:54', User OID: 'PatientReportedOutcome (US3312046)', ODM File OID: 'adf2a39c-9bf5-4630-b5a1-ae0d268fb77c'	System	11 Sep 2020 23:25:21
User entered 'Yes (Y)'	System	11 Sep 2020 23:25:21

US3312046

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(3)

Generated On: 26 Nov 2020 10:51:05

Please record - **SWELLING/HARDNESS AT INJECTION SITE (in mm)**

Measure the largest size across any injection site swelling/hardness with the ruler provided.

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E037D92C-2F6A-4B91-B9C7-F8A20B33EADC)', Time: '2020-09-11T18:25:03', User OID: 'PatientReportedOutcome (US3312046)', ODM File OID: 'adf2a39c-9bf5-4630-b5a1-ae0d268fb77c' User entered '4'	System	11 Sep 2020 23:25:21
	System	11 Sep 2020 23:25:21



**US3312046**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(3)**

**Generated On: 26 Nov 2020 10:51:05**

[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 (E037D92C-2F6A-4B91-B9C7-F8A20B33EADC)', Time: '2020-09-11T18:25:13', User OID: 'PatientReportedOutcome (US3312046)', ODM File OID: 'adf2a39c-9bf5-4630-b5a1-ae0d268fb77c'	System	11 Sep 2020 23:25:21
User entered 'None (1)'	System	11 Sep 2020 23:25:21

**US3312046**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(3)**

**Generated On: 26 Nov 2020 10:51:05**

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E037D92C-2F6A-4B91-B9C7-F8A20B33EADC)', Time: '2020-09-11T18:25:18', User OID: 'PatientReportedOutcome (US3312046)', ODM File OID: 'adf2a39c-9bf5-4630-b5a1-ae0d268fb77c'	System	11 Sep 2020 23:25:21
User entered '11 Sep 2020 18:25'	System	11 Sep 2020 23:25:21

**US3312046**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(3)**

**Generated On: 26 Nov 2020 10:51:05**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '11 Sep 2020 12:00'	System	09 Sep 2020 18:57:30

**US3312046**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(3)**

**Generated On: 26 Nov 2020 10:51:05**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '12 Sep 2020 11:59'	System	09 Sep 2020 18:57:30

**US3312046**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(4)**

**Generated On: 26 Nov 2020 10:51:05**

**TIMEPOINT**

Audit	User	Time (GMT)
Data entry locked.	System	09 Sep 2020 18:57:30
User entered 'Day 4'	System	09 Sep 2020 18:57:30

**US3312046**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(4)**

**Generated On: 26 Nov 2020 10:51:05**

[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 (E037D92C-2F6A-4B91-B9C7-F8A20B33EADC)', Time: '2020-09-12T19:11:12', User OID: 'PatientReportedOutcome (US3312046)', ODM File OID: '19fc8603-0b10-4951-ba51-6786dfdefc71'	System	13 Sep 2020 00:12:18
User entered 'Does not interfere with activity (2)'	System	13 Sep 2020 00:12:18

**US3312046**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(4)**

**Generated On: 26 Nov 2020 10:51:05**

Is there any **REDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E037D92C-2F6A-4B91-B9C7-F8A20B33EADC)', Time: '2020-09-12T19:11:17', User OID: 'PatientReportedOutcome (US3312046)', ODM File OID: '19fc8603-0b10-4951-ba51-6786dfdefc71'	System	13 Sep 2020 00:12:18
User entered 'Yes (Y)'	System	13 Sep 2020 00:12:18

**US3312046**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(4)**

**Generated On: 26 Nov 2020 10:51:05**

**Please record - REDNESS AT INJECTION SITE (in mm)**

Measure the largest size across any injection site redness with the ruler provided.

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E037D92C-2F6A-4B91-B9C7-F8A20B33EADC)', Time: '2020-09-12T19:11:46', User OID: 'PatientReportedOutcome (US3312046)', ODM File OID: '19fc8603-0b10-4951-ba51-6786dfdefc71' User entered '4'	System	13 Sep 2020 00:12:18
	System	13 Sep 2020 00:12:18



**US3312046**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(4)**

**Generated On: 26 Nov 2020 10:51:05**

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E037D92C-2F6A-4B91-B9C7-F8A20B33EADC)', Time: '2020-09-12T19:11:37', User OID: 'PatientReportedOutcome (US3312046)', ODM File OID: '19fc8603-0b10-4951-ba51-6786dfdefc71'	System	13 Sep 2020 00:12:18
User entered 'Yes (Y)'	System	13 Sep 2020 00:12:18

US3312046

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(4)

Generated On: 26 Nov 2020 10:51:05

Please record - **SWELLING/HARDNESS AT INJECTION SITE (in mm)**

Measure the largest size across any injection site swelling/hardness with the ruler provided.

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E037D92C-2F6A-4B91-B9C7-F8A20B33EADC)', Time: '2020-09-12T19:11:53', User OID: 'PatientReportedOutcome (US3312046)', ODM File OID: '19fc8603-0b10-4951-ba51-6786dfdefc71' User entered '4'	System	13 Sep 2020 00:12:18
	System	13 Sep 2020 00:12:18

**US3312046**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(4)**

**Generated On: 26 Nov 2020 10:51:05**

[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 (E037D92C-2F6A-4B91-B9C7-F8A20B33EADC)', Time: '2020-09-12T19:11:57', User OID: 'PatientReportedOutcome (US3312046)', ODM File OID: '19fc8603-0b10-4951-ba51-6786dfdefc71'	System	13 Sep 2020 00:12:18
User entered 'None (1)'	System	13 Sep 2020 00:12:18

**US3312046**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(4)**

**Generated On: 26 Nov 2020 10:51:05**

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E037D92C-2F6A-4B91-B9C7-F8A20B33EADC)', Time: '2020-09-12T19:12:16', User OID: 'PatientReportedOutcome (US3312046)', ODM File OID: '19fc8603-0b10-4951-ba51-6786dfdefc71'	System	13 Sep 2020 00:12:18
User entered '12 Sep 2020 19:12'	System	13 Sep 2020 00:12:18

**US3312046**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(4)**

**Generated On: 26 Nov 2020 10:51:05**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '12 Sep 2020 12:00'	System	09 Sep 2020 18:57:30

**US3312046**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(4)**

**Generated On: 26 Nov 2020 10:51:05**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '13 Sep 2020 11:59'	System	09 Sep 2020 18:57:30

**US3312046**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(5)**

**Generated On: 26 Nov 2020 10:51:05**

**TIMEPOINT**

Audit	User	Time (GMT)
Data entry locked.	System	09 Sep 2020 18:57:30
User entered 'Day 5'	System	09 Sep 2020 18:57:30

**US3312046**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(5)**

**Generated On: 26 Nov 2020 10:51:05**

[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 (E037D92C-2F6A-4B91-B9C7-F8A20B33EADC)', Time: '2020-09-13T18:42:09', User OID: 'PatientReportedOutcome (US3312046)', ODM File OID: '328f556e-8677-48e8-9016-2d0c6f79b0a2'	System	13 Sep 2020 23:42:30
User entered 'None (1)'	System	13 Sep 2020 23:42:30



**US3312046**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(5)**

**Generated On: 26 Nov 2020 10:51:05**

Is there any **REDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E037D92C-2F6A-4B91-B9C7-F8A20B33EADC)', Time: '2020-09-13T18:42:13', User OID: 'PatientReportedOutcome (US3312046)', ODM File OID: '328f556e-8677-48e8-9016-2d0c6f79b0a2'	System	13 Sep 2020 23:42:30
User entered 'No (N)'	System	13 Sep 2020 23:42:30

**US3312046**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(5)**

**Generated On: 26 Nov 2020 10:51:05**

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E037D92C-2F6A-4B91-B9C7-F8A20B33EADC)', Time: '2020-09-13T18:42:21', User OID: 'PatientReportedOutcome (US3312046)', ODM File OID: '328f556e-8677-48e8-9016-2d0c6f79b0a2'	System	13 Sep 2020 23:42:30
User entered 'No (N)'	System	13 Sep 2020 23:42:30

US3312046

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(5)

Generated On: 26 Nov 2020 10:51:05

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 (E037D92C-2F6A-4B91-B9C7-F8A20B33EADC)', Time: '2020-09-13T18:42:24', User OID: 'PatientReportedOutcome (US3312046)', ODM File OID: '328f556e-8677-48e8-9016-2d0c6f79b0a2'	System	13 Sep 2020 23:42:30
User entered 'None (1)'	System	13 Sep 2020 23:42:30

**US3312046**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(5)**

**Generated On: 26 Nov 2020 10:51:05**

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E037D92C-2F6A-4B91-B9C7-F8A20B33EADC)', Time: '2020-09-13T18:42:28', User OID: 'PatientReportedOutcome (US3312046)', ODM File OID: '328f556e-8677-48e8-9016-2d0c6f79b0a2'	System	13 Sep 2020 23:42:30
User entered '13 Sep 2020 18:42'	System	13 Sep 2020 23:42:30

**US3312046**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(5)**

**Generated On: 26 Nov 2020 10:51:05**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '13 Sep 2020 12:00'	System	09 Sep 2020 18:57:30

**US3312046**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(5)**

**Generated On: 26 Nov 2020 10:51:05**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '14 Sep 2020 11:59'	System	09 Sep 2020 18:57:30

**US3312046**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(6)**

**Generated On: 26 Nov 2020 10:51:05**

**TIMEPOINT**

Audit	User	Time (GMT)
Data entry locked.	System	09 Sep 2020 18:57:30
User entered 'Day 6'	System	09 Sep 2020 18:57:30

**US3312046**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(6)**

**Generated On: 26 Nov 2020 10:51:05**

[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 (E037D92C-2F6A-4B91-B9C7-F8A20B33EADC)', Time: '2020-09-14T19:06:23', User OID: 'PatientReportedOutcome (US3312046)', ODM File OID: '31ff265b-df9c-4def-9a3e-41335a987ff0'	System	15 Sep 2020 00:06:45
User entered 'None (1)'	System	15 Sep 2020 00:06:45



**US3312046**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(6)**

**Generated On: 26 Nov 2020 10:51:05**

Is there any **REDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E037D92C-2F6A-4B91-B9C7-F8A20B33EADC)', Time: '2020-09-14T19:06:27', User OID: 'PatientReportedOutcome (US3312046)', ODM File OID: '31ff265b-df9c-4def-9a3e-41335a987ff0'	System	15 Sep 2020 00:06:45
User entered 'No (N)'	System	15 Sep 2020 00:06:45

**US3312046**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(6)**

**Generated On: 26 Nov 2020 10:51:05**

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E037D92C-2F6A-4B91-B9C7-F8A20B33EADC)', Time: '2020-09-14T19:06:32', User OID: 'PatientReportedOutcome (US3312046)', ODM File OID: '31ff265b-df9c-4def-9a3e-41335a987ff0'	System	15 Sep 2020 00:06:45
User entered 'No (N)'	System	15 Sep 2020 00:06:45

US3312046

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(6)

Generated On: 26 Nov 2020 10:51:05

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 (E037D92C-2F6A-4B91-B9C7-F8A20B33EADC)', Time: '2020-09-14T19:06:36', User OID: 'PatientReportedOutcome (US3312046)', ODM File OID: '31ff265b-df9c-4def-9a3e-41335a987ff0'	System	15 Sep 2020 00:06:45
User entered 'None (1)'	System	15 Sep 2020 00:06:45

**US3312046**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(6)**

**Generated On: 26 Nov 2020 10:51:05**

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E037D92C-2F6A-4B91-B9C7-F8A20B33EADC)', Time: '2020-09-14T19:06:40', User OID: 'PatientReportedOutcome (US3312046)', ODM File OID: '31ff265b-df9c-4def-9a3e-41335a987ff0'	System	15 Sep 2020 00:06:45
User entered '14 Sep 2020 19:06'	System	15 Sep 2020 00:06:45

**US3312046**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(6)**

**Generated On: 26 Nov 2020 10:51:05**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '14 Sep 2020 12:00'	System	09 Sep 2020 18:57:30

**US3312046**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(6)**

**Generated On: 26 Nov 2020 10:51:05**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '15 Sep 2020 11:59'	System	09 Sep 2020 18:57:30

**US3312046**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(7)**

**Generated On: 26 Nov 2020 10:51:05**

**TIMEPOINT**

Audit	User	Time (GMT)
Data entry locked.	System	09 Sep 2020 18:57:30
User entered 'Day 7'	System	09 Sep 2020 18:57:30

**US3312046**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(7)**

**Generated On: 26 Nov 2020 10:51:05**

[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 (E037D92C-2F6A-4B91-B9C7-F8A20B33EADC)', Time: '2020-09-15T20:34:11', User OID: 'PatientReportedOutcome (US3312046)', ODM File OID: '711b765b-30ed-424b-b5cf-02dcab1c941d'	System	16 Sep 2020 01:34:34
User entered 'None (1)'	System	16 Sep 2020 01:34:34



US3312046

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(7)

Generated On: 26 Nov 2020 10:51:05

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E037D92C-2F6A-4B91-B9C7-F8A20B33EADC)', Time: '2020-09-15T20:34:17', User OID: 'PatientReportedOutcome (US3312046)', ODM File OID: '711b765b-30ed-424b-b5cf-02dcab1c941d'	System	16 Sep 2020 01:34:34
User entered 'No (N)'	System	16 Sep 2020 01:34:34

**US3312046**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(7)**

**Generated On: 26 Nov 2020 10:51:05**

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E037D92C-2F6A-4B91-B9C7-F8A20B33EADC)', Time: '2020-09-15T20:34:22', User OID: 'PatientReportedOutcome (US3312046)', ODM File OID: '711b765b-30ed-424b-b5cf-02dcab1c941d'	System	16 Sep 2020 01:34:34
User entered 'No (N)'	System	16 Sep 2020 01:34:34

US3312046

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(7)

Generated On: 26 Nov 2020 10:51:05

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 (E037D92C-2F6A-4B91-B9C7-F8A20B33EADC)', Time: '2020-09-15T20:34:26', User OID: 'PatientReportedOutcome (US3312046)', ODM File OID: '711b765b-30ed-424b-b5cf-02dcab1c941d'	System	16 Sep 2020 01:34:34
User entered 'None (1)'	System	16 Sep 2020 01:34:34

**US3312046**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(7)**

**Generated On: 26 Nov 2020 10:51:05**

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E037D92C-2F6A-4B91-B9C7-F8A20B33EADC)', Time: '2020-09-15T20:34:30', User OID: 'PatientReportedOutcome (US3312046)', ODM File OID: '711b765b-30ed-424b-b5cf-02dcab1c941d' User entered '15 Sep 2020 20:34'	System	16 Sep 2020 01:34:34
	System	16 Sep 2020 01:34:34

**US3312046**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(7)**

**Generated On: 26 Nov 2020 10:51:05**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '15 Sep 2020 12:00'	System	09 Sep 2020 18:57:30

**US3312046**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(7)**

**Generated On: 26 Nov 2020 10:51:05**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '16 Sep 2020 11:59'	System	09 Sep 2020 18:57:30

**US3312046**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(1/1)**

**Generated On: 26 Nov 2020 10:51:05**

**TIMEPOINT**

Audit	User	Time (GMT)
Data entry locked.	System	09 Sep 2020 18:57:30
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	09 Sep 2020 18:57:30

**US3312046**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(1/1)**

**Generated On: 26 Nov 2020 10:51:05**

**HEADACHE**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E037D92C-2F6A-4B91-B9C7-F8A20B33EADC)', Time: '2020-09-09T14:22:17', User OID: 'PatientReportedOutcome (US3312046)', ODM File OID: 'd41871ae-7533-474d-b2b3-7215e1374d13'	System	09 Sep 2020 19:22:50
User entered 'None (0)'	System	09 Sep 2020 19:22:50



**US3312046**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(1/1)**

**Generated On: 26 Nov 2020 10:51:05**

**FATIGUE**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E037D92C-2F6A-4B91-B9C7-F8A20B33EADC)', Time: '2020-09-09T14:22:20', User OID: 'PatientReportedOutcome (US3312046)', ODM File OID: 'd41871ae-7533-474d-b2b3-7215e1374d13'	System	09 Sep 2020 19:22:50
User entered 'None (0)'	System	09 Sep 2020 19:22:50

**US3312046**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(1/1)**

**Generated On: 26 Nov 2020 10:51:05**

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E037D92C-2F6A-4B91-B9C7-F8A20B33EADC)', Time: '2020-09-09T14:22:23', User OID: 'PatientReportedOutcome (US3312046)', ODM File OID: 'd41871ae-7533-474d-b2b3-7215e1374d13'	System	09 Sep 2020 19:22:50
User entered 'None (0)'	System	09 Sep 2020 19:22:50

**US3312046**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(1/1)**

**Generated On: 26 Nov 2020 10:51:05**

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E037D92C-2F6A-4B91-B9C7-F8A20B33EADC)', Time: '2020-09-09T14:22:26', User OID: 'PatientReportedOutcome (US3312046)', ODM File OID: 'd41871ae-7533-474d-b2b3-7215e1374d13'	System	09 Sep 2020 19:22:50
User entered 'None (0)'	System	09 Sep 2020 19:22:50

**US3312046**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(1/1)**

**Generated On: 26 Nov 2020 10:51:05**

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E037D92C-2F6A-4B91-B9C7-F8A20B33EADC)', Time: '2020-09-09T14:22:30', User OID: 'PatientReportedOutcome (US3312046)', ODM File OID: 'd41871ae-7533-474d-b2b3-7215e1374d13'	System	09 Sep 2020 19:22:50
User entered 'None (0)'	System	09 Sep 2020 19:22:50

**US3312046**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(1/1)**

**Generated On: 26 Nov 2020 10:51:05**

**CHILLS**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E037D92C-2F6A-4B91-B9C7-F8A20B33EADC)', Time: '2020-09-09T14:22:33', User OID: 'PatientReportedOutcome (US3312046)', ODM File OID: 'd41871ae-7533-474d-b2b3-7215e1374d13'	System	09 Sep 2020 19:22:50
User entered 'None (0)'	System	09 Sep 2020 19:22:50

US3312046

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 26 Nov 2020 10:51:05

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 (E037D92C-2F6A-4B91-B9C7-F8A20B33EADC)', Time: '2020-09-09T14:22:38', User OID: 'PatientReportedOutcome (US3312046)', ODM File OID: 'd41871ae-7533-474d-b2b3-7215e1374d13'	System	09 Sep 2020 19:22:50
User entered 'No (N)'	System	09 Sep 2020 19:22:50

**US3312046**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(1/1)**

**Generated On: 26 Nov 2020 10:51:05**

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E037D92C-2F6A-4B91-B9C7-F8A20B33EADC)', Time: '2020-09-09T14:22:44', User OID: 'PatientReportedOutcome (US3312046)', ODM File OID: 'd41871ae-7533-474d-b2b3-7215e1374d13'	System	09 Sep 2020 19:22:50
User entered '09 Sep 2020 14:22'	System	09 Sep 2020 19:22:50

**US3312046**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(1/1)**

**Generated On: 26 Nov 2020 10:51:05**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '09 Sep 2020 14:10'	System	09 Sep 2020 18:57:30



**US3312046**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(1/1)**

**Generated On: 26 Nov 2020 10:51:05**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '09 Sep 2020 16:40'	System	09 Sep 2020 18:57:30

**US3312046**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(1/2)**

**Generated On: 26 Nov 2020 10:51:05**

**TIMEPOINT**

Audit	User	Time (GMT)
Data entry locked.	System	09 Sep 2020 18:57:30
User entered 'Day 1, after vaccination (at home)'	System	09 Sep 2020 18:57:30

**US3312046**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(1/2)**

**Generated On: 26 Nov 2020 10:51:05**

**HEADACHE**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E037D92C-2F6A-4B91-B9C7-F8A20B33EADC)', Time: '2020-09-09T19:46:26', User OID: 'PatientReportedOutcome (US3312046)', ODM File OID: '20445ad4-b07b-4c4c-bf16-d2c6cefc2d08'	System	10 Sep 2020 00:46:54
User entered 'None (0)'	System	10 Sep 2020 00:46:54

**US3312046**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(1/2)**

**Generated On: 26 Nov 2020 10:51:05**

**FATIGUE**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E037D92C-2F6A-4B91-B9C7-F8A20B33EADC)', Time: '2020-09-09T19:46:30', User OID: 'PatientReportedOutcome (US3312046)', ODM File OID: '20445ad4-b07b-4c4c-bf16-d2c6cefc2d08'	System	10 Sep 2020 00:46:54
User entered 'None (0)'	System	10 Sep 2020 00:46:54

**US3312046**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(1/2)**

**Generated On: 26 Nov 2020 10:51:05**

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E037D92C-2F6A-4B91-B9C7-F8A20B33EADC)', Time: '2020-09-09T19:46:34', User OID: 'PatientReportedOutcome (US3312046)', ODM File OID: '20445ad4-b07b-4c4c-bf16-d2c6cefc2d08'	System	10 Sep 2020 00:46:54
User entered 'None (0)'	System	10 Sep 2020 00:46:54

**US3312046**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(1/2)**

**Generated On: 26 Nov 2020 10:51:05**

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E037D92C-2F6A-4B91-B9C7-F8A20B33EADC)', Time: '2020-09-09T19:46:38', User OID: 'PatientReportedOutcome (US3312046)', ODM File OID: '20445ad4-b07b-4c4c-bf16-d2c6cefc2d08'	System	10 Sep 2020 00:46:54
User entered 'None (0)'	System	10 Sep 2020 00:46:54

**US3312046**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(1/2)**

**Generated On: 26 Nov 2020 10:51:05**

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E037D92C-2F6A-4B91-B9C7-F8A20B33EADC)', Time: '2020-09-09T19:46:41', User OID: 'PatientReportedOutcome (US3312046)', ODM File OID: '20445ad4-b07b-4c4c-bf16-d2c6cefc2d08'	System	10 Sep 2020 00:46:54
User entered 'None (0)'	System	10 Sep 2020 00:46:54

**US3312046**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(1/2)**

**Generated On: 26 Nov 2020 10:51:05**

**CHILLS**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E037D92C-2F6A-4B91-B9C7-F8A20B33EADC)', Time: '2020-09-09T19:46:44', User OID: 'PatientReportedOutcome (US3312046)', ODM File OID: '20445ad4-b07b-4c4c-bf16-d2c6cefc2d08'	System	10 Sep 2020 00:46:54
User entered 'None (0)'	System	10 Sep 2020 00:46:54



**US3312046**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(1/2)**

**Generated On: 26 Nov 2020 10:51:05**

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 (E037D92C-2F6A-4B91-B9C7-F8A20B33EADC)', Time: '2020-09-09T19:46:49', User OID: 'PatientReportedOutcome (US3312046)', ODM File OID: '20445ad4-b07b-4c4c-bf16-d2c6cefc2d08'	System	10 Sep 2020 00:46:54
User entered 'No (N)'	System	10 Sep 2020 00:46:54

**US3312046**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(1/2)**

**Generated On: 26 Nov 2020 10:51:05**

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E037D92C-2F6A-4B91-B9C7-F8A20B33EADC)', Time: '2020-09-09T19:46:53', User OID: 'PatientReportedOutcome (US3312046)', ODM File OID: '20445ad4-b07b-4c4c-bf16-d2c6cefc2d08'	System	10 Sep 2020 00:46:54
User entered '09 Sep 2020 19:46'	System	10 Sep 2020 00:46:54

**US3312046**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(1/2)**

**Generated On: 26 Nov 2020 10:51:05**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '09 Sep 2020 17:35'	System	09 Sep 2020 18:57:30

**US3312046**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(1/2)**

**Generated On: 26 Nov 2020 10:51:05**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '10 Sep 2020 11:59'	System	09 Sep 2020 18:57:30

**US3312046**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(2)**

**Generated On: 26 Nov 2020 10:51:05**

**TIMEPOINT**

Audit	User	Time (GMT)
Data entry locked.	System	09 Sep 2020 18:57:30
User entered 'Day 2'	System	09 Sep 2020 18:57:30

**US3312046**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(2)**

**Generated On: 26 Nov 2020 10:51:05**

**HEADACHE**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E037D92C-2F6A-4B91-B9C7-F8A20B33EADC)', Time: '2020-09-10T19:08:10', User OID: 'PatientReportedOutcome (US3312046)', ODM File OID: '46e9ea34-d470-4f60-9eba-b28927a83cc2'	System	11 Sep 2020 00:08:58
User entered 'No interference with activity (1)'	System	11 Sep 2020 00:08:58

**US3312046**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(2)**

**Generated On: 26 Nov 2020 10:51:05**

**FATIGUE**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E037D92C-2F6A-4B91-B9C7-F8A20B33EADC)', Time: '2020-09-10T19:08:21', User OID: 'PatientReportedOutcome (US3312046)', ODM File OID: '46e9ea34-d470-4f60-9eba-b28927a83cc2'	System	11 Sep 2020 00:08:58
User entered 'Some interference with activity (2)'	System	11 Sep 2020 00:08:58

**US3312046**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(2)**

**Generated On: 26 Nov 2020 10:51:05**

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E037D92C-2F6A-4B91-B9C7-F8A20B33EADC)', Time: '2020-09-10T19:08:28', User OID: 'PatientReportedOutcome (US3312046)', ODM File OID: '46e9ea34-d470-4f60-9eba-b28927a83cc2'	System	11 Sep 2020 00:08:58
User entered 'Some interference with activity (2)'	System	11 Sep 2020 00:08:58



**US3312046**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(2)**

**Generated On: 26 Nov 2020 10:51:05**

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E037D92C-2F6A-4B91-B9C7-F8A20B33EADC)', Time: '2020-09-10T19:08:34', User OID: 'PatientReportedOutcome (US3312046)', ODM File OID: '46e9ea34-d470-4f60-9eba-b28927a83cc2'	System	11 Sep 2020 00:08:58
User entered 'No interference with activity (1)'	System	11 Sep 2020 00:08:58

**US3312046**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(2)**

**Generated On: 26 Nov 2020 10:51:05**

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E037D92C-2F6A-4B91-B9C7-F8A20B33EADC)', Time: '2020-09-10T19:08:39', User OID: 'PatientReportedOutcome (US3312046)', ODM File OID: '46e9ea34-d470-4f60-9eba-b28927a83cc2'	System	11 Sep 2020 00:08:58
User entered 'None (0)'	System	11 Sep 2020 00:08:58

**US3312046**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(2)**

**Generated On: 26 Nov 2020 10:51:05**

**CHILLS**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E037D92C-2F6A-4B91-B9C7-F8A20B33EADC)', Time: '2020-09-10T19:08:43', User OID: 'PatientReportedOutcome (US3312046)', ODM File OID: '46e9ea34-d470-4f60-9eba-b28927a83cc2'	System	11 Sep 2020 00:08:58
User entered 'None (0)'	System	11 Sep 2020 00:08:58

**US3312046**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(2)**

**Generated On: 26 Nov 2020 10:51:05**

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 (E037D92C-2F6A-4B91-B9C7-F8A20B33EADC)', Time: '2020-09-10T19:08:50', User OID: 'PatientReportedOutcome (US3312046)', ODM File OID: '46e9ea34-d470-4f60-9eba-b28927a83cc2'	System	11 Sep 2020 00:08:58
User entered 'No (N)'	System	11 Sep 2020 00:08:58

**US3312046**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(2)**

**Generated On: 26 Nov 2020 10:51:05**

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E037D92C-2F6A-4B91-B9C7-F8A20B33EADC)', Time: '2020-09-10T19:08:54', User OID: 'PatientReportedOutcome (US3312046)', ODM File OID: '46e9ea34-d470-4f60-9eba-b28927a83cc2'	System	11 Sep 2020 00:08:58
User entered '10 Sep 2020 19:08'	System	11 Sep 2020 00:08:58

**US3312046**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(2)**

**Generated On: 26 Nov 2020 10:51:05**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '10 Sep 2020 12:00'	System	09 Sep 2020 18:57:30

**US3312046**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(2)**

**Generated On: 26 Nov 2020 10:51:05**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '11 Sep 2020 11:59'	System	09 Sep 2020 18:57:30

**US3312046**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(3)**

**Generated On: 26 Nov 2020 10:51:05**

**TIMEPOINT**

Audit	User	Time (GMT)
Data entry locked.	System	09 Sep 2020 18:57:30
User entered 'Day 3'	System	09 Sep 2020 18:57:30



**US3312046**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(3)**

**Generated On: 26 Nov 2020 10:51:05**

**HEADACHE**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E037D92C-2F6A-4B91-B9C7-F8A20B33EADC)', Time: '2020-09-11T18:25:29', User OID: 'PatientReportedOutcome (US3312046)', ODM File OID: '4ba8ced3-ea91-49c8-a6f3-2a6d65f070ad' User entered 'None (0)'	System	11 Sep 2020 23:26:05
	System	11 Sep 2020 23:26:05

**US3312046**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(3)**

**Generated On: 26 Nov 2020 10:51:05**

**FATIGUE**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E037D92C-2F6A-4B91-B9C7-F8A20B33EADC)', Time: '2020-09-11T18:25:33', User OID: 'PatientReportedOutcome (US3312046)', ODM File OID: '4ba8ced3-ea91-49c8-a6f3-2a6d65f070ad' User entered 'None (0)'	System	11 Sep 2020 23:26:05
	System	11 Sep 2020 23:26:05

**US3312046**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(3)**

**Generated On: 26 Nov 2020 10:51:05**

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E037D92C-2F6A-4B91-B9C7-F8A20B33EADC)', Time: '2020-09-11T18:25:37', User OID: 'PatientReportedOutcome (US3312046)', ODM File OID: '4ba8ced3-ea91-49c8-a6f3-2a6d65f070ad' User entered 'None (0)'	System	11 Sep 2020 23:26:05
	System	11 Sep 2020 23:26:05

**US3312046**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(3)**

**Generated On: 26 Nov 2020 10:51:05**

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E037D92C-2F6A-4B91-B9C7-F8A20B33EADC)', Time: '2020-09-11T18:25:42', User OID: 'PatientReportedOutcome (US3312046)', ODM File OID: '4ba8ced3-ea91-49c8-a6f3-2a6d65f070ad'	System	11 Sep 2020 23:26:05
User entered 'None (0)'	System	11 Sep 2020 23:26:05

**US3312046**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(3)**

**Generated On: 26 Nov 2020 10:51:05**

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E037D92C-2F6A-4B91-B9C7-F8A20B33EADC)', Time: '2020-09-11T18:25:46', User OID: 'PatientReportedOutcome (US3312046)', ODM File OID: '4ba8ced3-ea91-49c8-a6f3-2a6d65f070ad'	System	11 Sep 2020 23:26:05
User entered 'None (0)'	System	11 Sep 2020 23:26:05

**US3312046**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(3)**

**Generated On: 26 Nov 2020 10:51:05**

**CHILLS**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E037D92C-2F6A-4B91-B9C7-F8A20B33EADC)', Time: '2020-09-11T18:25:52', User OID: 'PatientReportedOutcome (US3312046)', ODM File OID: '4ba8ced3-ea91-49c8-a6f3-2a6d65f070ad'	System	11 Sep 2020 23:26:05
User entered 'None (0)'	System	11 Sep 2020 23:26:05

**US3312046**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(3)**

**Generated On: 26 Nov 2020 10:51:05**

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 (E037D92C-2F6A-4B91-B9C7-F8A20B33EADC)', Time: '2020-09-11T18:25:57', User OID: 'PatientReportedOutcome (US3312046)', ODM File OID: '4ba8ced3-ea91-49c8-a6f3-2a6d65f070ad'	System	11 Sep 2020 23:26:05
User entered 'No (N)'	System	11 Sep 2020 23:26:05

**US3312046**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(3)**

**Generated On: 26 Nov 2020 10:51:05**

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E037D92C-2F6A-4B91-B9C7-F8A20B33EADC)', Time: '2020-09-11T18:26:01', User OID: 'PatientReportedOutcome (US3312046)', ODM File OID: '4ba8ced3-ea91-49c8-a6f3-2a6d65f070ad'	System	11 Sep 2020 23:26:05
User entered '11 Sep 2020 18:26'	System	11 Sep 2020 23:26:05



**US3312046**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(3)**

**Generated On: 26 Nov 2020 10:51:05**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '11 Sep 2020 12:00'	System	09 Sep 2020 18:57:30

**US3312046**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(3)**

**Generated On: 26 Nov 2020 10:51:05**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '12 Sep 2020 11:59'	System	09 Sep 2020 18:57:30

**US3312046**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(4)**

**Generated On: 26 Nov 2020 10:51:05**

**TIMEPOINT**

Audit	User	Time (GMT)
Data entry locked.	System	09 Sep 2020 18:57:30
User entered 'Day 4'	System	09 Sep 2020 18:57:30

**US3312046**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(4)**

**Generated On: 26 Nov 2020 10:51:05**

**HEADACHE**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E037D92C-2F6A-4B91-B9C7-F8A20B33EADC)', Time: '2020-09-12T19:12:23', User OID: 'PatientReportedOutcome (US3312046)', ODM File OID: '87643b19-2ad5-4bdf-a9ba-86dd293d6b12'	System	13 Sep 2020 00:12:59
User entered 'None (0)'	System	13 Sep 2020 00:12:59

**US3312046**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(4)**

**Generated On: 26 Nov 2020 10:51:05**

**FATIGUE**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E037D92C-2F6A-4B91-B9C7-F8A20B33EADC)', Time: '2020-09-12T19:12:32', User OID: 'PatientReportedOutcome (US3312046)', ODM File OID: '87643b19-2ad5-4bdf-a9ba-86dd293d6b12'	System	13 Sep 2020 00:12:59
User entered 'No interference with activity (1)'	System	13 Sep 2020 00:12:59

**US3312046**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(4)**

**Generated On: 26 Nov 2020 10:51:05**

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E037D92C-2F6A-4B91-B9C7-F8A20B33EADC)', Time: '2020-09-12T19:12:37', User OID: 'PatientReportedOutcome (US3312046)', ODM File OID: '87643b19-2ad5-4bdf-a9ba-86dd293d6b12'	System	13 Sep 2020 00:12:59
User entered 'None (0)'	System	13 Sep 2020 00:12:59

**US3312046**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(4)**

**Generated On: 26 Nov 2020 10:51:05**

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E037D92C-2F6A-4B91-B9C7-F8A20B33EADC)', Time: '2020-09-12T19:12:41', User OID: 'PatientReportedOutcome (US3312046)', ODM File OID: '87643b19-2ad5-4bdf-a9ba-86dd293d6b12'	System	13 Sep 2020 00:12:59
User entered 'None (0)'	System	13 Sep 2020 00:12:59

**US3312046**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(4)**

**Generated On: 26 Nov 2020 10:51:05**

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E037D92C-2F6A-4B91-B9C7-F8A20B33EADC)', Time: '2020-09-12T19:12:44', User OID: 'PatientReportedOutcome (US3312046)', ODM File OID: '87643b19-2ad5-4bdf-a9ba-86dd293d6b12'	System	13 Sep 2020 00:12:59
User entered 'None (0)'	System	13 Sep 2020 00:12:59



**US3312046**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(4)**

**Generated On: 26 Nov 2020 10:51:05**

**CHILLS**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E037D92C-2F6A-4B91-B9C7-F8A20B33EADC)', Time: '2020-09-12T19:12:47', User OID: 'PatientReportedOutcome (US3312046)', ODM File OID: '87643b19-2ad5-4bdf-a9ba-86dd293d6b12'	System	13 Sep 2020 00:12:59
User entered 'None (0)'	System	13 Sep 2020 00:12:59

US3312046

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 26 Nov 2020 10:51:05

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 (E037D92C-2F6A-4B91-B9C7-F8A20B33EADC)', Time: '2020-09-12T19:12:53', User OID: 'PatientReportedOutcome (US3312046)', ODM File OID: '87643b19-2ad5-4bdf-a9ba-86dd293d6b12'	System	13 Sep 2020 00:12:59
User entered 'No (N)'	System	13 Sep 2020 00:12:59

**US3312046**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(4)**

**Generated On: 26 Nov 2020 10:51:05**

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E037D92C-2F6A-4B91-B9C7-F8A20B33EADC)', Time: '2020-09-12T19:12:56', User OID: 'PatientReportedOutcome (US3312046)', ODM File OID: '87643b19-2ad5-4bdf-a9ba-86dd293d6b12'	System	13 Sep 2020 00:12:59
User entered '12 Sep 2020 19:12'	System	13 Sep 2020 00:12:59

**US3312046**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(4)**

**Generated On: 26 Nov 2020 10:51:05**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '12 Sep 2020 12:00'	System	09 Sep 2020 18:57:30

**US3312046**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(4)**

**Generated On: 26 Nov 2020 10:51:05**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '13 Sep 2020 11:59'	System	09 Sep 2020 18:57:30

**US3312046**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(5)**

**Generated On: 26 Nov 2020 10:51:05**

**TIMEPOINT**

Audit	User	Time (GMT)
Data entry locked.	System	09 Sep 2020 18:57:30
User entered 'Day 5'	System	09 Sep 2020 18:57:30

**US3312046**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(5)**

**Generated On: 26 Nov 2020 10:51:05**

**HEADACHE**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E037D92C-2F6A-4B91-B9C7-F8A20B33EADC)', Time: '2020-09-13T18:42:37', User OID: 'PatientReportedOutcome (US3312046)', ODM File OID: 'd3ecb5fe-0717-4e20-a1c4-88e2adaa25b8'	System	13 Sep 2020 23:43:07
User entered 'None (0)'	System	13 Sep 2020 23:43:07

**US3312046**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(5)**

**Generated On: 26 Nov 2020 10:51:05**

**FATIGUE**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E037D92C-2F6A-4B91-B9C7-F8A20B33EADC)', Time: '2020-09-13T18:42:40', User OID: 'PatientReportedOutcome (US3312046)', ODM File OID: 'd3ecb5fe-0717-4e20-a1c4-88e2adaa25b8'	System	13 Sep 2020 23:43:07
User entered 'None (0)'	System	13 Sep 2020 23:43:07



**US3312046**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(5)**

**Generated On: 26 Nov 2020 10:51:05**

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E037D92C-2F6A-4B91-B9C7-F8A20B33EADC)', Time: '2020-09-13T18:42:43', User OID: 'PatientReportedOutcome (US3312046)', ODM File OID: 'd3ecb5fe-0717-4e20-a1c4-88e2adaa25b8'	System	13 Sep 2020 23:43:07
User entered 'None (0)'	System	13 Sep 2020 23:43:07

**US3312046**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(5)**

**Generated On: 26 Nov 2020 10:51:05**

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E037D92C-2F6A-4B91-B9C7-F8A20B33EADC)', Time: '2020-09-13T18:42:48', User OID: 'PatientReportedOutcome (US3312046)', ODM File OID: 'd3ecb5fe-0717-4e20-a1c4-88e2adaa25b8'	System	13 Sep 2020 23:43:07
User entered 'None (0)'	System	13 Sep 2020 23:43:07

**US3312046**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(5)**

**Generated On: 26 Nov 2020 10:51:05**

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E037D92C-2F6A-4B91-B9C7-F8A20B33EADC)', Time: '2020-09-13T18:42:50', User OID: 'PatientReportedOutcome (US3312046)', ODM File OID: 'd3ecb5fe-0717-4e20-a1c4-88e2adaa25b8'	System	13 Sep 2020 23:43:07
User entered 'None (0)'	System	13 Sep 2020 23:43:07

**US3312046**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(5)**

**Generated On: 26 Nov 2020 10:51:05**

**CHILLS**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E037D92C-2F6A-4B91-B9C7-F8A20B33EADC)', Time: '2020-09-13T18:42:54', User OID: 'PatientReportedOutcome (US3312046)', ODM File OID: 'd3ecb5fe-0717-4e20-a1c4-88e2adaa25b8'	System	13 Sep 2020 23:43:07
User entered 'None (0)'	System	13 Sep 2020 23:43:07

**US3312046**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(5)**

**Generated On: 26 Nov 2020 10:51:05**

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 (E037D92C-2F6A-4B91-B9C7-F8A20B33EADC)', Time: '2020-09-13T18:43:00', User OID: 'PatientReportedOutcome (US3312046)', ODM File OID: 'd3ecb5fe-0717-4e20-a1c4-88e2adaa25b8'	System	13 Sep 2020 23:43:07
User entered 'No (N)'	System	13 Sep 2020 23:43:07

**US3312046**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(5)**

**Generated On: 26 Nov 2020 10:51:05**

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E037D92C-2F6A-4B91-B9C7-F8A20B33EADC)', Time: '2020-09-13T18:43:03', User OID: 'PatientReportedOutcome (US3312046)', ODM File OID: 'd3ecb5fe-0717-4e20-a1c4-88e2adaa25b8' User entered '13 Sep 2020 18:43'	System	13 Sep 2020 23:43:07
	System	13 Sep 2020 23:43:07

**US3312046**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(5)**

**Generated On: 26 Nov 2020 10:51:05**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '13 Sep 2020 12:00'	System	09 Sep 2020 18:57:30

**US3312046**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(5)**

**Generated On: 26 Nov 2020 10:51:05**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '14 Sep 2020 11:59'	System	09 Sep 2020 18:57:30



**US3312046**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(6)**

**Generated On: 26 Nov 2020 10:51:05**

**TIMEPOINT**

Audit	User	Time (GMT)
Data entry locked.	System	09 Sep 2020 18:57:30
User entered 'Day 6'	System	09 Sep 2020 18:57:30

**US3312046**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(6)**

**Generated On: 26 Nov 2020 10:51:05**

**HEADACHE**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E037D92C-2F6A-4B91-B9C7-F8A20B33EADC)', Time: '2020-09-14T19:06:45', User OID: 'PatientReportedOutcome (US3312046)', ODM File OID: 'b4b1d43c-d1ef-4d60-868e-db3684ffe868'	System	15 Sep 2020 00:07:17
User entered 'None (0)'	System	15 Sep 2020 00:07:17

**US3312046**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(6)**

**Generated On: 26 Nov 2020 10:51:05**

**FATIGUE**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E037D92C-2F6A-4B91-B9C7-F8A20B33EADC)', Time: '2020-09-14T19:06:50', User OID: 'PatientReportedOutcome (US3312046)', ODM File OID: 'b4b1d43c-d1ef-4d60-868e-db3684ffe868'	System	15 Sep 2020 00:07:17
User entered 'None (0)'	System	15 Sep 2020 00:07:17

**US3312046**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(6)**

**Generated On: 26 Nov 2020 10:51:05**

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E037D92C-2F6A-4B91-B9C7-F8A20B33EADC)', Time: '2020-09-14T19:06:53', User OID: 'PatientReportedOutcome (US3312046)', ODM File OID: 'b4b1d43c-d1ef-4d60-868e-db3684ffe868'	System	15 Sep 2020 00:07:17
User entered 'None (0)'	System	15 Sep 2020 00:07:17

**US3312046**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(6)**

**Generated On: 26 Nov 2020 10:51:05**

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E037D92C-2F6A-4B91-B9C7-F8A20B33EADC)', Time: '2020-09-14T19:06:57', User OID: 'PatientReportedOutcome (US3312046)', ODM File OID: 'b4b1d43c-d1ef-4d60-868e-db3684ffe868'	System	15 Sep 2020 00:07:17
User entered 'None (0)'	System	15 Sep 2020 00:07:17

**US3312046**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(6)**

**Generated On: 26 Nov 2020 10:51:05**

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E037D92C-2F6A-4B91-B9C7-F8A20B33EADC)', Time: '2020-09-14T19:07:01', User OID: 'PatientReportedOutcome (US3312046)', ODM File OID: 'b4b1d43c-d1ef-4d60-868e-db3684ffe868'	System	15 Sep 2020 00:07:17
User entered 'None (0)'	System	15 Sep 2020 00:07:17

**US3312046**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(6)**

**Generated On: 26 Nov 2020 10:51:05**

**CHILLS**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E037D92C-2F6A-4B91-B9C7-F8A20B33EADC)', Time: '2020-09-14T19:07:05', User OID: 'PatientReportedOutcome (US3312046)', ODM File OID: 'b4b1d43c-d1ef-4d60-868e-db3684ffe868'	System	15 Sep 2020 00:07:17
User entered 'None (0)'	System	15 Sep 2020 00:07:17

**US3312046**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(6)**

**Generated On: 26 Nov 2020 10:51:05**

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 (E037D92C-2F6A-4B91-B9C7-F8A20B33EADC)', Time: '2020-09-14T19:07:10', User OID: 'PatientReportedOutcome (US3312046)', ODM File OID: 'b4b1d43c-d1ef-4d60-868e-db3684ffe868'	System	15 Sep 2020 00:07:17
User entered 'No (N)'	System	15 Sep 2020 00:07:17



**US3312046**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(6)**

**Generated On: 26 Nov 2020 10:51:05**

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E037D92C-2F6A-4B91-B9C7-F8A20B33EADC)', Time: '2020-09-14T19:07:14', User OID: 'PatientReportedOutcome (US3312046)', ODM File OID: 'b4b1d43c-d1ef-4d60-868e-db3684ffe868'	System	15 Sep 2020 00:07:17
User entered '14 Sep 2020 19:07'	System	15 Sep 2020 00:07:17

**US3312046**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(6)**

**Generated On: 26 Nov 2020 10:51:05**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '14 Sep 2020 12:00'	System	09 Sep 2020 18:57:30

**US3312046**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(6)**

**Generated On: 26 Nov 2020 10:51:05**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '15 Sep 2020 11:59'	System	09 Sep 2020 18:57:30

**US3312046**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(7)**

**Generated On: 26 Nov 2020 10:51:05**

**TIMEPOINT**

Audit	User	Time (GMT)
Data entry locked.	System	09 Sep 2020 18:57:30
User entered 'Day 7'	System	09 Sep 2020 18:57:30

**US3312046**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(7)**

**Generated On: 26 Nov 2020 10:51:05**

**HEADACHE**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E037D92C-2F6A-4B91-B9C7-F8A20B33EADC)', Time: '2020-09-15T20:34:36', User OID: 'PatientReportedOutcome (US3312046)', ODM File OID: 'c5f582de-d210-4b00-a1ab-cc0df33e1119'	System	16 Sep 2020 01:35:05
User entered 'None (0)'	System	16 Sep 2020 01:35:05

**US3312046**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(7)**

**Generated On: 26 Nov 2020 10:51:05**

**FATIGUE**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E037D92C-2F6A-4B91-B9C7-F8A20B33EADC)', Time: '2020-09-15T20:34:39', User OID: 'PatientReportedOutcome (US3312046)', ODM File OID: 'c5f582de-d210-4b00-a1ab-cc0df33e1119'	System	16 Sep 2020 01:35:05
User entered 'None (0)'	System	16 Sep 2020 01:35:05

**US3312046**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(7)**

**Generated On: 26 Nov 2020 10:51:05**

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E037D92C-2F6A-4B91-B9C7-F8A20B33EADC)', Time: '2020-09-15T20:34:43', User OID: 'PatientReportedOutcome (US3312046)', ODM File OID: 'c5f582de-d210-4b00-a1ab-cc0df33e1119'	System	16 Sep 2020 01:35:05
User entered 'None (0)'	System	16 Sep 2020 01:35:05

**US3312046**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(7)**

**Generated On: 26 Nov 2020 10:51:05**

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E037D92C-2F6A-4B91-B9C7-F8A20B33EADC)', Time: '2020-09-15T20:34:46', User OID: 'PatientReportedOutcome (US3312046)', ODM File OID: 'c5f582de-d210-4b00-a1ab-cc0df33e1119'	System	16 Sep 2020 01:35:05
User entered 'None (0)'	System	16 Sep 2020 01:35:05



**US3312046**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(7)**

**Generated On: 26 Nov 2020 10:51:05**

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E037D92C-2F6A-4B91-B9C7-F8A20B33EADC)', Time: '2020-09-15T20:34:49', User OID: 'PatientReportedOutcome (US3312046)', ODM File OID: 'c5f582de-d210-4b00-a1ab-cc0df33e1119'	System	16 Sep 2020 01:35:05
User entered 'None (0)'	System	16 Sep 2020 01:35:05

**US3312046**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(7)**

**Generated On: 26 Nov 2020 10:51:05**

**CHILLS**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E037D92C-2F6A-4B91-B9C7-F8A20B33EADC)', Time: '2020-09-15T20:34:52', User OID: 'PatientReportedOutcome (US3312046)', ODM File OID: 'c5f582de-d210-4b00-a1ab-cc0df33e1119'	System	16 Sep 2020 01:35:05
User entered 'None (0)'	System	16 Sep 2020 01:35:05

US3312046

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 26 Nov 2020 10:51:05

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 (E037D92C-2F6A-4B91-B9C7-F8A20B33EADC)', Time: '2020-09-15T20:34:58', User OID: 'PatientReportedOutcome (US3312046)', ODM File OID: 'c5f582de-d210-4b00-a1ab-cc0df33e1119'	System	16 Sep 2020 01:35:05
User entered 'No (N)'	System	16 Sep 2020 01:35:05

**US3312046**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(7)**

**Generated On: 26 Nov 2020 10:51:05**

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E037D92C-2F6A-4B91-B9C7-F8A20B33EADC)', Time: '2020-09-15T20:35:01', User OID: 'PatientReportedOutcome (US3312046)', ODM File OID: 'c5f582de-d210-4b00-a1ab-cc0df33e1119'	System	16 Sep 2020 01:35:05
User entered '15 Sep 2020 20:35'	System	16 Sep 2020 01:35:05

**US3312046**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(7)**

**Generated On: 26 Nov 2020 10:51:05**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '15 Sep 2020 12:00'	System	09 Sep 2020 18:57:30

**US3312046**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(7)**

**Generated On: 26 Nov 2020 10:51:05**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '16 Sep 2020 11:59'	System	09 Sep 2020 18:57:30

**US3312046**

**Folder: Safety Call Day 36 (1)**

**Form: Safety Call**

**Generated On: 26 Nov 2020 10:51:05**

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Karol Moore (b) (4) (b) (4)	17 Sep 2020 20:34:30

**US3312046**

**Folder: Safety Call Day 36 (1)**

**Form: Safety Call**

**Generated On: 26 Nov 2020 10:51:05**

**Date of Contact or Contact Attempt** (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered '16 Sep 2020'	Karol Moore (b) (4) (b) (4)	17 Sep 2020 20:34:30



**US3312046**

**Folder: Safety Call Day 36 (1)**

**Form: Safety Call**

**Generated On: 26 Nov 2020 10:51:05**

[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)	17 Sep 2020 20:34:30

**US3312046**

**Folder: Safety Call Day 36 (1)**

**Form: Safety Call**

**Generated On: 26 Nov 2020 10:51:05**

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
User entered empty.	Karol Moore (b) (4) (b) (4)	17 Sep 2020 20:34:30

**US3312046**

**Folder: Safety Call Day 36 (1)**

**Form: Continuing**

**Generated On: 26 Nov 2020 10:51:05**

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Karol Moore (b) (4) (b) (4)	17 Sep 2020 20:34:33

**US3312046**

**Folder: Safety Call Day 36 (1)**

**Form: Continuing**

**Generated On: 26 Nov 2020 10:51:05**

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered 'I'	System	17 Sep 2020 20:34:33

**US3312046**

**Folder: Safety Call Day 43 (1)**

**Form: Safety Call**

**Generated On: 26 Nov 2020 10:51:05**

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Karol Moore (b) (4) (b) (4)	24 Sep 2020 00:41:49

**US3312046**

**Folder: Safety Call Day 43 (1)**

**Form: Safety Call**

**Generated On: 26 Nov 2020 10:51:05**

**Date of Contact or Contact Attempt** (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered '23 Sep 2020'	Karol Moore (b) (4) (b) (4)	24 Sep 2020 00:41:49

**US3312046**

**Folder: Safety Call Day 43 (1)**

**Form: Safety Call**

**Generated On: 26 Nov 2020 10:51:05**

[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)	24 Sep 2020 00:41:49

**US3312046**

**Folder: Safety Call Day 43 (1)**

**Form: Safety Call**

**Generated On: 26 Nov 2020 10:51:05**

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
User entered empty.	Karol Moore (b) (4) (b) (4)	24 Sep 2020 00:41:49



**US3312046**

**Folder: Safety Call Day 43 (1)**

**Form: Continuing**

**Generated On: 26 Nov 2020 10:51:05**

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Karol Moore (b) (4) (b) (4)	24 Sep 2020 00:41:39

**US3312046**

**Folder: Safety Call Day 43 (1)**

**Form: Continuing**

**Generated On: 26 Nov 2020 10:51:05**

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered 'I'	System	24 Sep 2020 00:41:39

**US3312046**

**Folder: Safety Call Day 50 (1)**

**Form: Safety Call**

**Generated On: 26 Nov 2020 10:51:05**

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	14 Oct 2020 19:52:35

**US3312046**

**Folder: Safety Call Day 50 (1)**

**Form: Safety Call**

**Generated On: 26 Nov 2020 10:51:05**

**Date of Contact or Contact Attempt** (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered '30 Sep 2020'	(b) (4), (b) (6)	14 Oct 2020 19:52:35

**US3312046**

**Folder: Safety Call Day 50 (1)**

**Form: Safety Call**

**Generated On: 26 Nov 2020 10:51:05**

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
User entered 'Contact Made (CONTACT MADE)'	(b) (4), (b) (6)	14 Oct 2020 19:52:35

**US3312046**

**Folder: Safety Call Day 50 (1)**

**Form: Safety Call**

**Generated On: 26 Nov 2020 10:51:05**

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	14 Oct 2020 19:52:35

US3312046

Folder: Safety Call Day 50 (1)

Form: Continuing

Generated On: 26 Nov 2020 10:51:05

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	14 Oct 2020 19:52:42

**US3312046**

**Folder: Safety Call Day 50 (1)**

**Form: Continuing**

**Generated On: 26 Nov 2020 10:51:05**

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered 'I'	System	14 Oct 2020 19:52:42



**US3312046**

**Folder: Visit 3 Day 57 (1)**

**Form: Visit Date**

**Generated On: 26 Nov 2020 10:51:05**

[Was this visit performed?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Monica Atwood (b) (4) (b) (4)	10 Nov 2020 21:53:41

US3312046

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 26 Nov 2020 10:51:05

[Visit date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User entered empty.	Monica Atwood (b) (4) (b) (4)	10 Nov 2020 21:53:41

US3312046

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 26 Nov 2020 10:51:05

Was visit performed at the participant's home or at the clinic?

Audit	User	Time (GMT)
User entered empty.	Monica Atwood (b) (4) (b) (4)	10 Nov 2020 21:53:41

**US3312046**

**Folder: Visit 3 Day 57 (1)**

**Form: Visit Date**

**Generated On: 26 Nov 2020 10:51:05**

[Folder OID](#)

Audit	User	Time (GMT)
User entered 'VISIT3'	System	10 Nov 2020 21:53:41

US3312046

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 10:51:05

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Monica Atwood (b) (4) (b) (4)	10 Nov 2020 21:53:58

US3312046

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 10:51:05

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered empty.	Monica Atwood (b) (4) (b) (4)	10 Nov 2020 21:53:58

**US3312046**

**Folder: Visit 3 Day 57 (1)**

**Form: Vital Signs**

**Generated On: 26 Nov 2020 10:51:05**

**Time of assessment (00:00-23:59)**

Audit	User	Time (GMT)
User entered empty.	Monica Atwood (b) (4) (b) (4)	10 Nov 2020 21:53:58

**US3312046**

**Folder: Visit 3 Day 57 (1)**

**Form: Vital Signs**

**Generated On: 26 Nov 2020 10:51:05**

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	10 Nov 2020 21:53:58



US3312046

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 10:51:05

Temperature (xxx.x)

Audit	User	Time (GMT)
User entered empty.	Monica Atwood (b) (4) (b) (4)	10 Nov 2020 21:53:58

**US3312046**

**Folder: Visit 3 Day 57 (1)**

**Form: Vital Signs**

**Generated On: 26 Nov 2020 10:51:05**

[Route of measurement](#)

Audit	User	Time (GMT)
User entered empty.	Monica Atwood (b) (4) (b) (4)	10 Nov 2020 21:53:58

**US3312046**

**Folder: Visit 3 Day 57 (1)**

**Form: Vital Signs**

**Generated On: 26 Nov 2020 10:51:05**

[If Other, specify](#)

Audit	User	Time (GMT)
User entered empty.	Monica Atwood (b) (4) (b) (4)	10 Nov 2020 21:53:58

**US3312046**

**Folder: Visit 3 Day 57 (1)**

**Form: Vital Signs**

**Generated On: 26 Nov 2020 10:51:05**

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
User entered empty.	Monica Atwood (b) (4) (b) (4)	10 Nov 2020 21:53:58

**US3312046**

**Folder: Visit 3 Day 57 (1)**

**Form: Vital Signs**

**Generated On: 26 Nov 2020 10:51:05**

[Pulse units](#)

Audit	User	Time (GMT)
User entered empty.	System	10 Nov 2020 21:53:58

US3312046

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 10:51:05

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
User entered empty.	Monica Atwood (b) (4) (b) (4)	10 Nov 2020 21:53:58

**US3312046**

**Folder: Visit 3 Day 57 (1)**

**Form: Vital Signs**

**Generated On: 26 Nov 2020 10:51:05**

[Respiratory Rate units](#)

Audit	User	Time (GMT)
User entered empty.	System	10 Nov 2020 21:53:58

US3312046

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 10:51:05

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
User entered empty.	Monica Atwood (b) (4) (b) (4)	10 Nov 2020 21:53:58



**US3312046**

**Folder: Visit 3 Day 57 (1)**

**Form: Vital Signs**

**Generated On: 26 Nov 2020 10:51:05**

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered empty.	System	10 Nov 2020 21:53:58

US3312046

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 10:51:05

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
User entered empty.	Monica Atwood (b) (4) (b) (4)	10 Nov 2020 21:53:58

**US3312046**

**Folder: Visit 3 Day 57 (1)**

**Form: Vital Signs**

**Generated On: 26 Nov 2020 10:51:05**

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered empty.	System	10 Nov 2020 21:53:58

**US3312046**

**Folder: Visit 3 Day 57 (1)**

**Form: Physical Examination**

**Generated On: 26 Nov 2020 10:51:05**

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Monica Atwood (b) (4) (b) (4)	10 Nov 2020 21:54:09

US3312046

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Generated On: 26 Nov 2020 10:51:05

Date of examination (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered empty.	Monica Atwood (b) (4) (b) (4)	10 Nov 2020 21:54:09

US3312046

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 10:51:05

[Was the sample collected?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Monica Atwood (b) (4) (b) (4)	10 Nov 2020 21:54:18

US3312046

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 10:51:05

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered empty.	Monica Atwood (b) (4) (b) (4)	10 Nov 2020 21:54:18

**US3312046**

**Folder: Visit 3 Day 57 (1)**

**Form: Immunogenicity Assessment**

**Generated On: 26 Nov 2020 10:51:05**

**Collection time (00:00-23:59)**

Audit	User	Time (GMT)
User entered empty.	Monica Atwood (b) (4) (b) (4)	10 Nov 2020 21:54:18



**US3312046**

**Folder: Visit 3 Day 57 (1)**

**Form: Immunogenicity Assessment**

**Generated On: 26 Nov 2020 10:51:05**

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	10 Nov 2020 21:54:18

US3312046

Folder: Visit 3 Day 57 (1)

Form: Continuing

Generated On: 26 Nov 2020 10:51:05

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Monica Atwood (b) (4) (b) (4)	06 Nov 2020 15:08:12

**US3312046**

**Folder: Visit 3 Day 57 (1)**

**Form: Continuing**

**Generated On: 26 Nov 2020 10:51:05**

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered '1'	System	06 Nov 2020 15:08:12

**US3312046**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:51:05**

**TIMEPOINT**

Audit	User	Time (GMT)
Data entry locked.	System	12 Aug 2020 17:29:06
User entered 'Day 71'	System	12 Aug 2020 17:29:06

**US3312046**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:51:05**

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E037D92C-2F6A-4B91-B9C7-F8A20B33EADC)', Time: '2020-10-23T18:04:24', User OID: 'PatientReportedOutcome (US3312046)', ODM File OID: '79eb6de9-11c0-4de0-8dda-70ddf71ad024' User entered 'No (N)'	System	23 Oct 2020 23:04:39
	System	23 Oct 2020 23:04:39

**US3312046**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:51:05**

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E037D92C-2F6A-4B91-B9C7-F8A20B33EADC)', Time: '2020-10-23T18:04:21', User OID: 'PatientReportedOutcome (US3312046)', ODM File OID: '79eb6de9-11c0-4de0-8dda-70ddf71ad024'	System	23 Oct 2020 23:04:39
User entered 'No (N)'	System	23 Oct 2020 23:04:39

**US3312046**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:51:05**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E037D92C-2F6A-4B91-B9C7-F8A20B33EADC)', Time: '2020-10-23T18:04:37', User OID: 'PatientReportedOutcome (US3312046)', ODM File OID: '79eb6de9-11c0-4de0-8dda-70ddf71ad024' User entered '23 Oct 2020 18:04:37'	System	23 Oct 2020 23:04:39
	System	23 Oct 2020 23:04:39

**US3312046**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:51:05**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data entry locked.	System	12 Aug 2020 17:29:06
User entered '19 Oct 2020 00:01'	System	12 Aug 2020 17:29:06



**US3312046**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:51:05**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data entry locked.	System	12 Aug 2020 17:29:06
User entered '23 Oct 2020 23:59'	System	12 Aug 2020 17:29:06

**US3312046**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:51:05**

**TIMEPOINT**

Audit	User	Time (GMT)
Data entry locked.	System	12 Aug 2020 17:29:06
User entered 'Day 78'	System	12 Aug 2020 17:29:06

**US3312046**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:51:05**

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E037D92C-2F6A-4B91-B9C7-F8A20B33EADC)', Time: '2020-10-26T13:10:03', User OID: 'PatientReportedOutcome (US3312046)', ODM File OID: '5b23eb1b-6ad3-4d58-bbfd-d23da5c5db50'	System	26 Oct 2020 18:10:18
User entered 'No (N)'	System	26 Oct 2020 18:10:18

**US3312046**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:51:05**

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E037D92C-2F6A-4B91-B9C7-F8A20B33EADC)', Time: '2020-10-26T13:10:08', User OID: 'PatientReportedOutcome (US3312046)', ODM File OID: '5b23eb1b-6ad3-4d58-bbfd-d23da5c5db50'	System	26 Oct 2020 18:10:18
User entered 'No (N)'	System	26 Oct 2020 18:10:18

**US3312046**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:51:05**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E037D92C-2F6A-4B91-B9C7-F8A20B33EADC)', Time: '2020-10-26T13:10:15', User OID: 'PatientReportedOutcome (US3312046)', ODM File OID: '5b23eb1b-6ad3-4d58-bbfd-d23da5c5db50'	System	26 Oct 2020 18:10:18
User entered '26 Oct 2020 13:10:15'	System	26 Oct 2020 18:10:18

**US3312046**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:51:05**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data entry locked.	System	12 Aug 2020 17:29:06
User entered '26 Oct 2020 00:01'	System	12 Aug 2020 17:29:06

**US3312046**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:51:05**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data entry locked.	System	12 Aug 2020 17:29:06
User entered '30 Oct 2020 23:59'	System	12 Aug 2020 17:29:06

**US3312046**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:51:05**

**TIMEPOINT**

Audit	User	Time (GMT)
Data entry locked.	System	12 Aug 2020 17:29:06
User entered 'Day 92'	System	12 Aug 2020 17:29:06



**US3312046**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:51:05**

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E037D92C-2F6A-4B91-B9C7-F8A20B33EADC)', Time: '2020-11-09T06:35:31', User OID: 'PatientReportedOutcome (US3312046)', ODM File OID: '5cd5be6d-c176-4c4a-9f6b-00debe9a9205'	System	09 Nov 2020 12:35:53
User entered 'No (N)'	System	09 Nov 2020 12:35:53

**US3312046**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:51:05**

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E037D92C-2F6A-4B91-B9C7-F8A20B33EADC)', Time: '2020-11-09T06:35:38', User OID: 'PatientReportedOutcome (US3312046)', ODM File OID: '5cd5be6d-c176-4c4a-9f6b-00debe9a9205'	System	09 Nov 2020 12:35:53
User entered 'No (N)'	System	09 Nov 2020 12:35:53

**US3312046**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:51:05**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E037D92C-2F6A-4B91-B9C7-F8A20B33EADC)', Time: '2020-11-09T06:35:47', User OID: 'PatientReportedOutcome (US3312046)', ODM File OID: '5cd5be6d-c176-4c4a-9f6b-00debe9a9205' User entered '09 Nov 2020 06:35:47'	System	09 Nov 2020 12:35:53
	System	09 Nov 2020 12:35:53

**US3312046**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:51:05**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data entry locked.	System	12 Aug 2020 17:29:06
User entered '09 Nov 2020 00:01'	System	12 Aug 2020 17:29:06

**US3312046**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:51:05**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data entry locked.	System	12 Aug 2020 17:29:06
User entered '13 Nov 2020 23:59'	System	12 Aug 2020 17:29:06

**US3312046**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:51:05**

**TIMEPOINT**

Audit	User	Time (GMT)
Data entry locked.	System	12 Aug 2020 17:29:06
User entered 'Day 99'	System	12 Aug 2020 17:29:06

**US3312046**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:51:05**

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E037D92C-2F6A-4B91-B9C7-F8A20B33EADC)', Time: '2020-11-18T16:51:58', User OID: 'PatientReportedOutcome (US3312046)', ODM File OID: 'b257a045-5585-43f2-8fb2-e17c4b2acefe'	System	18 Nov 2020 22:52:09
User entered 'No (N)'	System	18 Nov 2020 22:52:09

**US3312046**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:51:05**

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E037D92C-2F6A-4B91-B9C7-F8A20B33EADC)', Time: '2020-11-18T16:52:02', User OID: 'PatientReportedOutcome (US3312046)', ODM File OID: 'b257a045-5585-43f2-8fb2-e17c4b2acefe'	System	18 Nov 2020 22:52:09
User entered 'No (N)'	System	18 Nov 2020 22:52:09



**US3312046**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:51:05**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E037D92C-2F6A-4B91-B9C7-F8A20B33EADC)', Time: '2020-11-18T16:52:06', User OID: 'PatientReportedOutcome (US3312046)', ODM File OID: 'b257a045-5585-43f2-8fb2-e17c4b2acefe' User entered '18 Nov 2020 16:52:06'	System	18 Nov 2020 22:52:09
	System	18 Nov 2020 22:52:09

**US3312046**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:51:05**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data entry locked.	System	12 Aug 2020 17:29:06
User entered '16 Nov 2020 00:01'	System	12 Aug 2020 17:29:06

**US3312046**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:51:05**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data entry locked.	System	12 Aug 2020 17:29:06
User entered '20 Nov 2020 23:59'	System	12 Aug 2020 17:29:06

**US3312046**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:51:05**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:02:21
Amendment Manager: User entered 'Day 61'	System	19 Nov 2020 05:02:21

**US3312046**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:51:05**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:02:21
Amendment Manager: User entered '09 Oct 2020 00:01'	System	19 Nov 2020 05:02:21

**US3312046**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:51:05**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:02:21
Amendment Manager: User entered '13 Oct 2020 23:59'	System	19 Nov 2020 05:02:21

**US3312046**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:51:05**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:02:21
Amendment Manager: User entered 'Day 68'	System	19 Nov 2020 05:02:21

**US3312046**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:51:05**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:02:21
Amendment Manager: User entered '16 Oct 2020 00:01'	System	19 Nov 2020 05:02:21



**US3312046**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:51:05**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:02:21
Amendment Manager: User entered '20 Oct 2020 23:59'	System	19 Nov 2020 05:02:21

**US3312046**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:51:05**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:02:21
Amendment Manager: User entered 'Day 75'	System	19 Nov 2020 05:02:21

**US3312046**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:51:05**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:02:21
Amendment Manager: User entered '23 Oct 2020 00:01'	System	19 Nov 2020 05:02:21

**US3312046**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:51:05**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:02:21
Amendment Manager: User entered '27 Oct 2020 23:59'	System	19 Nov 2020 05:02:21

**US3312046**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:51:05**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:02:21
Amendment Manager: User entered 'Day 82'	System	19 Nov 2020 05:02:21

**US3312046**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:51:05**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:02:21
Amendment Manager: User entered '30 Oct 2020 00:01'	System	19 Nov 2020 05:02:21

**US3312046**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:51:05**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:02:21
Amendment Manager: User entered '03 Nov 2020 23:59'	System	19 Nov 2020 05:02:21

**US3312046**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:51:05**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:02:21
Amendment Manager: User entered 'Day 89'	System	19 Nov 2020 05:02:21



**US3312046**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:51:05**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:02:21
Amendment Manager: User entered '06 Nov 2020 00:01'	System	19 Nov 2020 05:02:21

**US3312046**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:51:05**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:02:21
Amendment Manager: User entered '10 Nov 2020 23:59'	System	19 Nov 2020 05:02:21

**US3312046**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:51:05**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:02:21
Amendment Manager: User entered 'Day 96'	System	19 Nov 2020 05:02:21

**US3312046**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:51:05**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:02:21
Amendment Manager: User entered '13 Nov 2020 00:01'	System	19 Nov 2020 05:02:21

**US3312046**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:51:05**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:02:21
Amendment Manager: User entered '17 Nov 2020 23:59'	System	19 Nov 2020 05:02:21

**US3312046**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:51:05**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:02:21
Amendment Manager: User entered 'Day 103'	System	19 Nov 2020 05:02:21

**US3312046**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:51:05**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:02:21
Amendment Manager: User entered '20 Nov 2020 00:01'	System	19 Nov 2020 05:02:21

**US3312046**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:51:05**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:02:21
Amendment Manager: User entered '24 Nov 2020 23:59'	System	19 Nov 2020 05:02:21



**US3312046**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:51:05**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:02:21
Amendment Manager: User entered 'Day 110'	System	19 Nov 2020 05:02:21

**US3312046**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:51:05**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:02:21
Amendment Manager: User entered '27 Nov 2020 00:01'	System	19 Nov 2020 05:02:21

**US3312046**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:51:05**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:02:21
Amendment Manager: User entered '01 Dec 2020 23:59'	System	19 Nov 2020 05:02:21

**US3312046**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:51:05**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:02:21
Amendment Manager: User entered 'Day 117'	System	19 Nov 2020 05:02:21

**US3312046**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:51:05**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:02:21
Amendment Manager: User entered '04 Dec 2020 00:01'	System	19 Nov 2020 05:02:21

**US3312046**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:51:05**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:02:21
Amendment Manager: User entered '08 Dec 2020 23:59'	System	19 Nov 2020 05:02:21

**US3312046**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:51:05**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:02:21
Amendment Manager: User entered 'Day 124'	System	19 Nov 2020 05:02:21

**US3312046**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:51:05**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:02:21
Amendment Manager: User entered '11 Dec 2020 00:01'	System	19 Nov 2020 05:02:21



**US3312046**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:51:05**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:02:21
Amendment Manager: User entered '15 Dec 2020 23:59'	System	19 Nov 2020 05:02:21

**US3312046**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:51:05**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:02:21
Amendment Manager: User entered 'Day 131'	System	19 Nov 2020 05:02:21

**US3312046**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:51:05**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:02:21
Amendment Manager: User entered '18 Dec 2020 00:01'	System	19 Nov 2020 05:02:21

**US3312046**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:51:05**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:02:21
Amendment Manager: User entered '22 Dec 2020 23:59'	System	19 Nov 2020 05:02:21

**US3312046**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:51:05**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:02:21
Amendment Manager: User entered 'Day 138'	System	19 Nov 2020 05:02:21

**US3312046**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:51:05**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:02:21
Amendment Manager: User entered '25 Dec 2020 00:01'	System	19 Nov 2020 05:02:21

**US3312046**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:51:05**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:02:21
Amendment Manager: User entered '29 Dec 2020 23:59'	System	19 Nov 2020 05:02:21

**US3312046**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:51:05**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:02:21
Amendment Manager: User entered 'Day 145'	System	19 Nov 2020 05:02:21



**US3312046**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:51:05**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:02:21
Amendment Manager: User entered '01 Jan 2021 00:01'	System	19 Nov 2020 05:02:21

**US3312046**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:51:05**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:02:21
Amendment Manager: User entered '05 Jan 2021 23:59'	System	19 Nov 2020 05:02:21

**US3312046**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:51:05**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:02:21
Amendment Manager: User entered 'Day 152'	System	19 Nov 2020 05:02:21

**US3312046**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:51:05**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:02:21
Amendment Manager: User entered '08 Jan 2021 00:01'	System	19 Nov 2020 05:02:21

**US3312046**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:51:05**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:02:21
Amendment Manager: User entered '12 Jan 2021 23:59'	System	19 Nov 2020 05:02:21

**US3312046**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:51:05**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:02:21
Amendment Manager: User entered 'Day 159'	System	19 Nov 2020 05:02:21

**US3312046**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:51:05**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:02:21
Amendment Manager: User entered '15 Jan 2021 00:01'	System	19 Nov 2020 05:02:21

**US3312046**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:51:05**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:02:21
Amendment Manager: User entered '19 Jan 2021 23:59'	System	19 Nov 2020 05:02:21



**US3312046**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:51:05**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:02:21
Amendment Manager: User entered 'Day 166'	System	19 Nov 2020 05:02:21

**US3312046**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:51:05**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:02:21
Amendment Manager: User entered '22 Jan 2021 00:01'	System	19 Nov 2020 05:02:21

**US3312046**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:51:05**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:02:21
Amendment Manager: User entered '26 Jan 2021 23:59'	System	19 Nov 2020 05:02:21

**US3312046**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:51:05**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:02:21
Amendment Manager: User entered 'Day 173'	System	19 Nov 2020 05:02:21

**US3312046**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:51:05**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:02:21
Amendment Manager: User entered '29 Jan 2021 00:01'	System	19 Nov 2020 05:02:21

**US3312046**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:51:05**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:02:21
Amendment Manager: User entered '02 Feb 2021 23:59'	System	19 Nov 2020 05:02:21

**US3312046**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:51:05**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:02:21
Amendment Manager: User entered 'Day 180'	System	19 Nov 2020 05:02:21

**US3312046**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:51:05**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:02:21
Amendment Manager: User entered '05 Feb 2021 00:01'	System	19 Nov 2020 05:02:21



**US3312046**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:51:05**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:02:21
Amendment Manager: User entered '09 Feb 2021 23:59'	System	19 Nov 2020 05:02:21

**US3312046**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:51:05**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:02:21
Amendment Manager: User entered 'Day 187'	System	19 Nov 2020 05:02:21

**US3312046**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:51:05**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:02:21
Amendment Manager: User entered '12 Feb 2021 00:01'	System	19 Nov 2020 05:02:21

**US3312046**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:51:05**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:02:21
Amendment Manager: User entered '16 Feb 2021 23:59'	System	19 Nov 2020 05:02:21

**US3312046**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:51:05**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:02:21
Amendment Manager: User entered 'Day 194'	System	19 Nov 2020 05:02:21

**US3312046**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:51:05**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:02:21
Amendment Manager: User entered '19 Feb 2021 00:01'	System	19 Nov 2020 05:02:21

**US3312046**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:51:05**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:02:21
Amendment Manager: User entered '23 Feb 2021 23:59'	System	19 Nov 2020 05:02:21

**US3312046**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:51:05**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:02:21
Amendment Manager: User entered 'Day 201'	System	19 Nov 2020 05:02:21



**US3312046**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:51:05**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:02:21
Amendment Manager: User entered '26 Feb 2021 00:01'	System	19 Nov 2020 05:02:21

**US3312046**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:51:05**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:02:21
Amendment Manager: User entered '02 Mar 2021 23:59'	System	19 Nov 2020 05:02:21

**US3312046**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:51:05**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:02:21
Amendment Manager: User entered 'Day 208'	System	19 Nov 2020 05:02:21

**US3312046**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:51:05**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:02:21
Amendment Manager: User entered '05 Mar 2021 00:01'	System	19 Nov 2020 05:02:21

**US3312046**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:51:05**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:02:21
Amendment Manager: User entered '09 Mar 2021 23:59'	System	19 Nov 2020 05:02:21

**US3312046**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:51:05**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:02:21
Amendment Manager: User entered 'Day 215'	System	19 Nov 2020 05:02:21

**US3312046**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:51:05**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:02:21
Amendment Manager: User entered '12 Mar 2021 00:01'	System	19 Nov 2020 05:02:21

**US3312046**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:51:05**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:02:21
Amendment Manager: User entered '16 Mar 2021 23:59'	System	19 Nov 2020 05:02:21



**US3312046**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:51:05**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:02:21
Amendment Manager: User entered 'Day 222'	System	19 Nov 2020 05:02:21

**US3312046**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:51:05**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:02:21
Amendment Manager: User entered '19 Mar 2021 00:01'	System	19 Nov 2020 05:02:21

**US3312046**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:51:05**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:02:21
Amendment Manager: User entered '23 Mar 2021 23:59'	System	19 Nov 2020 05:02:21

**US3312046**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:51:05**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:02:21
Amendment Manager: User entered 'Day 229'	System	19 Nov 2020 05:02:21

**US3312046**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:51:05**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:02:21
Amendment Manager: User entered '26 Mar 2021 00:01'	System	19 Nov 2020 05:02:21

**US3312046**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:51:05**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:02:21
Amendment Manager: User entered '30 Mar 2021 23:59'	System	19 Nov 2020 05:02:21

**US3312046**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:51:05**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:02:21
Amendment Manager: User entered 'Day 236'	System	19 Nov 2020 05:02:21

**US3312046**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:51:05**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:02:21
Amendment Manager: User entered '02 Apr 2021 00:01'	System	19 Nov 2020 05:02:21



**US3312046**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:51:05**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:02:21
Amendment Manager: User entered '06 Apr 2021 23:59'	System	19 Nov 2020 05:02:21

**US3312046**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:51:05**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:02:21
Amendment Manager: User entered 'Day 243'	System	19 Nov 2020 05:02:21

**US3312046**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:51:05**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:02:21
Amendment Manager: User entered '09 Apr 2021 00:01'	System	19 Nov 2020 05:02:21

**US3312046**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:51:05**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:02:21
Amendment Manager: User entered '13 Apr 2021 23:59'	System	19 Nov 2020 05:02:21

**US3312046**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:51:05**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:02:21
Amendment Manager: User entered 'Day 250'	System	19 Nov 2020 05:02:21

**US3312046**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:51:05**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:02:21
Amendment Manager: User entered '16 Apr 2021 00:01'	System	19 Nov 2020 05:02:21

**US3312046**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:51:05**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:02:21
Amendment Manager: User entered '20 Apr 2021 23:59'	System	19 Nov 2020 05:02:21

**US3312046**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:51:05**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:02:21
Amendment Manager: User entered 'Day 257'	System	19 Nov 2020 05:02:21



**US3312046**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:51:05**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:02:21
Amendment Manager: User entered '23 Apr 2021 00:01'	System	19 Nov 2020 05:02:21

**US3312046**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:51:05**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:02:21
Amendment Manager: User entered '27 Apr 2021 23:59'	System	19 Nov 2020 05:02:21

**US3312046**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:51:05**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:02:21
Amendment Manager: User entered 'Day 264'	System	19 Nov 2020 05:02:21

**US3312046**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:51:05**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:02:21
Amendment Manager: User entered '30 Apr 2021 00:01'	System	19 Nov 2020 05:02:21

**US3312046**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:51:05**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:02:21
Amendment Manager: User entered '04 May 2021 23:59'	System	19 Nov 2020 05:02:21

**US3312046**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:51:05**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:02:21
Amendment Manager: User entered 'Day 271'	System	19 Nov 2020 05:02:21

**US3312046**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:51:05**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:02:21
Amendment Manager: User entered '07 May 2021 00:01'	System	19 Nov 2020 05:02:21

**US3312046**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:51:05**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:02:21
Amendment Manager: User entered '11 May 2021 23:59'	System	19 Nov 2020 05:02:21



**US3312046**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:51:05**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:02:21
Amendment Manager: User entered 'Day 278'	System	19 Nov 2020 05:02:21

**US3312046**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:51:05**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:02:21
Amendment Manager: User entered '14 May 2021 00:01'	System	19 Nov 2020 05:02:21

**US3312046**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:51:05**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:02:21
Amendment Manager: User entered '18 May 2021 23:59'	System	19 Nov 2020 05:02:21

**US3312046**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:51:05**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:02:21
Amendment Manager: User entered 'Day 285'	System	19 Nov 2020 05:02:21

**US3312046**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:51:05**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:02:21
Amendment Manager: User entered '21 May 2021 00:01'	System	19 Nov 2020 05:02:21

**US3312046**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:51:05**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:02:21
Amendment Manager: User entered '25 May 2021 23:59'	System	19 Nov 2020 05:02:21

**US3312046**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:51:05**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:02:21
Amendment Manager: User entered 'Day 292'	System	19 Nov 2020 05:02:21

**US3312046**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:51:05**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:02:21
Amendment Manager: User entered '28 May 2021 00:01'	System	19 Nov 2020 05:02:21



**US3312046**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:51:05**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:02:21
Amendment Manager: User entered '01 Jun 2021 23:59'	System	19 Nov 2020 05:02:21

**US3312046**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:51:05**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:02:21
Amendment Manager: User entered 'Day 299'	System	19 Nov 2020 05:02:21

**US3312046**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:51:05**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:02:21
Amendment Manager: User entered '04 Jun 2021 00:01'	System	19 Nov 2020 05:02:21

**US3312046**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:51:05**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:02:21
Amendment Manager: User entered '08 Jun 2021 23:59'	System	19 Nov 2020 05:02:21

**US3312046**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:51:05**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:02:21
Amendment Manager: User entered 'Day 306'	System	19 Nov 2020 05:02:21

**US3312046**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:51:05**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:02:21
Amendment Manager: User entered '11 Jun 2021 00:01'	System	19 Nov 2020 05:02:21

**US3312046**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:51:05**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:02:21
Amendment Manager: User entered '15 Jun 2021 23:59'	System	19 Nov 2020 05:02:21

**US3312046**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:51:05**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:02:21
Amendment Manager: User entered 'Day 313'	System	19 Nov 2020 05:02:21



**US3312046**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:51:05**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:02:21
Amendment Manager: User entered '18 Jun 2021 00:01'	System	19 Nov 2020 05:02:21

**US3312046**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:51:05**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:02:21
Amendment Manager: User entered '22 Jun 2021 23:59'	System	19 Nov 2020 05:02:21

**US3312046**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:51:05**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:02:21
Amendment Manager: User entered 'Day 320'	System	19 Nov 2020 05:02:21

**US3312046**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:51:05**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:02:21
Amendment Manager: User entered '25 Jun 2021 00:01'	System	19 Nov 2020 05:02:21

**US3312046**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:51:05**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:02:21
Amendment Manager: User entered '29 Jun 2021 23:59'	System	19 Nov 2020 05:02:21

**US3312046**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:51:05**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:02:21
Amendment Manager: User entered 'Day 327'	System	19 Nov 2020 05:02:21

**US3312046**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:51:05**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:02:21
Amendment Manager: User entered '02 Jul 2021 00:01'	System	19 Nov 2020 05:02:21

**US3312046**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:51:05**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:02:21
Amendment Manager: User entered '06 Jul 2021 23:59'	System	19 Nov 2020 05:02:21



**US3312046**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:51:05**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:02:21
Amendment Manager: User entered 'Day 334'	System	19 Nov 2020 05:02:21

**US3312046**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:51:05**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:02:21
Amendment Manager: User entered '09 Jul 2021 00:01'	System	19 Nov 2020 05:02:21

**US3312046**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:51:05**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:02:21
Amendment Manager: User entered '13 Jul 2021 23:59'	System	19 Nov 2020 05:02:21

**US3312046**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:51:05**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:02:21
Amendment Manager: User entered 'Day 341'	System	19 Nov 2020 05:02:21

**US3312046**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:51:05**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:02:21
Amendment Manager: User entered '16 Jul 2021 00:01'	System	19 Nov 2020 05:02:21

**US3312046**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:51:05**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:02:21
Amendment Manager: User entered '20 Jul 2021 23:59'	System	19 Nov 2020 05:02:21

**US3312046**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:51:05**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:02:21
Amendment Manager: User entered 'Day 348'	System	19 Nov 2020 05:02:21

**US3312046**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:51:05**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:02:21
Amendment Manager: User entered '23 Jul 2021 00:01'	System	19 Nov 2020 05:02:21



**US3312046**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:51:05**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:02:21
Amendment Manager: User entered '27 Jul 2021 23:59'	System	19 Nov 2020 05:02:21

**US3312046**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:51:05**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:02:21
Amendment Manager: User entered 'Day 355'	System	19 Nov 2020 05:02:21

**US3312046**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:51:05**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:02:21
Amendment Manager: User entered '30 Jul 2021 00:01'	System	19 Nov 2020 05:02:21

**US3312046**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:51:05**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:02:21
Amendment Manager: User entered '03 Aug 2021 23:59'	System	19 Nov 2020 05:02:21

**US3312046**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:51:05**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:02:21
Amendment Manager: User entered 'Day 362'	System	19 Nov 2020 05:02:21

**US3312046**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:51:05**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:02:21
Amendment Manager: User entered '06 Aug 2021 00:01'	System	19 Nov 2020 05:02:21

**US3312046**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:51:05**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:02:21
Amendment Manager: User entered '10 Aug 2021 23:59'	System	19 Nov 2020 05:02:21

**US3312046**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:51:05**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:02:21
Amendment Manager: User entered 'Day 369'	System	19 Nov 2020 05:02:21



**US3312046**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:51:05**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:02:21
Amendment Manager: User entered '13 Aug 2021 00:01'	System	19 Nov 2020 05:02:21

**US3312046**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:51:05**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:02:21
Amendment Manager: User entered '17 Aug 2021 23:59'	System	19 Nov 2020 05:02:21

**US3312046**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:51:05**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:02:21
Amendment Manager: User entered 'Day 376'	System	19 Nov 2020 05:02:21

**US3312046**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:51:05**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:02:21
Amendment Manager: User entered '20 Aug 2021 00:01'	System	19 Nov 2020 05:02:21

**US3312046**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:51:05**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:02:21
Amendment Manager: User entered '24 Aug 2021 23:59'	System	19 Nov 2020 05:02:21

**US3312046**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:51:05**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:02:21
Amendment Manager: User entered 'Day 383'	System	19 Nov 2020 05:02:21

**US3312046**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:51:05**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:02:21
Amendment Manager: User entered '27 Aug 2021 00:01'	System	19 Nov 2020 05:02:21

**US3312046**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:51:05**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:02:21
Amendment Manager: User entered '31 Aug 2021 23:59'	System	19 Nov 2020 05:02:21



**US3312046**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:51:05**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:02:21
Amendment Manager: User entered 'Day 390'	System	19 Nov 2020 05:02:21

**US3312046**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:51:05**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:02:21
Amendment Manager: User entered '03 Sep 2021 00:01'	System	19 Nov 2020 05:02:21

**US3312046**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:51:05**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:02:21
Amendment Manager: User entered '07 Sep 2021 23:59'	System	19 Nov 2020 05:02:21

**US3312046**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:51:05**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:02:21
Amendment Manager: User entered 'Day 397'	System	19 Nov 2020 05:02:21

**US3312046**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:51:05**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:02:21
Amendment Manager: User entered '10 Sep 2021 00:01'	System	19 Nov 2020 05:02:21

**US3312046**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:51:05**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:02:21
Amendment Manager: User entered '14 Sep 2021 23:59'	System	19 Nov 2020 05:02:21

**US3312046**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:51:05**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:02:21
Amendment Manager: User entered 'Day 404'	System	19 Nov 2020 05:02:21

**US3312046**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:51:05**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:02:21
Amendment Manager: User entered '17 Sep 2021 00:01'	System	19 Nov 2020 05:02:21



**US3312046**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:51:05**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:02:21
Amendment Manager: User entered '21 Sep 2021 23:59'	System	19 Nov 2020 05:02:21

**US3312046**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:51:05**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:02:21
Amendment Manager: User entered 'Day 411'	System	19 Nov 2020 05:02:21

**US3312046**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:51:05**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:02:21
Amendment Manager: User entered '24 Sep 2021 00:01'	System	19 Nov 2020 05:02:21

**US3312046**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:51:05**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:02:21
Amendment Manager: User entered '28 Sep 2021 23:59'	System	19 Nov 2020 05:02:21

**US3312046**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:51:05**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:02:21
Amendment Manager: User entered 'Day 418'	System	19 Nov 2020 05:02:21

**US3312046**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:51:05**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:02:21
Amendment Manager: User entered '01 Oct 2021 00:01'	System	19 Nov 2020 05:02:21

**US3312046**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:51:05**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:02:21
Amendment Manager: User entered '05 Oct 2021 23:59'	System	19 Nov 2020 05:02:21

**US3312046**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:51:05**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:02:21
Amendment Manager: User entered 'Day 425'	System	19 Nov 2020 05:02:21



**US3312046**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:51:05**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:02:21
Amendment Manager: User entered '08 Oct 2021 00:01'	System	19 Nov 2020 05:02:21

**US3312046**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:51:05**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:02:21
Amendment Manager: User entered '12 Oct 2021 23:59'	System	19 Nov 2020 05:02:21

**US3312046**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:51:05**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:02:21
Amendment Manager: User entered 'Day 432'	System	19 Nov 2020 05:02:21

**US3312046**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:51:05**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:02:21
Amendment Manager: User entered '15 Oct 2021 00:01'	System	19 Nov 2020 05:02:21

**US3312046**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:51:05**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:02:21
Amendment Manager: User entered '19 Oct 2021 23:59'	System	19 Nov 2020 05:02:21

**US3312046**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:51:05**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:02:21
Amendment Manager: User entered 'Day 439'	System	19 Nov 2020 05:02:21

**US3312046**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:51:05**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:02:21
Amendment Manager: User entered '22 Oct 2021 00:01'	System	19 Nov 2020 05:02:21

**US3312046**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:51:05**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:02:21
Amendment Manager: User entered '26 Oct 2021 23:59'	System	19 Nov 2020 05:02:21



**US3312046**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:51:05**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:02:21
Amendment Manager: User entered 'Day 446'	System	19 Nov 2020 05:02:21

**US3312046**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:51:05**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:02:21
Amendment Manager: User entered '29 Oct 2021 00:01'	System	19 Nov 2020 05:02:21

**US3312046**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:51:05**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:02:21
Amendment Manager: User entered '02 Nov 2021 23:59'	System	19 Nov 2020 05:02:21

**US3312046**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:51:05**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:02:21
Amendment Manager: User entered 'Day 453'	System	19 Nov 2020 05:02:21

**US3312046**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:51:05**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:02:21
Amendment Manager: User entered '05 Nov 2021 00:01'	System	19 Nov 2020 05:02:21

**US3312046**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:51:05**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:02:21
Amendment Manager: User entered '09 Nov 2021 23:59'	System	19 Nov 2020 05:02:21

**US3312046**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:51:05**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:02:21
Amendment Manager: User entered 'Day 460'	System	19 Nov 2020 05:02:21

**US3312046**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:51:05**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:02:21
Amendment Manager: User entered '12 Nov 2021 00:01'	System	19 Nov 2020 05:02:21



**US3312046**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:51:05**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:02:21
Amendment Manager: User entered '16 Nov 2021 23:59'	System	19 Nov 2020 05:02:21

**US3312046**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:51:05**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:02:21
Amendment Manager: User entered 'Day 467'	System	19 Nov 2020 05:02:21

**US3312046**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:51:05**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:02:21
Amendment Manager: User entered '19 Nov 2021 00:01'	System	19 Nov 2020 05:02:21

**US3312046**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:51:05**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:02:21
Amendment Manager: User entered '23 Nov 2021 23:59'	System	19 Nov 2020 05:02:21

**US3312046**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:51:05**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:02:21
Amendment Manager: User entered 'Day 474'	System	19 Nov 2020 05:02:21

**US3312046**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:51:05**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:02:21
Amendment Manager: User entered '26 Nov 2021 00:01'	System	19 Nov 2020 05:02:21

**US3312046**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:51:05**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:02:21
Amendment Manager: User entered '30 Nov 2021 23:59'	System	19 Nov 2020 05:02:21

**US3312046**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:51:05**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:02:21
Amendment Manager: User entered 'Day 481'	System	19 Nov 2020 05:02:21



**US3312046**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:51:05**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:02:21
Amendment Manager: User entered '03 Dec 2021 00:01'	System	19 Nov 2020 05:02:21

**US3312046**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:51:05**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:02:21
Amendment Manager: User entered '07 Dec 2021 23:59'	System	19 Nov 2020 05:02:21

**US3312046**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:51:05**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:02:21
Amendment Manager: User entered 'Day 488'	System	19 Nov 2020 05:02:21

**US3312046**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:51:05**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:02:21
Amendment Manager: User entered '10 Dec 2021 00:01'	System	19 Nov 2020 05:02:21

**US3312046**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:51:05**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:02:21
Amendment Manager: User entered '14 Dec 2021 23:59'	System	19 Nov 2020 05:02:21

**US3312046**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:51:05**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:02:21
Amendment Manager: User entered 'Day 495'	System	19 Nov 2020 05:02:21

**US3312046**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:51:05**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:02:21
Amendment Manager: User entered '17 Dec 2021 00:01'	System	19 Nov 2020 05:02:21

**US3312046**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:51:05**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:02:21
Amendment Manager: User entered '21 Dec 2021 23:59'	System	19 Nov 2020 05:02:21



**US3312046**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:51:05**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:02:21
Amendment Manager: User entered 'Day 502'	System	19 Nov 2020 05:02:21

**US3312046**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:51:05**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:02:21
Amendment Manager: User entered '24 Dec 2021 00:01'	System	19 Nov 2020 05:02:21

**US3312046**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:51:05**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:02:21
Amendment Manager: User entered '28 Dec 2021 23:59'	System	19 Nov 2020 05:02:21

**US3312046**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:51:05**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:02:21
Amendment Manager: User entered 'Day 509'	System	19 Nov 2020 05:02:21

**US3312046**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:51:05**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:02:21
Amendment Manager: User entered '31 Dec 2021 00:01'	System	19 Nov 2020 05:02:21

**US3312046**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:51:05**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:02:21
Amendment Manager: User entered '04 Jan 2022 23:59'	System	19 Nov 2020 05:02:21

**US3312046**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:51:05**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:02:21
Amendment Manager: User entered 'Day 516'	System	19 Nov 2020 05:02:21

**US3312046**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:51:05**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:02:21
Amendment Manager: User entered '07 Jan 2022 00:01'	System	19 Nov 2020 05:02:21



**US3312046**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:51:05**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:02:21
Amendment Manager: User entered '11 Jan 2022 23:59'	System	19 Nov 2020 05:02:21

**US3312046**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:51:05**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:02:21
Amendment Manager: User entered 'Day 523'	System	19 Nov 2020 05:02:21

**US3312046**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:51:05**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:02:21
Amendment Manager: User entered '14 Jan 2022 00:01'	System	19 Nov 2020 05:02:21

**US3312046**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:51:05**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:02:21
Amendment Manager: User entered '18 Jan 2022 23:59'	System	19 Nov 2020 05:02:21

**US3312046**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:51:05**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:02:21
Amendment Manager: User entered 'Day 530'	System	19 Nov 2020 05:02:21

**US3312046**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:51:05**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:02:21
Amendment Manager: User entered '21 Jan 2022 00:01'	System	19 Nov 2020 05:02:21

**US3312046**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:51:05**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:02:21
Amendment Manager: User entered '25 Jan 2022 23:59'	System	19 Nov 2020 05:02:21

**US3312046**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:51:05**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:02:21
Amendment Manager: User entered 'Day 537'	System	19 Nov 2020 05:02:21



**US3312046**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:51:05**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:02:21
Amendment Manager: User entered '28 Jan 2022 00:01'	System	19 Nov 2020 05:02:21

**US3312046**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:51:05**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:02:21
Amendment Manager: User entered '01 Feb 2022 23:59'	System	19 Nov 2020 05:02:21

**US3312046**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:51:05**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:02:21
Amendment Manager: User entered 'Day 544'	System	19 Nov 2020 05:02:21

**US3312046**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:51:05**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:02:21
Amendment Manager: User entered '04 Feb 2022 00:01'	System	19 Nov 2020 05:02:21

**US3312046**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:51:05**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:02:21
Amendment Manager: User entered '08 Feb 2022 23:59'	System	19 Nov 2020 05:02:21

**US3312046**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:51:05**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:02:21
Amendment Manager: User entered 'Day 551'	System	19 Nov 2020 05:02:21

**US3312046**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:51:05**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:02:21
Amendment Manager: User entered '11 Feb 2022 00:01'	System	19 Nov 2020 05:02:21

**US3312046**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:51:05**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:02:21
Amendment Manager: User entered '15 Feb 2022 23:59'	System	19 Nov 2020 05:02:21



**US3312046**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:51:05**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:02:21
Amendment Manager: User entered 'Day 558'	System	19 Nov 2020 05:02:21

**US3312046**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:51:05**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:02:21
Amendment Manager: User entered '18 Feb 2022 00:01'	System	19 Nov 2020 05:02:21

**US3312046**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:51:05**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:02:21
Amendment Manager: User entered '22 Feb 2022 23:59'	System	19 Nov 2020 05:02:21

**US3312046**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:51:05**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:02:21
Amendment Manager: User entered 'Day 565'	System	19 Nov 2020 05:02:21

**US3312046**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:51:05**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:02:21
Amendment Manager: User entered '25 Feb 2022 00:01'	System	19 Nov 2020 05:02:21

**US3312046**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:51:05**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:02:21
Amendment Manager: User entered '01 Mar 2022 23:59'	System	19 Nov 2020 05:02:21

**US3312046**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:51:05**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:02:21
Amendment Manager: User entered 'Day 572'	System	19 Nov 2020 05:02:21

**US3312046**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:51:05**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:02:21
Amendment Manager: User entered '04 Mar 2022 00:01'	System	19 Nov 2020 05:02:21



**US3312046**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:51:05**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:02:21
Amendment Manager: User entered '08 Mar 2022 23:59'	System	19 Nov 2020 05:02:21

**US3312046**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:51:05**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:02:21
Amendment Manager: User entered 'Day 579'	System	19 Nov 2020 05:02:21

**US3312046**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:51:05**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:02:21
Amendment Manager: User entered '11 Mar 2022 00:01'	System	19 Nov 2020 05:02:21

**US3312046**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:51:05**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:02:21
Amendment Manager: User entered '15 Mar 2022 23:59'	System	19 Nov 2020 05:02:21

**US3312046**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:51:05**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:02:21
Amendment Manager: User entered 'Day 586'	System	19 Nov 2020 05:02:21

**US3312046**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:51:05**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:02:21
Amendment Manager: User entered '18 Mar 2022 00:01'	System	19 Nov 2020 05:02:21

**US3312046**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:51:05**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:02:21
Amendment Manager: User entered '22 Mar 2022 23:59'	System	19 Nov 2020 05:02:21

**US3312046**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:51:05**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:02:21
Amendment Manager: User entered 'Day 593'	System	19 Nov 2020 05:02:21



**US3312046**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:51:05**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:02:21
Amendment Manager: User entered '25 Mar 2022 00:01'	System	19 Nov 2020 05:02:21

**US3312046**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:51:05**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:02:21
Amendment Manager: User entered '29 Mar 2022 23:59'	System	19 Nov 2020 05:02:21

**US3312046**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:51:05**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:02:21
Amendment Manager: User entered 'Day 600'	System	19 Nov 2020 05:02:21

**US3312046**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:51:05**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:02:21
Amendment Manager: User entered '01 Apr 2022 00:01'	System	19 Nov 2020 05:02:21

**US3312046**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:51:05**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:02:21
Amendment Manager: User entered '05 Apr 2022 23:59'	System	19 Nov 2020 05:02:21

**US3312046**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:51:05**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:02:21
Amendment Manager: User entered 'Day 607'	System	19 Nov 2020 05:02:21

**US3312046**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:51:05**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:02:21
Amendment Manager: User entered '08 Apr 2022 00:01'	System	19 Nov 2020 05:02:21

**US3312046**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:51:05**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:02:21
Amendment Manager: User entered '12 Apr 2022 23:59'	System	19 Nov 2020 05:02:21



**US3312046**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:51:05**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:02:21
Amendment Manager: User entered 'Day 614'	System	19 Nov 2020 05:02:21

**US3312046**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:51:05**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:02:21
Amendment Manager: User entered '15 Apr 2022 00:01'	System	19 Nov 2020 05:02:21

**US3312046**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:51:05**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:02:21
Amendment Manager: User entered '19 Apr 2022 23:59'	System	19 Nov 2020 05:02:21

**US3312046**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:51:05**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:02:21
Amendment Manager: User entered 'Day 621'	System	19 Nov 2020 05:02:21

**US3312046**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:51:05**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:02:21
Amendment Manager: User entered '22 Apr 2022 00:01'	System	19 Nov 2020 05:02:21

**US3312046**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:51:05**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:02:21
Amendment Manager: User entered '26 Apr 2022 23:59'	System	19 Nov 2020 05:02:21

**US3312046**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:51:05**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:02:21
Amendment Manager: User entered 'Day 628'	System	19 Nov 2020 05:02:21

**US3312046**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:51:05**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:02:21
Amendment Manager: User entered '29 Apr 2022 00:01'	System	19 Nov 2020 05:02:21



**US3312046**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:51:05**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:02:21
Amendment Manager: User entered '03 May 2022 23:59'	System	19 Nov 2020 05:02:21

**US3312046**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:51:05**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:02:21
Amendment Manager: User entered 'Day 635'	System	19 Nov 2020 05:02:21

**US3312046**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:51:05**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:02:21
Amendment Manager: User entered '06 May 2022 00:01'	System	19 Nov 2020 05:02:21

**US3312046**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:51:05**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:02:21
Amendment Manager: User entered '10 May 2022 23:59'	System	19 Nov 2020 05:02:21

**US3312046**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:51:05**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:02:21
Amendment Manager: User entered 'Day 642'	System	19 Nov 2020 05:02:21

**US3312046**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:51:05**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:02:21
Amendment Manager: User entered '13 May 2022 00:01'	System	19 Nov 2020 05:02:21

**US3312046**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:51:05**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:02:21
Amendment Manager: User entered '17 May 2022 23:59'	System	19 Nov 2020 05:02:21

**US3312046**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:51:05**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:02:21
Amendment Manager: User entered 'Day 649'	System	19 Nov 2020 05:02:21



**US3312046**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:51:05**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:02:21
Amendment Manager: User entered '20 May 2022 00:01'	System	19 Nov 2020 05:02:21

**US3312046**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:51:05**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:02:21
Amendment Manager: User entered '24 May 2022 23:59'	System	19 Nov 2020 05:02:21

**US3312046**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:51:05**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:02:21
Amendment Manager: User entered 'Day 656'	System	19 Nov 2020 05:02:21

**US3312046**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:51:05**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:02:21
Amendment Manager: User entered '27 May 2022 00:01'	System	19 Nov 2020 05:02:21

**US3312046**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:51:05**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:02:21
Amendment Manager: User entered '31 May 2022 23:59'	System	19 Nov 2020 05:02:21

**US3312046**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:51:05**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:02:21
Amendment Manager: User entered 'Day 663'	System	19 Nov 2020 05:02:21

**US3312046**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:51:05**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:02:21
Amendment Manager: User entered '03 Jun 2022 00:01'	System	19 Nov 2020 05:02:21

**US3312046**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:51:05**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:02:21
Amendment Manager: User entered '07 Jun 2022 23:59'	System	19 Nov 2020 05:02:21



**US3312046**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:51:05**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:02:21
Amendment Manager: User entered 'Day 670'	System	19 Nov 2020 05:02:21

**US3312046**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:51:05**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:02:21
Amendment Manager: User entered '10 Jun 2022 00:01'	System	19 Nov 2020 05:02:21

**US3312046**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:51:05**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:02:21
Amendment Manager: User entered '14 Jun 2022 23:59'	System	19 Nov 2020 05:02:21

**US3312046**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:51:05**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:02:21
Amendment Manager: User entered 'Day 677'	System	19 Nov 2020 05:02:21

**US3312046**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:51:05**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:02:21
Amendment Manager: User entered '17 Jun 2022 00:01'	System	19 Nov 2020 05:02:21

**US3312046**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:51:05**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:02:21
Amendment Manager: User entered '21 Jun 2022 23:59'	System	19 Nov 2020 05:02:21

**US3312046**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:51:05**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:02:21
Amendment Manager: User entered 'Day 684'	System	19 Nov 2020 05:02:21

**US3312046**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:51:05**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:02:21
Amendment Manager: User entered '24 Jun 2022 00:01'	System	19 Nov 2020 05:02:21



**US3312046**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:51:05**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:02:21
Amendment Manager: User entered '28 Jun 2022 23:59'	System	19 Nov 2020 05:02:21

**US3312046**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:51:05**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:02:21
Amendment Manager: User entered 'Day 691'	System	19 Nov 2020 05:02:21

**US3312046**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:51:05**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:02:21
Amendment Manager: User entered '01 Jul 2022 00:01'	System	19 Nov 2020 05:02:21

**US3312046**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:51:05**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:02:21
Amendment Manager: User entered '05 Jul 2022 23:59'	System	19 Nov 2020 05:02:21

**US3312046**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:51:05**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:02:21
Amendment Manager: User entered 'Day 698'	System	19 Nov 2020 05:02:21

**US3312046**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:51:05**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:02:21
Amendment Manager: User entered '08 Jul 2022 00:01'	System	19 Nov 2020 05:02:21

**US3312046**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:51:05**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:02:21
Amendment Manager: User entered '12 Jul 2022 23:59'	System	19 Nov 2020 05:02:21

**US3312046**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:51:05**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:02:21
Amendment Manager: User entered 'Day 705'	System	19 Nov 2020 05:02:21



**US3312046**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:51:05**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:02:21
Amendment Manager: User entered '15 Jul 2022 00:01'	System	19 Nov 2020 05:02:21

**US3312046**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:51:05**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:02:21
Amendment Manager: User entered '19 Jul 2022 23:59'	System	19 Nov 2020 05:02:21

**US3312046**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:51:05**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:02:21
Amendment Manager: User entered 'Day 712'	System	19 Nov 2020 05:02:21

**US3312046**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:51:05**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:02:21
Amendment Manager: User entered '22 Jul 2022 00:01'	System	19 Nov 2020 05:02:21

**US3312046**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:51:05**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:02:21
Amendment Manager: User entered '26 Jul 2022 23:59'	System	19 Nov 2020 05:02:21

**US3312046**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:51:05**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:02:21
Amendment Manager: User entered 'Day 719'	System	19 Nov 2020 05:02:21

**US3312046**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:51:05**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:02:21
Amendment Manager: User entered '29 Jul 2022 00:01'	System	19 Nov 2020 05:02:21

**US3312046**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:51:05**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:02:21
Amendment Manager: User entered '02 Aug 2022 23:59'	System	19 Nov 2020 05:02:21



**US3312046**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:51:05**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:02:21
Amendment Manager: User entered 'Day 726'	System	19 Nov 2020 05:02:21

**US3312046**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:51:05**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:02:21
Amendment Manager: User entered '05 Aug 2022 00:01'	System	19 Nov 2020 05:02:21

**US3312046**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:51:05**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:02:21
Amendment Manager: User entered '09 Aug 2022 23:59'	System	19 Nov 2020 05:02:21

**US3312046**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:51:05**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:02:21
Amendment Manager: User entered 'Day 733'	System	19 Nov 2020 05:02:21

**US3312046**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:51:05**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:02:21
Amendment Manager: User entered '12 Aug 2022 00:01'	System	19 Nov 2020 05:02:21

**US3312046**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:51:05**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:02:21
Amendment Manager: User entered '16 Aug 2022 23:59'	System	19 Nov 2020 05:02:21

**US3312046**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:51:05**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:02:21
Amendment Manager: User entered 'Day 740'	System	19 Nov 2020 05:02:21

**US3312046**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:51:05**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:02:21
Amendment Manager: User entered '19 Aug 2022 00:01'	System	19 Nov 2020 05:02:21



**US3312046**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:51:05**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:02:21
Amendment Manager: User entered '23 Aug 2022 23:59'	System	19 Nov 2020 05:02:21

**US3312046**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:51:05**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:02:21
Amendment Manager: User entered 'Day 747'	System	19 Nov 2020 05:02:21

**US3312046**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:51:05**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:02:21
Amendment Manager: User entered '26 Aug 2022 00:01'	System	19 Nov 2020 05:02:21

**US3312046**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:51:05**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:02:21
Amendment Manager: User entered '30 Aug 2022 23:59'	System	19 Nov 2020 05:02:21

**US3312046**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:51:05**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:02:21
Amendment Manager: User entered 'Day 754'	System	19 Nov 2020 05:02:21

**US3312046**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:51:05**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:02:21
Amendment Manager: User entered '02 Sep 2022 00:01'	System	19 Nov 2020 05:02:21

**US3312046**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:51:05**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:02:21
Amendment Manager: User entered '06 Sep 2022 23:59'	System	19 Nov 2020 05:02:21

**US3312046**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:51:05**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:02:21
Amendment Manager: User entered 'Day 761'	System	19 Nov 2020 05:02:21



**US3312046**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:51:05**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:02:21
Amendment Manager: User entered '09 Sep 2022 00:01'	System	19 Nov 2020 05:02:21

**US3312046**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:51:05**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:02:21
Amendment Manager: User entered '13 Sep 2022 23:59'	System	19 Nov 2020 05:02:21

**US3312046**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:51:05**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:02:21
Amendment Manager: User entered 'Day 768'	System	19 Nov 2020 05:02:21

**US3312046**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:51:05**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:02:21
Amendment Manager: User entered '16 Sep 2022 00:01'	System	19 Nov 2020 05:02:21

**US3312046**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:51:05**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:02:21
Amendment Manager: User entered '20 Sep 2022 23:59'	System	19 Nov 2020 05:02:21

**US3312046**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:51:05**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:02:21
Amendment Manager: User entered 'Day 775'	System	19 Nov 2020 05:02:21

**US3312046**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:51:05**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:02:21
Amendment Manager: User entered '23 Sep 2022 00:01'	System	19 Nov 2020 05:02:21

**US3312046**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:51:05**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:02:21
Amendment Manager: User entered '27 Sep 2022 23:59'	System	19 Nov 2020 05:02:21



**US3312046**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:51:05**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:02:21
Amendment Manager: User entered 'Day 782'	System	19 Nov 2020 05:02:21

**US3312046**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:51:05**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:02:21
Amendment Manager: User entered '30 Sep 2022 00:01'	System	19 Nov 2020 05:02:21

**US3312046**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:51:05**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:02:21
Amendment Manager: User entered '04 Oct 2022 23:59'	System	19 Nov 2020 05:02:21

**US3312046**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:51:05**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:02:21
Amendment Manager: User entered 'Day 789'	System	19 Nov 2020 05:02:21

**US3312046**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:51:05**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:02:21
Amendment Manager: User entered '07 Oct 2022 00:01'	System	19 Nov 2020 05:02:21

**US3312046**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:51:05**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:02:21
Amendment Manager: User entered '11 Oct 2022 23:59'	System	19 Nov 2020 05:02:21

**US3312046**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:51:05**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:02:21
Amendment Manager: User entered 'Day 796'	System	19 Nov 2020 05:02:21

**US3312046**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:51:05**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:02:21
Amendment Manager: User entered '14 Oct 2022 00:01'	System	19 Nov 2020 05:02:21



**US3312046**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:51:05**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:02:21
Amendment Manager: User entered '18 Oct 2022 23:59'	System	19 Nov 2020 05:02:21

**US3312046**

**Folder: Safety Call Day 85 (1)**

**Form: Safety Call**

**Generated On: 26 Nov 2020 10:51:05**

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Monica Atwood (b) (4) (b) (4)	06 Nov 2020 15:08:29

**US3312046**

**Folder: Safety Call Day 85 (1)**

**Form: Safety Call**

**Generated On: 26 Nov 2020 10:51:05**

**Date of Contact or Contact Attempt** (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered '4 Nov 2020'	Monica Atwood (b) (4) (b) (4)	06 Nov 2020 15:08:29

**US3312046**

**Folder: Safety Call Day 85 (1)**

**Form: Safety Call**

**Generated On: 26 Nov 2020 10:51:05**

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
User entered 'Contact Made (CONTACT MADE)'	Monica Atwood (b) (4) (b) (4)	06 Nov 2020 15:08:29

**US3312046**

**Folder: Safety Call Day 85 (1)**

**Form: Safety Call**

**Generated On: 26 Nov 2020 10:51:05**

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
User entered empty.	Monica Atwood (b) (4) (b) (4)	06 Nov 2020 15:08:29

**US3312046**

**Folder: Safety Call Day 85 (1)**

**Form: Continuing**

**Generated On: 26 Nov 2020 10:51:05**

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Monica Atwood (b) (4) (b) (4)	06 Nov 2020 15:08:33

**US3312046**

**Folder: Safety Call Day 85 (1)**

**Form: Continuing**

**Generated On: 26 Nov 2020 10:51:05**

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered 'I'	System	06 Nov 2020 15:08:33

**US3312046**

**Folder: Covid-19 Assessment 13 Oct 2020**

**Form: COVID-19 Contact**

**Generated On: 26 Nov 2020 10:51:05**

[Date of Contact](#)

Audit	User	Time (GMT)
User entered '13 Oct 2020'	Karol Moore (b) (4) (b) (4)	09 Nov 2020 16:31:11



**US3312046**

**Folder: Covid-19 Assessment 13 Oct 2020**

**Form: COVID-19 Contact**

**Generated On: 26 Nov 2020 10:51:05**

[Time of Contact](#)

Audit	User	Time (GMT)
User entered '16:10'	Karol Moore (b) (4) (b) (4)	09 Nov 2020 16:31:11

**US3312046**

**Folder: Covid-19 Assessment 13 Oct 2020**

**Form: COVID-19 Contact**

**Generated On: 26 Nov 2020 10:51:05**

[Date and Time of Contact \(derived\)](#)

Audit	User	Time (GMT)
User entered '13 Oct 2020 16:10'	System	09 Nov 2020 16:31:11

US3312046

Folder: Covid-19 Assessment 13 Oct 2020

Form: COVID-19 Contact

Generated On: 26 Nov 2020 10:51:05

[Type of Contact](#)

Audit	User	Time (GMT)
User entered 'Safety Call (Safety Call)'	Karol Moore (b) (4) (b) (4)	09 Nov 2020 16:31:11

US3312046

Folder: Covid-19 Assessment 13 Oct 2020

Form: COVID-19 Contact

Generated On: 26 Nov 2020 10:51:05

[Has the subject reported symptoms of SARS-COV-2?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Karol Moore (b) (4) (b) (4)	09 Nov 2020 16:31:11

US3312046

Folder: Covid-19 Assessment 13 Oct 2020

Form: Symptom Log (1)

Generated On: 26 Nov 2020 10:51:05

[Symptom Day](#)

Audit	User	Time (GMT)
User entered 'Day 1 (Day 1)'	Karol Moore (b) (4) (b) (4)	09 Nov 2020 16:37:50

US3312046

Folder: Covid-19 Assessment 13 Oct 2020

Form: Symptom Log (1)

Generated On: 26 Nov 2020 10:51:05

[Date](#)

Audit	User	Time (GMT)
User entered '07 Oct 2020'	Karol Moore (b) (4) (b) (4)	09 Nov 2020 16:37:50

US3312046

Folder: Covid-19 Assessment 13 Oct 2020

Form: Symptom Log (1)

Generated On: 26 Nov 2020 10:51:05

[Assessment Not Done](#)

Audit	User	Time (GMT)
User entered '0'	Karol Moore (b) (4) (b) (4)	09 Nov 2020 16:37:50

US3312046

Folder: Covid-19 Assessment 13 Oct 2020

Form: Symptom Log (1)

Generated On: 26 Nov 2020 10:51:05

[O2 Saturation](#)

Audit	User	Time (GMT)
User entered empty.	Karol Moore (b) (4) (b) (4)	09 Nov 2020 16:37:50



**US3312046**

**Folder: Covid-19 Assessment 13 Oct 2020**

**Form: Symptom Log (1)**

**Generated On: 26 Nov 2020 10:51:05**

[O2 Saturation Units](#)

Audit	User	Time (GMT)
User entered empty.	System	09 Nov 2020 16:37:50

US3312046

Folder: Covid-19 Assessment 13 Oct 2020

Form: Symptom Log (1)

Generated On: 26 Nov 2020 10:51:05

[Temperature](#)

Audit	User	Time (GMT)
User entered empty.	Karol Moore (b) (4) (b) (4)	09 Nov 2020 16:37:50

US3312046

Folder: Covid-19 Assessment 13 Oct 2020

Form: Symptom Log (1)

Generated On: 26 Nov 2020 10:51:05

[Chills](#)

Audit	User	Time (GMT)
User entered 'None (None)'	Karol Moore (b) (4) (b) (4)	09 Nov 2020 16:37:50

US3312046

Folder: Covid-19 Assessment 13 Oct 2020

Form: Symptom Log (1)

Generated On: 26 Nov 2020 10:51:05

[Cough](#)

Audit	User	Time (GMT)
User entered 'None (None)'	Karol Moore (b) (4) (b) (4)	09 Nov 2020 16:37:50

US3312046

Folder: Covid-19 Assessment 13 Oct 2020

Form: Symptom Log (1)

Generated On: 26 Nov 2020 10:51:05

[Shortness of Breath](#)

Audit	User	Time (GMT)
User entered 'None (None)'	Karol Moore (b) (4) (b) (4)	09 Nov 2020 16:37:50

US3312046

Folder: Covid-19 Assessment 13 Oct 2020

Form: Symptom Log (1)

Generated On: 26 Nov 2020 10:51:05

[Difficulty Breathing](#)

Audit	User	Time (GMT)
User entered 'None (None)'	Karol Moore (b) (4) (b) (4)	09 Nov 2020 16:37:50

US3312046

Folder: Covid-19 Assessment 13 Oct 2020

Form: Symptom Log (1)

Generated On: 26 Nov 2020 10:51:05

[Fatigue](#)

Audit	User	Time (GMT)
User entered 'Mild (Mild)'	Karol Moore (b) (4) (b) (4)	09 Nov 2020 16:37:50

US3312046

Folder: Covid-19 Assessment 13 Oct 2020

Form: Symptom Log (1)

Generated On: 26 Nov 2020 10:51:05

Muscle Aches (Myalgia)

Audit	User	Time (GMT)
User entered 'None (None)'	Karol Moore (b) (4) (b) (4)	09 Nov 2020 16:37:50



US3312046

Folder: Covid-19 Assessment 13 Oct 2020

Form: Symptom Log (1)

Generated On: 26 Nov 2020 10:51:05

[Body Aches](#)

Audit	User	Time (GMT)
User entered 'None (None)'	Karol Moore (b) (4) (b) (4)	09 Nov 2020 16:37:50

US3312046

Folder: Covid-19 Assessment 13 Oct 2020

Form: Symptom Log (1)

Generated On: 26 Nov 2020 10:51:05

[Headache](#)

Audit	User	Time (GMT)
User entered 'Mild (Mild)'	Karol Moore (b) (4) (b) (4)	09 Nov 2020 16:37:50

US3312046

Folder: Covid-19 Assessment 13 Oct 2020

Form: Symptom Log (1)

Generated On: 26 Nov 2020 10:51:05

[New Loss of Taste](#)

Audit	User	Time (GMT)
User entered 'None (None)'	Karol Moore (b) (4) (b) (4)	09 Nov 2020 16:37:50

US3312046

Folder: Covid-19 Assessment 13 Oct 2020

Form: Symptom Log (1)

Generated On: 26 Nov 2020 10:51:05

[New Loss of Smell](#)

Audit	User	Time (GMT)
User entered 'None (None)'	Karol Moore (b) (4) (b) (4)	09 Nov 2020 16:37:50

US3312046

Folder: Covid-19 Assessment 13 Oct 2020

Form: Symptom Log (1)

Generated On: 26 Nov 2020 10:51:05

[Nasal Congestion](#)

Audit	User	Time (GMT)
User entered 'None (None)'	Karol Moore (b) (4) (b) (4)	09 Nov 2020 16:37:50

US3312046

Folder: Covid-19 Assessment 13 Oct 2020

Form: Symptom Log (1)

Generated On: 26 Nov 2020 10:51:05

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
User entered 'None (None)'	Karol Moore (b) (4) (b) (4)	09 Nov 2020 16:37:50

US3312046

Folder: Covid-19 Assessment 13 Oct 2020

Form: Symptom Log (1)

Generated On: 26 Nov 2020 10:51:05

[Nausea](#)

Audit	User	Time (GMT)
User entered 'Mild (Mild)'	Karol Moore (b) (4) (b) (4)	09 Nov 2020 16:37:50

US3312046

Folder: Covid-19 Assessment 13 Oct 2020

Form: Symptom Log (1)

Generated On: 26 Nov 2020 10:51:05

[Vomiting](#)

Audit	User	Time (GMT)
User entered 'Mild (Mild)'	Karol Moore (b) (4) (b) (4)	09 Nov 2020 16:37:50



US3312046

Folder: Covid-19 Assessment 13 Oct 2020

Form: Symptom Log (1)

Generated On: 26 Nov 2020 10:51:05

[Diarrhea](#)

Audit	User	Time (GMT)
User entered 'None (None)'	Karol Moore (b) (4) (b) (4)	09 Nov 2020 16:37:50

US3312046

Folder: Covid-19 Assessment 13 Oct 2020

Form: Symptom Log (1)

Generated On: 26 Nov 2020 10:51:05

[Sore Throat](#)

Audit	User	Time (GMT)
User entered 'Mild (Mild)'	Karol Moore (b) (4) (b) (4)	09 Nov 2020 16:37:50

US3312046

Folder: Covid-19 Assessment 13 Oct 2020

Form: Symptom Log (2)

Generated On: 26 Nov 2020 10:51:05

[Symptom Day](#)

Audit	User	Time (GMT)
User entered 'Day 2 (Day 2)'	Karol Moore (b) (4) (b) (4)	09 Nov 2020 16:38:35

US3312046

Folder: Covid-19 Assessment 13 Oct 2020

Form: Symptom Log (2)

Generated On: 26 Nov 2020 10:51:05

[Date](#)

Audit	User	Time (GMT)
User entered '08 Oct 2020'	Karol Moore (b) (4) (b) (4)	09 Nov 2020 16:38:35

US3312046

Folder: Covid-19 Assessment 13 Oct 2020

Form: Symptom Log (2)

Generated On: 26 Nov 2020 10:51:05

[Assessment Not Done](#)

Audit	User	Time (GMT)
User entered '0'	Karol Moore (b) (4) (b) (4)	09 Nov 2020 16:38:35

US3312046

Folder: Covid-19 Assessment 13 Oct 2020

Form: Symptom Log (2)

Generated On: 26 Nov 2020 10:51:05

[O2 Saturation](#)

Audit	User	Time (GMT)
User entered empty.	Karol Moore (b) (4) (b) (4)	09 Nov 2020 16:38:35

**US3312046**

**Folder: Covid-19 Assessment 13 Oct 2020**

**Form: Symptom Log (2)**

**Generated On: 26 Nov 2020 10:51:05**

[O2 Saturation Units](#)

Audit	User	Time (GMT)
User entered empty.	System	09 Nov 2020 16:38:35

US3312046

Folder: Covid-19 Assessment 13 Oct 2020

Form: Symptom Log (2)

Generated On: 26 Nov 2020 10:51:05

[Temperature](#)

Audit	User	Time (GMT)
User entered empty.	Karol Moore (b) (4) (b) (4)	09 Nov 2020 16:38:35



US3312046

Folder: Covid-19 Assessment 13 Oct 2020

Form: Symptom Log (2)

Generated On: 26 Nov 2020 10:51:05

[Chills](#)

Audit	User	Time (GMT)
User entered 'None (None)'	Karol Moore (b) (4) (b) (4)	09 Nov 2020 16:38:35

US3312046

Folder: Covid-19 Assessment 13 Oct 2020

Form: Symptom Log (2)

Generated On: 26 Nov 2020 10:51:05

[Cough](#)

Audit	User	Time (GMT)
User entered 'None (None)'	Karol Moore (b) (4) (b) (4)	09 Nov 2020 16:38:35

US3312046

Folder: Covid-19 Assessment 13 Oct 2020

Form: Symptom Log (2)

Generated On: 26 Nov 2020 10:51:05

[Shortness of Breath](#)

Audit	User	Time (GMT)
User entered 'None (None)'	Karol Moore (b) (4) (b) (4)	09 Nov 2020 16:38:35

US3312046

Folder: Covid-19 Assessment 13 Oct 2020

Form: Symptom Log (2)

Generated On: 26 Nov 2020 10:51:05

[Difficulty Breathing](#)

Audit	User	Time (GMT)
User entered 'None (None)'	Karol Moore (b) (4) (b) (4)	09 Nov 2020 16:38:35

US3312046

Folder: Covid-19 Assessment 13 Oct 2020

Form: Symptom Log (2)

Generated On: 26 Nov 2020 10:51:05

[Fatigue](#)

Audit	User	Time (GMT)
User entered 'Mild (Mild)'	Karol Moore (b) (4) (b) (4)	09 Nov 2020 16:38:35

US3312046

Folder: Covid-19 Assessment 13 Oct 2020

Form: Symptom Log (2)

Generated On: 26 Nov 2020 10:51:05

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
User entered 'None (None)'	Karol Moore (b) (4) (b) (4)	09 Nov 2020 16:38:35

US3312046

Folder: Covid-19 Assessment 13 Oct 2020

Form: Symptom Log (2)

Generated On: 26 Nov 2020 10:51:05

[Body Aches](#)

Audit	User	Time (GMT)
User entered 'None (None)'	Karol Moore (b) (4) (b) (4)	09 Nov 2020 16:38:35

US3312046

Folder: Covid-19 Assessment 13 Oct 2020

Form: Symptom Log (2)

Generated On: 26 Nov 2020 10:51:05

[Headache](#)

Audit	User	Time (GMT)
User entered 'None (None)'	Karol Moore (b) (4) (b) (4)	09 Nov 2020 16:38:35



US3312046

Folder: Covid-19 Assessment 13 Oct 2020

Form: Symptom Log (2)

Generated On: 26 Nov 2020 10:51:05

[New Loss of Taste](#)

Audit	User	Time (GMT)
User entered 'None (None)'	Karol Moore (b) (4) (b) (4)	09 Nov 2020 16:38:35

US3312046

Folder: Covid-19 Assessment 13 Oct 2020

Form: Symptom Log (2)

Generated On: 26 Nov 2020 10:51:05

[New Loss of Smell](#)

Audit	User	Time (GMT)
User entered 'None (None)'	Karol Moore (b) (4) (b) (4)	09 Nov 2020 16:38:35

US3312046

Folder: Covid-19 Assessment 13 Oct 2020

Form: Symptom Log (2)

Generated On: 26 Nov 2020 10:51:05

[Nasal Congestion](#)

Audit	User	Time (GMT)
User entered 'None (None)'	Karol Moore (b) (4) (b) (4)	09 Nov 2020 16:38:35

US3312046

Folder: Covid-19 Assessment 13 Oct 2020

Form: Symptom Log (2)

Generated On: 26 Nov 2020 10:51:05

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
User entered 'None (None)'	Karol Moore (b) (4) (b) (4)	09 Nov 2020 16:38:35

US3312046

Folder: Covid-19 Assessment 13 Oct 2020

Form: Symptom Log (2)

Generated On: 26 Nov 2020 10:51:05

[Nausea](#)

Audit	User	Time (GMT)
User entered 'Mild (Mild)'	Karol Moore (b) (4) (b) (4)	09 Nov 2020 16:38:35

US3312046

Folder: Covid-19 Assessment 13 Oct 2020

Form: Symptom Log (2)

Generated On: 26 Nov 2020 10:51:05

[Vomiting](#)

Audit	User	Time (GMT)
User entered 'None (None)'	Karol Moore (b) (4) (b) (4)	09 Nov 2020 16:38:35

US3312046

Folder: Covid-19 Assessment 13 Oct 2020

Form: Symptom Log (2)

Generated On: 26 Nov 2020 10:51:05

[Diarrhea](#)

Audit	User	Time (GMT)
User entered 'None (None)'	Karol Moore (b) (4) (b) (4)	09 Nov 2020 16:38:35

US3312046

Folder: Covid-19 Assessment 13 Oct 2020

Form: Symptom Log (2)

Generated On: 26 Nov 2020 10:51:05

[Sore Throat](#)

Audit	User	Time (GMT)
User entered 'Mild (Mild)'	Karol Moore (b) (4) (b) (4)	09 Nov 2020 16:38:35



US3312046

Folder: Covid-19 Assessment 13 Oct 2020

Form: Symptom Log (3)

Generated On: 26 Nov 2020 10:51:05

[Symptom Day](#)

Audit	User	Time (GMT)
User entered 'Day 3 (Day 3)'	Karol Moore (b) (4) (b) (4)	09 Nov 2020 16:40:09

US3312046

Folder: Covid-19 Assessment 13 Oct 2020

Form: Symptom Log (3)

Generated On: 26 Nov 2020 10:51:05

[Date](#)

Audit	User	Time (GMT)
User entered '09 Oct 2020'	Karol Moore (b) (4) (b) (4)	09 Nov 2020 16:40:09

US3312046

Folder: Covid-19 Assessment 13 Oct 2020

Form: Symptom Log (3)

Generated On: 26 Nov 2020 10:51:05

[Assessment Not Done](#)

Audit	User	Time (GMT)
User entered '0'	Karol Moore (b) (4) (b) (4)	09 Nov 2020 16:40:09

US3312046

Folder: Covid-19 Assessment 13 Oct 2020

Form: Symptom Log (3)

Generated On: 26 Nov 2020 10:51:05

[O2 Saturation](#)

Audit	User	Time (GMT)
User entered empty.	Karol Moore (b) (4) (b) (4)	09 Nov 2020 16:40:09

**US3312046**

**Folder: Covid-19 Assessment 13 Oct 2020**

**Form: Symptom Log (3)**

**Generated On: 26 Nov 2020 10:51:05**

[O2 Saturation Units](#)

Audit	User	Time (GMT)
User entered empty.	System	09 Nov 2020 16:40:09

US3312046

Folder: Covid-19 Assessment 13 Oct 2020

Form: Symptom Log (3)

Generated On: 26 Nov 2020 10:51:05

[Temperature](#)

Audit	User	Time (GMT)
User entered empty.	Karol Moore (b) (4) (b) (4)	09 Nov 2020 16:40:09

US3312046

Folder: Covid-19 Assessment 13 Oct 2020

Form: Symptom Log (3)

Generated On: 26 Nov 2020 10:51:05

[Chills](#)

Audit	User	Time (GMT)
User entered 'None (None)'	Karol Moore (b) (4) (b) (4)	09 Nov 2020 16:40:09

US3312046

Folder: Covid-19 Assessment 13 Oct 2020

Form: Symptom Log (3)

Generated On: 26 Nov 2020 10:51:05

[Cough](#)

Audit	User	Time (GMT)
User entered 'None (None)'	Karol Moore (b) (4) (b) (4)	09 Nov 2020 16:40:09



US3312046

Folder: Covid-19 Assessment 13 Oct 2020

Form: Symptom Log (3)

Generated On: 26 Nov 2020 10:51:05

[Shortness of Breath](#)

Audit	User	Time (GMT)
User entered 'None (None)'	Karol Moore (b) (4) (b) (4)	09 Nov 2020 16:40:09

US3312046

Folder: Covid-19 Assessment 13 Oct 2020

Form: Symptom Log (3)

Generated On: 26 Nov 2020 10:51:05

[Difficulty Breathing](#)

Audit	User	Time (GMT)
User entered 'None (None)'	Karol Moore (b) (4) (b) (4)	09 Nov 2020 16:40:09

US3312046

Folder: Covid-19 Assessment 13 Oct 2020

Form: Symptom Log (3)

Generated On: 26 Nov 2020 10:51:05

[Fatigue](#)

Audit	User	Time (GMT)
User entered 'Mild (Mild)'	Karol Moore (b) (4) (b) (4)	09 Nov 2020 16:40:09

US3312046

Folder: Covid-19 Assessment 13 Oct 2020

Form: Symptom Log (3)

Generated On: 26 Nov 2020 10:51:05

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
User entered 'None (None)'	Karol Moore (b) (4) (b) (4)	09 Nov 2020 16:40:09

US3312046

Folder: Covid-19 Assessment 13 Oct 2020

Form: Symptom Log (3)

Generated On: 26 Nov 2020 10:51:05

[Body Aches](#)

Audit	User	Time (GMT)
User entered 'None (None)'	Karol Moore (b) (4) (b) (4)	09 Nov 2020 16:40:09

US3312046

Folder: Covid-19 Assessment 13 Oct 2020

Form: Symptom Log (3)

Generated On: 26 Nov 2020 10:51:05

[Headache](#)

Audit	User	Time (GMT)
User entered 'None (None)'	Karol Moore (b) (4) (b) (4)	09 Nov 2020 16:40:09

US3312046

Folder: Covid-19 Assessment 13 Oct 2020

Form: Symptom Log (3)

Generated On: 26 Nov 2020 10:51:05

[New Loss of Taste](#)

Audit	User	Time (GMT)
User entered 'None (None)'	Karol Moore (b) (4) (b) (4)	09 Nov 2020 16:40:09

US3312046

Folder: Covid-19 Assessment 13 Oct 2020

Form: Symptom Log (3)

Generated On: 26 Nov 2020 10:51:05

[New Loss of Smell](#)

Audit	User	Time (GMT)
User entered 'None (None)'	Karol Moore (b) (4) (b) (4)	09 Nov 2020 16:40:09



US3312046

Folder: Covid-19 Assessment 13 Oct 2020

Form: Symptom Log (3)

Generated On: 26 Nov 2020 10:51:05

[Nasal Congestion](#)

Audit	User	Time (GMT)
User entered 'None (None)'	Karol Moore (b) (4) (b) (4)	09 Nov 2020 16:40:09

US3312046

Folder: Covid-19 Assessment 13 Oct 2020

Form: Symptom Log (3)

Generated On: 26 Nov 2020 10:51:05

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
User entered 'None (None)'	Karol Moore (b) (4) (b) (4)	09 Nov 2020 16:40:09

US3312046

Folder: Covid-19 Assessment 13 Oct 2020

Form: Symptom Log (3)

Generated On: 26 Nov 2020 10:51:05

[Nausea](#)

Audit	User	Time (GMT)
User entered 'Mild (Mild)'	Karol Moore (b) (4) (b) (4)	09 Nov 2020 16:40:09

US3312046

Folder: Covid-19 Assessment 13 Oct 2020

Form: Symptom Log (3)

Generated On: 26 Nov 2020 10:51:05

[Vomiting](#)

Audit	User	Time (GMT)
User entered 'None (None)'	Karol Moore (b) (4) (b) (4)	09 Nov 2020 16:40:09

US3312046

Folder: Covid-19 Assessment 13 Oct 2020

Form: Symptom Log (3)

Generated On: 26 Nov 2020 10:51:05

[Diarrhea](#)

Audit	User	Time (GMT)
User entered 'None (None)'	Karol Moore (b) (4) (b) (4)	09 Nov 2020 16:40:09

US3312046

Folder: Covid-19 Assessment 13 Oct 2020

Form: Symptom Log (3)

Generated On: 26 Nov 2020 10:51:05

[Sore Throat](#)

Audit	User	Time (GMT)
User entered 'Mild (Mild)'	Karol Moore (b) (4) (b) (4)	09 Nov 2020 16:40:09

US3312046

Folder: Covid-19 Assessment 13 Oct 2020

Form: Symptom Log (4)

Generated On: 26 Nov 2020 10:51:05

[Symptom Day](#)

Audit	User	Time (GMT)
User entered 'Day 4 (Day 4)'	Karol Moore (b) (4) (b) (4)	09 Nov 2020 16:40:41

**US3312046**

**Folder: Covid-19 Assessment 13 Oct 2020**

**Form: Symptom Log (4)**

**Generated On: 26 Nov 2020 10:51:05**

[Date](#)

Audit	User	Time (GMT)
User entered '10 Oct 2020'	Karol Moore (b) (4) (b) (4)	09 Nov 2020 16:40:41



US3312046

Folder: Covid-19 Assessment 13 Oct 2020

Form: Symptom Log (4)

Generated On: 26 Nov 2020 10:51:05

[Assessment Not Done](#)

Audit	User	Time (GMT)
User entered '0'	Karol Moore (b) (4) (b) (4)	09 Nov 2020 16:40:41

US3312046

Folder: Covid-19 Assessment 13 Oct 2020

Form: Symptom Log (4)

Generated On: 26 Nov 2020 10:51:05

[O2 Saturation](#)

Audit	User	Time (GMT)
User entered empty.	Karol Moore (b) (4) (b) (4)	09 Nov 2020 16:40:41

**US3312046**

**Folder: Covid-19 Assessment 13 Oct 2020**

**Form: Symptom Log (4)**

**Generated On: 26 Nov 2020 10:51:05**

[O2 Saturation Units](#)

Audit	User	Time (GMT)
User entered empty.	System	09 Nov 2020 16:40:41

US3312046

Folder: Covid-19 Assessment 13 Oct 2020

Form: Symptom Log (4)

Generated On: 26 Nov 2020 10:51:05

[Temperature](#)

Audit	User	Time (GMT)
User entered empty.	Karol Moore (b) (4) (b) (4)	09 Nov 2020 16:40:41

US3312046

Folder: Covid-19 Assessment 13 Oct 2020

Form: Symptom Log (4)

Generated On: 26 Nov 2020 10:51:05

[Chills](#)

Audit	User	Time (GMT)
User entered 'None (None)'	Karol Moore (b) (4) (b) (4)	09 Nov 2020 16:40:41

US3312046

Folder: Covid-19 Assessment 13 Oct 2020

Form: Symptom Log (4)

Generated On: 26 Nov 2020 10:51:05

[Cough](#)

Audit	User	Time (GMT)
User entered 'None (None)'	Karol Moore (b) (4) (b) (4)	09 Nov 2020 16:40:41

US3312046

Folder: Covid-19 Assessment 13 Oct 2020

Form: Symptom Log (4)

Generated On: 26 Nov 2020 10:51:05

[Shortness of Breath](#)

Audit	User	Time (GMT)
User entered 'None (None)'	Karol Moore (b) (4) (b) (4)	09 Nov 2020 16:40:41

US3312046

Folder: Covid-19 Assessment 13 Oct 2020

Form: Symptom Log (4)

Generated On: 26 Nov 2020 10:51:05

[Difficulty Breathing](#)

Audit	User	Time (GMT)
User entered 'None (None)'	Karol Moore (b) (4) (b) (4)	09 Nov 2020 16:40:41



US3312046

Folder: Covid-19 Assessment 13 Oct 2020

Form: Symptom Log (4)

Generated On: 26 Nov 2020 10:51:05

[Fatigue](#)

Audit	User	Time (GMT)
User entered 'Mild (Mild)'	Karol Moore (b) (4) (b) (4)	09 Nov 2020 16:40:41

US3312046

Folder: Covid-19 Assessment 13 Oct 2020

Form: Symptom Log (4)

Generated On: 26 Nov 2020 10:51:05

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
User entered 'None (None)'	Karol Moore (b) (4) (b) (4)	09 Nov 2020 16:40:41

US3312046

Folder: Covid-19 Assessment 13 Oct 2020

Form: Symptom Log (4)

Generated On: 26 Nov 2020 10:51:05

[Body Aches](#)

Audit	User	Time (GMT)
User entered 'None (None)'	Karol Moore (b) (4) (b) (4)	09 Nov 2020 16:40:41

US3312046

Folder: Covid-19 Assessment 13 Oct 2020

Form: Symptom Log (4)

Generated On: 26 Nov 2020 10:51:05

[Headache](#)

Audit	User	Time (GMT)
User entered 'None (None)'	Karol Moore (b) (4) (b) (4)	09 Nov 2020 16:40:41

US3312046

Folder: Covid-19 Assessment 13 Oct 2020

Form: Symptom Log (4)

Generated On: 26 Nov 2020 10:51:05

[New Loss of Taste](#)

Audit	User	Time (GMT)
User entered 'None (None)'	Karol Moore (b) (4) (b) (4)	09 Nov 2020 16:40:41

US3312046

Folder: Covid-19 Assessment 13 Oct 2020

Form: Symptom Log (4)

Generated On: 26 Nov 2020 10:51:05

[New Loss of Smell](#)

Audit	User	Time (GMT)
User entered 'None (None)'	Karol Moore (b) (4) (b) (4)	09 Nov 2020 16:40:41

US3312046

Folder: Covid-19 Assessment 13 Oct 2020

Form: Symptom Log (4)

Generated On: 26 Nov 2020 10:51:05

[Nasal Congestion](#)

Audit	User	Time (GMT)
User entered 'None (None)'	Karol Moore (b) (4) (b) (4)	09 Nov 2020 16:40:41

US3312046

Folder: Covid-19 Assessment 13 Oct 2020

Form: Symptom Log (4)

Generated On: 26 Nov 2020 10:51:05

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
User entered 'None (None)'	Karol Moore (b) (4) (b) (4)	09 Nov 2020 16:40:41



US3312046

Folder: Covid-19 Assessment 13 Oct 2020

Form: Symptom Log (4)

Generated On: 26 Nov 2020 10:51:05

[Nausea](#)

Audit	User	Time (GMT)
User entered 'Mild (Mild)'	Karol Moore (b) (4) (b) (4)	09 Nov 2020 16:40:41

US3312046

Folder: Covid-19 Assessment 13 Oct 2020

Form: Symptom Log (4)

Generated On: 26 Nov 2020 10:51:05

[Vomiting](#)

Audit	User	Time (GMT)
User entered 'None (None)'	Karol Moore (b) (4) (b) (4)	09 Nov 2020 16:40:41

US3312046

Folder: Covid-19 Assessment 13 Oct 2020

Form: Symptom Log (4)

Generated On: 26 Nov 2020 10:51:05

[Diarrhea](#)

Audit	User	Time (GMT)
User entered 'None (None)'	Karol Moore (b) (4) (b) (4)	09 Nov 2020 16:40:41

US3312046

Folder: Covid-19 Assessment 13 Oct 2020

Form: Symptom Log (4)

Generated On: 26 Nov 2020 10:51:05

[Sore Throat](#)

Audit	User	Time (GMT)
User entered 'Mild (Mild)'	Karol Moore (b) (4) (b) (4)	09 Nov 2020 16:40:41

US3312046

Folder: Covid-19 Assessment 13 Oct 2020

Form: Symptom Log (5)

Generated On: 26 Nov 2020 10:51:05

[Symptom Day](#)

Audit	User	Time (GMT)
User entered 'Day 5 (Day 5)'	Karol Moore (b) (4) (b) (4)	09 Nov 2020 16:41:00

US3312046

Folder: Covid-19 Assessment 13 Oct 2020

Form: Symptom Log (5)

Generated On: 26 Nov 2020 10:51:05

[Date](#)

Audit	User	Time (GMT)
User entered '11 Oct 2020'	Karol Moore (b) (4) (b) (4)	09 Nov 2020 16:41:00

US3312046

Folder: Covid-19 Assessment 13 Oct 2020

Form: Symptom Log (5)

Generated On: 26 Nov 2020 10:51:05

[Assessment Not Done](#)

Audit	User	Time (GMT)
User entered '0'	Karol Moore (b) (4) (b) (4)	09 Nov 2020 16:41:00

US3312046

Folder: Covid-19 Assessment 13 Oct 2020

Form: Symptom Log (5)

Generated On: 26 Nov 2020 10:51:05

[O2 Saturation](#)

Audit	User	Time (GMT)
User entered empty.	Karol Moore (b) (4) (b) (4)	09 Nov 2020 16:41:00



**US3312046**

**Folder: Covid-19 Assessment 13 Oct 2020**

**Form: Symptom Log (5)**

**Generated On: 26 Nov 2020 10:51:05**

[O2 Saturation Units](#)

Audit	User	Time (GMT)
User entered empty.	System	09 Nov 2020 16:41:00

US3312046

Folder: Covid-19 Assessment 13 Oct 2020

Form: Symptom Log (5)

Generated On: 26 Nov 2020 10:51:05

[Temperature](#)

Audit	User	Time (GMT)
User entered empty.	Karol Moore (b) (4) (b) (4)	09 Nov 2020 16:41:00

US3312046

Folder: Covid-19 Assessment 13 Oct 2020

Form: Symptom Log (5)

Generated On: 26 Nov 2020 10:51:05

[Chills](#)

Audit	User	Time (GMT)
User entered 'None (None)'	Karol Moore (b) (4) (b) (4)	09 Nov 2020 16:41:00

US3312046

Folder: Covid-19 Assessment 13 Oct 2020

Form: Symptom Log (5)

Generated On: 26 Nov 2020 10:51:05

[Cough](#)

Audit	User	Time (GMT)
User entered 'None (None)'	Karol Moore (b) (4) (b) (4)	09 Nov 2020 16:41:00

US3312046

Folder: Covid-19 Assessment 13 Oct 2020

Form: Symptom Log (5)

Generated On: 26 Nov 2020 10:51:05

[Shortness of Breath](#)

Audit	User	Time (GMT)
User entered 'None (None)'	Karol Moore (b) (4) (b) (4)	09 Nov 2020 16:41:00

US3312046

Folder: Covid-19 Assessment 13 Oct 2020

Form: Symptom Log (5)

Generated On: 26 Nov 2020 10:51:05

[Difficulty Breathing](#)

Audit	User	Time (GMT)
User entered 'None (None)'	Karol Moore (b) (4) (b) (4)	09 Nov 2020 16:41:00

US3312046

Folder: Covid-19 Assessment 13 Oct 2020

Form: Symptom Log (5)

Generated On: 26 Nov 2020 10:51:05

[Fatigue](#)

Audit	User	Time (GMT)
User entered 'Mild (Mild)'	Karol Moore (b) (4) (b) (4)	09 Nov 2020 16:41:00

US3312046

Folder: Covid-19 Assessment 13 Oct 2020

Form: Symptom Log (5)

Generated On: 26 Nov 2020 10:51:05

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
User entered 'None (None)'	Karol Moore (b) (4) (b) (4)	09 Nov 2020 16:41:00



US3312046

Folder: Covid-19 Assessment 13 Oct 2020

Form: Symptom Log (5)

Generated On: 26 Nov 2020 10:51:05

[Body Aches](#)

Audit	User	Time (GMT)
User entered 'None (None)'	Karol Moore (b) (4) (b) (4)	09 Nov 2020 16:41:00

US3312046

Folder: Covid-19 Assessment 13 Oct 2020

Form: Symptom Log (5)

Generated On: 26 Nov 2020 10:51:05

[Headache](#)

Audit	User	Time (GMT)
User entered 'None (None)'	Karol Moore (b) (4) (b) (4)	09 Nov 2020 16:41:00

US3312046

Folder: Covid-19 Assessment 13 Oct 2020

Form: Symptom Log (5)

Generated On: 26 Nov 2020 10:51:05

[New Loss of Taste](#)

Audit	User	Time (GMT)
User entered 'None (None)'	Karol Moore (b) (4) (b) (4)	09 Nov 2020 16:41:00

US3312046

Folder: Covid-19 Assessment 13 Oct 2020

Form: Symptom Log (5)

Generated On: 26 Nov 2020 10:51:05

[New Loss of Smell](#)

Audit	User	Time (GMT)
User entered 'None (None)'	Karol Moore (b) (4) (b) (4)	09 Nov 2020 16:41:00

US3312046

Folder: Covid-19 Assessment 13 Oct 2020

Form: Symptom Log (5)

Generated On: 26 Nov 2020 10:51:05

[Nasal Congestion](#)

Audit	User	Time (GMT)
User entered 'None (None)'	Karol Moore (b) (4) (b) (4)	09 Nov 2020 16:41:00

US3312046

Folder: Covid-19 Assessment 13 Oct 2020

Form: Symptom Log (5)

Generated On: 26 Nov 2020 10:51:05

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
User entered 'None (None)'	Karol Moore (b) (4) (b) (4)	09 Nov 2020 16:41:00

US3312046

Folder: Covid-19 Assessment 13 Oct 2020

Form: Symptom Log (5)

Generated On: 26 Nov 2020 10:51:05

[Nausea](#)

Audit	User	Time (GMT)
User entered 'Mild (Mild)'	Karol Moore (b) (4) (b) (4)	09 Nov 2020 16:41:00

US3312046

Folder: Covid-19 Assessment 13 Oct 2020

Form: Symptom Log (5)

Generated On: 26 Nov 2020 10:51:05

[Vomiting](#)

Audit	User	Time (GMT)
User entered 'None (None)'	Karol Moore (b) (4) (b) (4)	09 Nov 2020 16:41:00



US3312046

Folder: Covid-19 Assessment 13 Oct 2020

Form: Symptom Log (5)

Generated On: 26 Nov 2020 10:51:05

[Diarrhea](#)

Audit	User	Time (GMT)
User entered 'None (None)'	Karol Moore (b) (4) (b) (4)	09 Nov 2020 16:41:00

US3312046

Folder: Covid-19 Assessment 13 Oct 2020

Form: Symptom Log (5)

Generated On: 26 Nov 2020 10:51:05

[Sore Throat](#)

Audit	User	Time (GMT)
User entered 'Mild (Mild)'	Karol Moore (b) (4) (b) (4)	09 Nov 2020 16:41:00

US3312046

Folder: Covid-19 Assessment 13 Oct 2020

Form: Symptom Log (6)

Generated On: 26 Nov 2020 10:51:05

[Symptom Day](#)

Audit	User	Time (GMT)
User entered 'Day 6 (Day 6)'	Karol Moore (b) (4) (b) (4)	09 Nov 2020 16:41:30

**US3312046**

**Folder: Covid-19 Assessment 13 Oct 2020**

**Form: Symptom Log (6)**

**Generated On: 26 Nov 2020 10:51:05**

[Date](#)

Audit	User	Time (GMT)
User entered '12 Oct 2020'	Karol Moore (b) (4) (b) (4)	09 Nov 2020 16:41:30

US3312046

Folder: Covid-19 Assessment 13 Oct 2020

Form: Symptom Log (6)

Generated On: 26 Nov 2020 10:51:05

[Assessment Not Done](#)

Audit	User	Time (GMT)
User entered '0'	Karol Moore (b) (4) (b) (4)	09 Nov 2020 16:41:30

US3312046

Folder: Covid-19 Assessment 13 Oct 2020

Form: Symptom Log (6)

Generated On: 26 Nov 2020 10:51:05

[O2 Saturation](#)

Audit	User	Time (GMT)
User entered empty.	Karol Moore (b) (4) (b) (4)	09 Nov 2020 16:41:30

**US3312046**

**Folder: Covid-19 Assessment 13 Oct 2020**

**Form: Symptom Log (6)**

**Generated On: 26 Nov 2020 10:51:05**

[O2 Saturation Units](#)

Audit	User	Time (GMT)
User entered empty.	System	09 Nov 2020 16:41:30

US3312046

Folder: Covid-19 Assessment 13 Oct 2020

Form: Symptom Log (6)

Generated On: 26 Nov 2020 10:51:05

[Temperature](#)

Audit	User	Time (GMT)
User entered empty.	Karol Moore (b) (4) (b) (4)	09 Nov 2020 16:41:30



US3312046

Folder: Covid-19 Assessment 13 Oct 2020

Form: Symptom Log (6)

Generated On: 26 Nov 2020 10:51:05

[Chills](#)

Audit	User	Time (GMT)
User entered 'None (None)'	Karol Moore (b) (4) (b) (4)	09 Nov 2020 16:41:30

US3312046

Folder: Covid-19 Assessment 13 Oct 2020

Form: Symptom Log (6)

Generated On: 26 Nov 2020 10:51:05

[Cough](#)

Audit	User	Time (GMT)
User entered 'None (None)'	Karol Moore (b) (4) (b) (4)	09 Nov 2020 16:41:30

US3312046

Folder: Covid-19 Assessment 13 Oct 2020

Form: Symptom Log (6)

Generated On: 26 Nov 2020 10:51:05

[Shortness of Breath](#)

Audit	User	Time (GMT)
User entered 'None (None)'	Karol Moore (b) (4) (b) (4)	09 Nov 2020 16:41:30

US3312046

Folder: Covid-19 Assessment 13 Oct 2020

Form: Symptom Log (6)

Generated On: 26 Nov 2020 10:51:05

[Difficulty Breathing](#)

Audit	User	Time (GMT)
User entered 'None (None)'	Karol Moore (b) (4) (b) (4)	09 Nov 2020 16:41:30

US3312046

Folder: Covid-19 Assessment 13 Oct 2020

Form: Symptom Log (6)

Generated On: 26 Nov 2020 10:51:05

[Fatigue](#)

Audit	User	Time (GMT)
User entered 'Mild (Mild)'	Karol Moore (b) (4) (b) (4)	09 Nov 2020 16:41:30

US3312046

Folder: Covid-19 Assessment 13 Oct 2020

Form: Symptom Log (6)

Generated On: 26 Nov 2020 10:51:05

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
User entered 'None (None)'	Karol Moore (b) (4) (b) (4)	09 Nov 2020 16:41:30

US3312046

Folder: Covid-19 Assessment 13 Oct 2020

Form: Symptom Log (6)

Generated On: 26 Nov 2020 10:51:05

[Body Aches](#)

Audit	User	Time (GMT)
User entered 'None (None)'	Karol Moore (b) (4) (b) (4)	09 Nov 2020 16:41:30

US3312046

Folder: Covid-19 Assessment 13 Oct 2020

Form: Symptom Log (6)

Generated On: 26 Nov 2020 10:51:05

[Headache](#)

Audit	User	Time (GMT)
User entered 'None (None)'	Karol Moore (b) (4) (b) (4)	09 Nov 2020 16:41:30



US3312046

Folder: Covid-19 Assessment 13 Oct 2020

Form: Symptom Log (6)

Generated On: 26 Nov 2020 10:51:05

[New Loss of Taste](#)

Audit	User	Time (GMT)
User entered 'None (None)'	Karol Moore (b) (4) (b) (4)	09 Nov 2020 16:41:30

US3312046

Folder: Covid-19 Assessment 13 Oct 2020

Form: Symptom Log (6)

Generated On: 26 Nov 2020 10:51:05

[New Loss of Smell](#)

Audit	User	Time (GMT)
User entered 'None (None)'	Karol Moore (b) (4) (b) (4)	09 Nov 2020 16:41:30

US3312046

Folder: Covid-19 Assessment 13 Oct 2020

Form: Symptom Log (6)

Generated On: 26 Nov 2020 10:51:05

[Nasal Congestion](#)

Audit	User	Time (GMT)
User entered 'None (None)'	Karol Moore (b) (4) (b) (4)	09 Nov 2020 16:41:30

US3312046

Folder: Covid-19 Assessment 13 Oct 2020

Form: Symptom Log (6)

Generated On: 26 Nov 2020 10:51:05

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
User entered 'None (None)'	Karol Moore (b) (4) (b) (4)	09 Nov 2020 16:41:30

US3312046

Folder: Covid-19 Assessment 13 Oct 2020

Form: Symptom Log (6)

Generated On: 26 Nov 2020 10:51:05

[Nausea](#)

Audit	User	Time (GMT)
User entered 'Mild (Mild)'	Karol Moore (b) (4) (b) (4)	09 Nov 2020 16:41:30

US3312046

Folder: Covid-19 Assessment 13 Oct 2020

Form: Symptom Log (6)

Generated On: 26 Nov 2020 10:51:05

[Vomiting](#)

Audit	User	Time (GMT)
User entered 'None (None)'	Karol Moore (b) (4) (b) (4)	09 Nov 2020 16:41:30

US3312046

Folder: Covid-19 Assessment 13 Oct 2020

Form: Symptom Log (6)

Generated On: 26 Nov 2020 10:51:05

[Diarrhea](#)

Audit	User	Time (GMT)
User entered 'None (None)'	Karol Moore (b) (4) (b) (4)	09 Nov 2020 16:41:30

US3312046

Folder: Covid-19 Assessment 13 Oct 2020

Form: Symptom Log (6)

Generated On: 26 Nov 2020 10:51:05

[Sore Throat](#)

Audit	User	Time (GMT)
User entered 'Mild (Mild)'	Karol Moore (b) (4) (b) (4)	09 Nov 2020 16:41:30



US3312046

Folder: Covid-19 Assessment 13 Oct 2020

Form: Symptom Log (7)

Generated On: 26 Nov 2020 10:51:05

[Symptom Day](#)

Audit	User	Time (GMT)
User entered 'Day 7 (Day 7)'	Karol Moore (b) (4) (b) (4)	09 Nov 2020 16:41:49

US3312046

Folder: Covid-19 Assessment 13 Oct 2020

Form: Symptom Log (7)

Generated On: 26 Nov 2020 10:51:05

[Date](#)

Audit	User	Time (GMT)
User entered '13 Oct 2020'	Karol Moore (b) (4) (b) (4)	09 Nov 2020 16:41:49

**US3312046**

**Folder: Covid-19 Assessment 13 Oct 2020**

**Form: Symptom Log (7)**

**Generated On: 26 Nov 2020 10:51:05**

[Assessment Not Done](#)

Audit	User	Time (GMT)
User entered '0'	Karol Moore (b) (4) (b) (4)	09 Nov 2020 16:41:49

US3312046

Folder: Covid-19 Assessment 13 Oct 2020

Form: Symptom Log (7)

Generated On: 26 Nov 2020 10:51:05

[O2 Saturation](#)

Audit	User	Time (GMT)
User entered empty.	Karol Moore (b) (4) (b) (4)	09 Nov 2020 16:41:49

**US3312046**

**Folder: Covid-19 Assessment 13 Oct 2020**

**Form: Symptom Log (7)**

**Generated On: 26 Nov 2020 10:51:05**

[O2 Saturation Units](#)

Audit	User	Time (GMT)
User entered empty.	System	09 Nov 2020 16:41:49

US3312046

Folder: Covid-19 Assessment 13 Oct 2020

Form: Symptom Log (7)

Generated On: 26 Nov 2020 10:51:05

[Temperature](#)

Audit	User	Time (GMT)
User entered empty.	Karol Moore (b) (4) (b) (4)	09 Nov 2020 16:41:49

US3312046

Folder: Covid-19 Assessment 13 Oct 2020

Form: Symptom Log (7)

Generated On: 26 Nov 2020 10:51:05

[Chills](#)

Audit	User	Time (GMT)
User entered 'None (None)'	Karol Moore (b) (4) (b) (4)	09 Nov 2020 16:41:49

US3312046

Folder: Covid-19 Assessment 13 Oct 2020

Form: Symptom Log (7)

Generated On: 26 Nov 2020 10:51:05

[Cough](#)

Audit	User	Time (GMT)
User entered 'None (None)'	Karol Moore (b) (4) (b) (4)	09 Nov 2020 16:41:49



US3312046

Folder: Covid-19 Assessment 13 Oct 2020

Form: Symptom Log (7)

Generated On: 26 Nov 2020 10:51:05

[Shortness of Breath](#)

Audit	User	Time (GMT)
User entered 'None (None)'	Karol Moore (b) (4) (b) (4)	09 Nov 2020 16:41:49

US3312046

Folder: Covid-19 Assessment 13 Oct 2020

Form: Symptom Log (7)

Generated On: 26 Nov 2020 10:51:05

[Difficulty Breathing](#)

Audit	User	Time (GMT)
User entered 'None (None)'	Karol Moore (b) (4) (b) (4)	09 Nov 2020 16:41:49

US3312046

Folder: Covid-19 Assessment 13 Oct 2020

Form: Symptom Log (7)

Generated On: 26 Nov 2020 10:51:05

[Fatigue](#)

Audit	User	Time (GMT)
User entered 'Mild (Mild)'	Karol Moore (b) (4) (b) (4)	09 Nov 2020 16:41:49

US3312046

Folder: Covid-19 Assessment 13 Oct 2020

Form: Symptom Log (7)

Generated On: 26 Nov 2020 10:51:05

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
User entered 'None (None)'	Karol Moore (b) (4) (b) (4)	09 Nov 2020 16:41:49

US3312046

Folder: Covid-19 Assessment 13 Oct 2020

Form: Symptom Log (7)

Generated On: 26 Nov 2020 10:51:05

[Body Aches](#)

Audit	User	Time (GMT)
User entered 'None (None)'	Karol Moore (b) (4) (b) (4)	09 Nov 2020 16:41:49

US3312046

Folder: Covid-19 Assessment 13 Oct 2020

Form: Symptom Log (7)

Generated On: 26 Nov 2020 10:51:05

[Headache](#)

Audit	User	Time (GMT)
User entered 'None (None)'	Karol Moore (b) (4) (b) (4)	09 Nov 2020 16:41:49

US3312046

Folder: Covid-19 Assessment 13 Oct 2020

Form: Symptom Log (7)

Generated On: 26 Nov 2020 10:51:05

[New Loss of Taste](#)

Audit	User	Time (GMT)
User entered 'None (None)'	Karol Moore (b) (4) (b) (4)	09 Nov 2020 16:41:49

US3312046

Folder: Covid-19 Assessment 13 Oct 2020

Form: Symptom Log (7)

Generated On: 26 Nov 2020 10:51:05

[New Loss of Smell](#)

Audit	User	Time (GMT)
User entered 'None (None)'	Karol Moore (b) (4) (b) (4)	09 Nov 2020 16:41:49



US3312046

Folder: Covid-19 Assessment 13 Oct 2020

Form: Symptom Log (7)

Generated On: 26 Nov 2020 10:51:05

[Nasal Congestion](#)

Audit	User	Time (GMT)
User entered 'None (None)'	Karol Moore (b) (4) (b) (4)	09 Nov 2020 16:41:49

US3312046

Folder: Covid-19 Assessment 13 Oct 2020

Form: Symptom Log (7)

Generated On: 26 Nov 2020 10:51:05

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
User entered 'None (None)'	Karol Moore (b) (4) (b) (4)	09 Nov 2020 16:41:49

US3312046

Folder: Covid-19 Assessment 13 Oct 2020

Form: Symptom Log (7)

Generated On: 26 Nov 2020 10:51:05

[Nausea](#)

Audit	User	Time (GMT)
User entered 'Mild (Mild)'	Karol Moore (b) (4) (b) (4)	09 Nov 2020 16:41:49

US3312046

Folder: Covid-19 Assessment 13 Oct 2020

Form: Symptom Log (7)

Generated On: 26 Nov 2020 10:51:05

[Vomiting](#)

Audit	User	Time (GMT)
User entered 'None (None)'	Karol Moore (b) (4) (b) (4)	09 Nov 2020 16:41:49

US3312046

Folder: Covid-19 Assessment 13 Oct 2020

Form: Symptom Log (7)

Generated On: 26 Nov 2020 10:51:05

[Diarrhea](#)

Audit	User	Time (GMT)
User entered 'None (None)'	Karol Moore (b) (4) (b) (4)	09 Nov 2020 16:41:49

US3312046

Folder: Covid-19 Assessment 13 Oct 2020

Form: Symptom Log (7)

Generated On: 26 Nov 2020 10:51:05

[Sore Throat](#)

Audit	User	Time (GMT)
User entered 'Mild (Mild)'	Karol Moore (b) (4) (b) (4)	09 Nov 2020 16:41:49

US3312046

Folder: Covid-19 Assessment 13 Oct 2020

Form: Symptom Log (8)

Generated On: 26 Nov 2020 10:51:05

[Symptom Day](#)

Audit	User	Time (GMT)
User entered 'Day 8 (Day 8)'	Karol Moore (b) (4) (b) (4)	09 Nov 2020 16:42:12

**US3312046**

**Folder: Covid-19 Assessment 13 Oct 2020**

**Form: Symptom Log (8)**

**Generated On: 26 Nov 2020 10:51:05**

[Date](#)

Audit	User	Time (GMT)
User entered '14 Oct 2020'	Karol Moore (b) (4) (b) (4)	09 Nov 2020 16:42:12



US3312046

Folder: Covid-19 Assessment 13 Oct 2020

Form: Symptom Log (8)

Generated On: 26 Nov 2020 10:51:05

[Assessment Not Done](#)

Audit	User	Time (GMT)
User entered '0'	Karol Moore (b) (4) (b) (4)	09 Nov 2020 16:42:12

US3312046

Folder: Covid-19 Assessment 13 Oct 2020

Form: Symptom Log (8)

Generated On: 26 Nov 2020 10:51:05

[O2 Saturation](#)

Audit	User	Time (GMT)
User entered empty.	Karol Moore (b) (4) (b) (4)	09 Nov 2020 16:42:12

**US3312046**

**Folder: Covid-19 Assessment 13 Oct 2020**

**Form: Symptom Log (8)**

**Generated On: 26 Nov 2020 10:51:05**

[O2 Saturation Units](#)

Audit	User	Time (GMT)
User entered empty.	System	09 Nov 2020 16:42:12

US3312046

Folder: Covid-19 Assessment 13 Oct 2020

Form: Symptom Log (8)

Generated On: 26 Nov 2020 10:51:05

[Temperature](#)

Audit	User	Time (GMT)
User entered empty.	Karol Moore (b) (4) (b) (4)	09 Nov 2020 16:42:12

US3312046

Folder: Covid-19 Assessment 13 Oct 2020

Form: Symptom Log (8)

Generated On: 26 Nov 2020 10:51:05

[Chills](#)

Audit	User	Time (GMT)
User entered 'None (None)'	Karol Moore (b) (4) (b) (4)	09 Nov 2020 16:42:12

US3312046

Folder: Covid-19 Assessment 13 Oct 2020

Form: Symptom Log (8)

Generated On: 26 Nov 2020 10:51:05

[Cough](#)

Audit	User	Time (GMT)
User entered 'None (None)'	Karol Moore (b) (4) (b) (4)	09 Nov 2020 16:42:12

US3312046

Folder: Covid-19 Assessment 13 Oct 2020

Form: Symptom Log (8)

Generated On: 26 Nov 2020 10:51:05

[Shortness of Breath](#)

Audit	User	Time (GMT)
User entered 'None (None)'	Karol Moore (b) (4) (b) (4)	09 Nov 2020 16:42:12

US3312046

Folder: Covid-19 Assessment 13 Oct 2020

Form: Symptom Log (8)

Generated On: 26 Nov 2020 10:51:05

[Difficulty Breathing](#)

Audit	User	Time (GMT)
User entered 'None (None)'	Karol Moore (b) (4) (b) (4)	09 Nov 2020 16:42:12



US3312046

Folder: Covid-19 Assessment 13 Oct 2020

Form: Symptom Log (8)

Generated On: 26 Nov 2020 10:51:05

[Fatigue](#)

Audit	User	Time (GMT)
User entered 'Mild (Mild)'	Karol Moore (b) (4) (b) (4)	09 Nov 2020 16:42:12

US3312046

Folder: Covid-19 Assessment 13 Oct 2020

Form: Symptom Log (8)

Generated On: 26 Nov 2020 10:51:05

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
User entered 'None (None)'	Karol Moore (b) (4) (b) (4)	09 Nov 2020 16:42:12

US3312046

Folder: Covid-19 Assessment 13 Oct 2020

Form: Symptom Log (8)

Generated On: 26 Nov 2020 10:51:05

[Body Aches](#)

Audit	User	Time (GMT)
User entered 'None (None)'	Karol Moore (b) (4) (b) (4)	09 Nov 2020 16:42:12

US3312046

Folder: Covid-19 Assessment 13 Oct 2020

Form: Symptom Log (8)

Generated On: 26 Nov 2020 10:51:05

[Headache](#)

Audit	User	Time (GMT)
User entered 'None (None)'	Karol Moore (b) (4) (b) (4)	09 Nov 2020 16:42:12

US3312046

Folder: Covid-19 Assessment 13 Oct 2020

Form: Symptom Log (8)

Generated On: 26 Nov 2020 10:51:05

[New Loss of Taste](#)

Audit	User	Time (GMT)
User entered 'None (None)'	Karol Moore (b) (4) (b) (4)	09 Nov 2020 16:42:12

US3312046

Folder: Covid-19 Assessment 13 Oct 2020

Form: Symptom Log (8)

Generated On: 26 Nov 2020 10:51:05

[New Loss of Smell](#)

Audit	User	Time (GMT)
User entered 'None (None)'	Karol Moore (b) (4) (b) (4)	09 Nov 2020 16:42:12

US3312046

Folder: Covid-19 Assessment 13 Oct 2020

Form: Symptom Log (8)

Generated On: 26 Nov 2020 10:51:05

[Nasal Congestion](#)

Audit	User	Time (GMT)
User entered 'None (None)'	Karol Moore (b) (4) (b) (4)	09 Nov 2020 16:42:12

US3312046

Folder: Covid-19 Assessment 13 Oct 2020

Form: Symptom Log (8)

Generated On: 26 Nov 2020 10:51:05

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
User entered 'None (None)'	Karol Moore (b) (4) (b) (4)	09 Nov 2020 16:42:12



US3312046

Folder: Covid-19 Assessment 13 Oct 2020

Form: Symptom Log (8)

Generated On: 26 Nov 2020 10:51:05

[Nausea](#)

Audit	User	Time (GMT)
User entered 'Mild (Mild)'	Karol Moore (b) (4) (b) (4)	09 Nov 2020 16:42:12

US3312046

Folder: Covid-19 Assessment 13 Oct 2020

Form: Symptom Log (8)

Generated On: 26 Nov 2020 10:51:05

[Vomiting](#)

Audit	User	Time (GMT)
User entered 'None (None)'	Karol Moore (b) (4) (b) (4)	09 Nov 2020 16:42:12

US3312046

Folder: Covid-19 Assessment 13 Oct 2020

Form: Symptom Log (8)

Generated On: 26 Nov 2020 10:51:05

[Diarrhea](#)

Audit	User	Time (GMT)
User entered 'None (None)'	Karol Moore (b) (4) (b) (4)	09 Nov 2020 16:42:12

US3312046

Folder: Covid-19 Assessment 13 Oct 2020

Form: Symptom Log (8)

Generated On: 26 Nov 2020 10:51:05

[Sore Throat](#)

Audit	User	Time (GMT)
User entered 'Mild (Mild)'	Karol Moore (b) (4) (b) (4)	09 Nov 2020 16:42:12

US3312046

Folder: Covid-19 Assessment 13 Oct 2020

Form: Symptom Log (9)

Generated On: 26 Nov 2020 10:51:05

[Symptom Day](#)

Audit	User	Time (GMT)
User entered 'Day 9 (Day 9)'	Karol Moore (b) (4) (b) (4)	09 Nov 2020 16:42:36

US3312046

Folder: Covid-19 Assessment 13 Oct 2020

Form: Symptom Log (9)

Generated On: 26 Nov 2020 10:51:05

[Date](#)

Audit	User	Time (GMT)
User entered '15 Oct 2020'	Karol Moore (b) (4) (b) (4)	09 Nov 2020 16:42:36

US3312046

Folder: Covid-19 Assessment 13 Oct 2020

Form: Symptom Log (9)

Generated On: 26 Nov 2020 10:51:05

[Assessment Not Done](#)

Audit	User	Time (GMT)
User entered '0'	Karol Moore (b) (4) (b) (4)	09 Nov 2020 16:42:36

US3312046

Folder: Covid-19 Assessment 13 Oct 2020

Form: Symptom Log (9)

Generated On: 26 Nov 2020 10:51:05

[O2 Saturation](#)

Audit	User	Time (GMT)
User entered empty.	Karol Moore (b) (4) (b) (4)	09 Nov 2020 16:42:36



**US3312046**

**Folder: Covid-19 Assessment 13 Oct 2020**

**Form: Symptom Log (9)**

**Generated On: 26 Nov 2020 10:51:05**

[O2 Saturation Units](#)

Audit	User	Time (GMT)
User entered empty.	System	09 Nov 2020 16:42:36

US3312046

Folder: Covid-19 Assessment 13 Oct 2020

Form: Symptom Log (9)

Generated On: 26 Nov 2020 10:51:05

[Temperature](#)

Audit	User	Time (GMT)
User entered empty.	Karol Moore (b) (4) (b) (4)	09 Nov 2020 16:42:36

US3312046

Folder: Covid-19 Assessment 13 Oct 2020

Form: Symptom Log (9)

Generated On: 26 Nov 2020 10:51:05

[Chills](#)

Audit	User	Time (GMT)
User entered 'None (None)'	Karol Moore (b) (4) (b) (4)	09 Nov 2020 16:42:36

US3312046

Folder: Covid-19 Assessment 13 Oct 2020

Form: Symptom Log (9)

Generated On: 26 Nov 2020 10:51:05

[Cough](#)

Audit	User	Time (GMT)
User entered 'None (None)'	Karol Moore (b) (4) (b) (4)	09 Nov 2020 16:42:36

US3312046

Folder: Covid-19 Assessment 13 Oct 2020

Form: Symptom Log (9)

Generated On: 26 Nov 2020 10:51:05

[Shortness of Breath](#)

Audit	User	Time (GMT)
User entered 'None (None)'	Karol Moore (b) (4) (b) (4)	09 Nov 2020 16:42:36

US3312046

Folder: Covid-19 Assessment 13 Oct 2020

Form: Symptom Log (9)

Generated On: 26 Nov 2020 10:51:05

[Difficulty Breathing](#)

Audit	User	Time (GMT)
User entered 'None (None)'	Karol Moore (b) (4) (b) (4)	09 Nov 2020 16:42:36

US3312046

Folder: Covid-19 Assessment 13 Oct 2020

Form: Symptom Log (9)

Generated On: 26 Nov 2020 10:51:05

[Fatigue](#)

Audit	User	Time (GMT)
User entered 'Mild (Mild)'	Karol Moore (b) (4) (b) (4)	09 Nov 2020 16:42:36

US3312046

Folder: Covid-19 Assessment 13 Oct 2020

Form: Symptom Log (9)

Generated On: 26 Nov 2020 10:51:05

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
User entered 'None (None)'	Karol Moore (b) (4) (b) (4)	09 Nov 2020 16:42:36



US3312046

Folder: Covid-19 Assessment 13 Oct 2020

Form: Symptom Log (9)

Generated On: 26 Nov 2020 10:51:05

[Body Aches](#)

Audit	User	Time (GMT)
User entered 'None (None)'	Karol Moore (b) (4) (b) (4)	09 Nov 2020 16:42:36

US3312046

Folder: Covid-19 Assessment 13 Oct 2020

Form: Symptom Log (9)

Generated On: 26 Nov 2020 10:51:05

[Headache](#)

Audit	User	Time (GMT)
User entered 'None (None)'	Karol Moore (b) (4) (b) (4)	09 Nov 2020 16:42:36

US3312046

Folder: Covid-19 Assessment 13 Oct 2020

Form: Symptom Log (9)

Generated On: 26 Nov 2020 10:51:05

[New Loss of Taste](#)

Audit	User	Time (GMT)
User entered 'None (None)'	Karol Moore (b) (4) (b) (4)	09 Nov 2020 16:42:36

US3312046

Folder: Covid-19 Assessment 13 Oct 2020

Form: Symptom Log (9)

Generated On: 26 Nov 2020 10:51:05

[New Loss of Smell](#)

Audit	User	Time (GMT)
User entered 'None (None)'	Karol Moore (b) (4) (b) (4)	09 Nov 2020 16:42:36

US3312046

Folder: Covid-19 Assessment 13 Oct 2020

Form: Symptom Log (9)

Generated On: 26 Nov 2020 10:51:05

[Nasal Congestion](#)

Audit	User	Time (GMT)
User entered 'None (None)'	Karol Moore (b) (4) (b) (4)	09 Nov 2020 16:42:36

US3312046

Folder: Covid-19 Assessment 13 Oct 2020

Form: Symptom Log (9)

Generated On: 26 Nov 2020 10:51:05

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
User entered 'None (None)'	Karol Moore (b) (4) (b) (4)	09 Nov 2020 16:42:36

US3312046

Folder: Covid-19 Assessment 13 Oct 2020

Form: Symptom Log (9)

Generated On: 26 Nov 2020 10:51:05

[Nausea](#)

Audit	User	Time (GMT)
User entered 'Mild (Mild)'	Karol Moore (b) (4) (b) (4)	09 Nov 2020 16:42:36

US3312046

Folder: Covid-19 Assessment 13 Oct 2020

Form: Symptom Log (9)

Generated On: 26 Nov 2020 10:51:05

[Vomiting](#)

Audit	User	Time (GMT)
User entered 'None (None)'	Karol Moore (b) (4) (b) (4)	09 Nov 2020 16:42:36



US3312046

Folder: Covid-19 Assessment 13 Oct 2020

Form: Symptom Log (9)

Generated On: 26 Nov 2020 10:51:05

[Diarrhea](#)

Audit	User	Time (GMT)
User entered 'None (None)'	Karol Moore (b) (4) (b) (4)	09 Nov 2020 16:42:36

US3312046

Folder: Covid-19 Assessment 13 Oct 2020

Form: Symptom Log (9)

Generated On: 26 Nov 2020 10:51:05

[Sore Throat](#)

Audit	User	Time (GMT)
User entered 'Mild (Mild)'	Karol Moore (b) (4) (b) (4)	09 Nov 2020 16:42:36

US3312046

Folder: Covid-19 Assessment 13 Oct 2020

Form: Symptom Log (10)

Generated On: 26 Nov 2020 10:51:05

[Symptom Day](#)

Audit	User	Time (GMT)
User entered 'Day 10 (Day 10)'	Karol Moore (b) (4) (b) (4)	09 Nov 2020 16:43:00

US3312046

Folder: Covid-19 Assessment 13 Oct 2020

Form: Symptom Log (10)

Generated On: 26 Nov 2020 10:51:05

[Date](#)

Audit	User	Time (GMT)
User entered '16 Oct 2020'	Karol Moore (b) (4) (b) (4)	09 Nov 2020 16:43:00

US3312046

Folder: Covid-19 Assessment 13 Oct 2020

Form: Symptom Log (10)

Generated On: 26 Nov 2020 10:51:05

[Assessment Not Done](#)

Audit	User	Time (GMT)
User entered '0'	Karol Moore (b) (4) (b) (4)	09 Nov 2020 16:43:00

US3312046

Folder: Covid-19 Assessment 13 Oct 2020

Form: Symptom Log (10)

Generated On: 26 Nov 2020 10:51:05

[O2 Saturation](#)

Audit	User	Time (GMT)
User entered '99'	Karol Moore (b) (4) (b) (4)	09 Nov 2020 16:43:00

**US3312046**

**Folder: Covid-19 Assessment 13 Oct 2020**

**Form: Symptom Log (10)**

**Generated On: 26 Nov 2020 10:51:05**

[O2 Saturation Units](#)

Audit	User	Time (GMT)
User entered '%'	System	09 Nov 2020 16:43:00

US3312046

Folder: Covid-19 Assessment 13 Oct 2020

Form: Symptom Log (10)

Generated On: 26 Nov 2020 10:51:05

[Temperature](#)

Audit	User	Time (GMT)
User entered '97.2' F	Karol Moore (b) (4) (b) (4)	09 Nov 2020 16:43:00



US3312046

Folder: Covid-19 Assessment 13 Oct 2020

Form: Symptom Log (10)

Generated On: 26 Nov 2020 10:51:05

[Chills](#)

Audit	User	Time (GMT)
User entered 'None (None)'	Karol Moore (b) (4) (b) (4)	09 Nov 2020 16:43:00

US3312046

Folder: Covid-19 Assessment 13 Oct 2020

Form: Symptom Log (10)

Generated On: 26 Nov 2020 10:51:05

[Cough](#)

Audit	User	Time (GMT)
User entered 'None (None)'	Karol Moore (b) (4) (b) (4)	09 Nov 2020 16:43:00

US3312046

Folder: Covid-19 Assessment 13 Oct 2020

Form: Symptom Log (10)

Generated On: 26 Nov 2020 10:51:05

[Shortness of Breath](#)

Audit	User	Time (GMT)
User entered 'None (None)'	Karol Moore (b) (4) (b) (4)	09 Nov 2020 16:43:00

US3312046

Folder: Covid-19 Assessment 13 Oct 2020

Form: Symptom Log (10)

Generated On: 26 Nov 2020 10:51:05

[Difficulty Breathing](#)

Audit	User	Time (GMT)
User entered 'None (None)'	Karol Moore (b) (4) (b) (4)	09 Nov 2020 16:43:00

US3312046

Folder: Covid-19 Assessment 13 Oct 2020

Form: Symptom Log (10)

Generated On: 26 Nov 2020 10:51:05

[Fatigue](#)

Audit	User	Time (GMT)
User entered 'Mild (Mild)'	Karol Moore (b) (4) (b) (4)	09 Nov 2020 16:43:00

US3312046

Folder: Covid-19 Assessment 13 Oct 2020

Form: Symptom Log (10)

Generated On: 26 Nov 2020 10:51:05

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
User entered 'None (None)'	Karol Moore (b) (4) (b) (4)	09 Nov 2020 16:43:00

US3312046

Folder: Covid-19 Assessment 13 Oct 2020

Form: Symptom Log (10)

Generated On: 26 Nov 2020 10:51:05

[Body Aches](#)

Audit	User	Time (GMT)
User entered 'None (None)'	Karol Moore (b) (4) (b) (4)	09 Nov 2020 16:43:00

US3312046

Folder: Covid-19 Assessment 13 Oct 2020

Form: Symptom Log (10)

Generated On: 26 Nov 2020 10:51:05

[Headache](#)

Audit	User	Time (GMT)
User entered 'None (None)'	Karol Moore (b) (4) (b) (4)	09 Nov 2020 16:43:00



US3312046

Folder: Covid-19 Assessment 13 Oct 2020

Form: Symptom Log (10)

Generated On: 26 Nov 2020 10:51:05

[New Loss of Taste](#)

Audit	User	Time (GMT)
User entered 'None (None)'	Karol Moore (b) (4) (b) (4)	09 Nov 2020 16:43:00

US3312046

Folder: Covid-19 Assessment 13 Oct 2020

Form: Symptom Log (10)

Generated On: 26 Nov 2020 10:51:05

[New Loss of Smell](#)

Audit	User	Time (GMT)
User entered 'None (None)'	Karol Moore (b) (4) (b) (4)	09 Nov 2020 16:43:00

US3312046

Folder: Covid-19 Assessment 13 Oct 2020

Form: Symptom Log (10)

Generated On: 26 Nov 2020 10:51:05

[Nasal Congestion](#)

Audit	User	Time (GMT)
User entered 'None (None)'	Karol Moore (b) (4) (b) (4)	09 Nov 2020 16:43:00

US3312046

Folder: Covid-19 Assessment 13 Oct 2020

Form: Symptom Log (10)

Generated On: 26 Nov 2020 10:51:05

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
User entered 'None (None)'	Karol Moore (b) (4) (b) (4)	09 Nov 2020 16:43:00

US3312046

Folder: Covid-19 Assessment 13 Oct 2020

Form: Symptom Log (10)

Generated On: 26 Nov 2020 10:51:05

[Nausea](#)

Audit	User	Time (GMT)
User entered 'Mild (Mild)'	Karol Moore (b) (4) (b) (4)	09 Nov 2020 16:43:00

US3312046

Folder: Covid-19 Assessment 13 Oct 2020

Form: Symptom Log (10)

Generated On: 26 Nov 2020 10:51:05

[Vomiting](#)

Audit	User	Time (GMT)
User entered 'None (None)'	Karol Moore (b) (4) (b) (4)	09 Nov 2020 16:43:00

US3312046

Folder: Covid-19 Assessment 13 Oct 2020

Form: Symptom Log (10)

Generated On: 26 Nov 2020 10:51:05

[Diarrhea](#)

Audit	User	Time (GMT)
User entered 'None (None)'	Karol Moore (b) (4) (b) (4)	09 Nov 2020 16:43:00

US3312046

Folder: Covid-19 Assessment 13 Oct 2020

Form: Symptom Log (10)

Generated On: 26 Nov 2020 10:51:05

[Sore Throat](#)

Audit	User	Time (GMT)
User entered 'Mild (Mild)'	Karol Moore (b) (4) (b) (4)	09 Nov 2020 16:43:00



US3312046

Folder: Covid-19 Assessment 13 Oct 2020

Form: Symptom Log (11)

Generated On: 26 Nov 2020 10:51:05

[Symptom Day](#)

Audit	User	Time (GMT)
User entered 'Day 11 (Day 11)'	Karol Moore (b) (4) (b) (4)	09 Nov 2020 16:43:45

US3312046

Folder: Covid-19 Assessment 13 Oct 2020

Form: Symptom Log (11)

Generated On: 26 Nov 2020 10:51:05

[Date](#)

Audit	User	Time (GMT)
User entered '17 Oct 2020'	Karol Moore (b) (4) (b) (4)	09 Nov 2020 16:43:45

**US3312046**

**Folder: Covid-19 Assessment 13 Oct 2020**

**Form: Symptom Log (11)**

**Generated On: 26 Nov 2020 10:51:05**

[Assessment Not Done](#)

Audit	User	Time (GMT)
User entered '0'	Karol Moore (b) (4) (b) (4)	09 Nov 2020 16:43:45

US3312046

Folder: Covid-19 Assessment 13 Oct 2020

Form: Symptom Log (11)

Generated On: 26 Nov 2020 10:51:05

[O2 Saturation](#)

Audit	User	Time (GMT)
User entered '97'	Karol Moore (b) (4) (b) (4)	09 Nov 2020 16:43:45

**US3312046**

**Folder: Covid-19 Assessment 13 Oct 2020**

**Form: Symptom Log (11)**

**Generated On: 26 Nov 2020 10:51:05**

[O2 Saturation Units](#)

Audit	User	Time (GMT)
User entered '%'	System	09 Nov 2020 16:43:45

US3312046

Folder: Covid-19 Assessment 13 Oct 2020

Form: Symptom Log (11)

Generated On: 26 Nov 2020 10:51:05

[Temperature](#)

Audit	User	Time (GMT)
User entered '96.8' F	Karol Moore (b) (4) (b) (4)	09 Nov 2020 16:43:45

US3312046

Folder: Covid-19 Assessment 13 Oct 2020

Form: Symptom Log (11)

Generated On: 26 Nov 2020 10:51:05

[Chills](#)

Audit	User	Time (GMT)
User entered 'None (None)'	Karol Moore (b) (4) (b) (4)	09 Nov 2020 16:43:45

US3312046

Folder: Covid-19 Assessment 13 Oct 2020

Form: Symptom Log (11)

Generated On: 26 Nov 2020 10:51:05

[Cough](#)

Audit	User	Time (GMT)
User entered 'None (None)'	Karol Moore (b) (4) (b) (4)	09 Nov 2020 16:43:45



US3312046

Folder: Covid-19 Assessment 13 Oct 2020

Form: Symptom Log (11)

Generated On: 26 Nov 2020 10:51:05

[Shortness of Breath](#)

Audit	User	Time (GMT)
User entered 'None (None)'	Karol Moore (b) (4) (b) (4)	09 Nov 2020 16:43:45

US3312046

Folder: Covid-19 Assessment 13 Oct 2020

Form: Symptom Log (11)

Generated On: 26 Nov 2020 10:51:05

[Difficulty Breathing](#)

Audit	User	Time (GMT)
User entered 'None (None)'	Karol Moore (b) (4) (b) (4)	09 Nov 2020 16:43:45

US3312046

Folder: Covid-19 Assessment 13 Oct 2020

Form: Symptom Log (11)

Generated On: 26 Nov 2020 10:51:05

[Fatigue](#)

Audit	User	Time (GMT)
User entered 'Mild (Mild)'	Karol Moore (b) (4) (b) (4)	09 Nov 2020 16:43:45

US3312046

Folder: Covid-19 Assessment 13 Oct 2020

Form: Symptom Log (11)

Generated On: 26 Nov 2020 10:51:05

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
User entered 'None (None)'	Karol Moore (b) (4) (b) (4)	09 Nov 2020 16:43:45

US3312046

Folder: Covid-19 Assessment 13 Oct 2020

Form: Symptom Log (11)

Generated On: 26 Nov 2020 10:51:05

[Body Aches](#)

Audit	User	Time (GMT)
User entered 'None (None)'	Karol Moore (b) (4) (b) (4)	09 Nov 2020 16:43:45

US3312046

Folder: Covid-19 Assessment 13 Oct 2020

Form: Symptom Log (11)

Generated On: 26 Nov 2020 10:51:05

[Headache](#)

Audit	User	Time (GMT)
User entered 'None (None)'	Karol Moore (b) (4) (b) (4)	09 Nov 2020 16:43:45

US3312046

Folder: Covid-19 Assessment 13 Oct 2020

Form: Symptom Log (11)

Generated On: 26 Nov 2020 10:51:05

[New Loss of Taste](#)

Audit	User	Time (GMT)
User entered 'None (None)'	Karol Moore (b) (4) (b) (4)	09 Nov 2020 16:43:45

US3312046

Folder: Covid-19 Assessment 13 Oct 2020

Form: Symptom Log (11)

Generated On: 26 Nov 2020 10:51:05

[New Loss of Smell](#)

Audit	User	Time (GMT)
User entered 'None (None)'	Karol Moore (b) (4) (b) (4)	09 Nov 2020 16:43:45



US3312046

Folder: Covid-19 Assessment 13 Oct 2020

Form: Symptom Log (11)

Generated On: 26 Nov 2020 10:51:05

[Nasal Congestion](#)

Audit	User	Time (GMT)
User entered 'None (None)'	Karol Moore (b) (4) (b) (4)	09 Nov 2020 16:43:45

**US3312046**

**Folder: Covid-19 Assessment 13 Oct 2020**

**Form: Symptom Log (11)**

**Generated On: 26 Nov 2020 10:51:05**

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
User entered 'None (None)'	Karol Moore (b) (4) (b) (4)	09 Nov 2020 16:43:45

US3312046

Folder: Covid-19 Assessment 13 Oct 2020

Form: Symptom Log (11)

Generated On: 26 Nov 2020 10:51:05

[Nausea](#)

Audit	User	Time (GMT)
User entered 'Mild (Mild)'	Karol Moore (b) (4) (b) (4)	09 Nov 2020 16:43:45

US3312046

Folder: Covid-19 Assessment 13 Oct 2020

Form: Symptom Log (11)

Generated On: 26 Nov 2020 10:51:05

[Vomiting](#)

Audit	User	Time (GMT)
User entered 'None (None)'	Karol Moore (b) (4) (b) (4)	09 Nov 2020 16:43:45

US3312046

Folder: Covid-19 Assessment 13 Oct 2020

Form: Symptom Log (11)

Generated On: 26 Nov 2020 10:51:05

[Diarrhea](#)

Audit	User	Time (GMT)
User entered 'None (None)'	Karol Moore (b) (4) (b) (4)	09 Nov 2020 16:43:45

US3312046

Folder: Covid-19 Assessment 13 Oct 2020

Form: Symptom Log (11)

Generated On: 26 Nov 2020 10:51:05

[Sore Throat](#)

Audit	User	Time (GMT)
User entered 'None (None)'	Karol Moore (b) (4) (b) (4)	09 Nov 2020 16:43:45

US3312046

Folder: Covid-19 Assessment 13 Oct 2020

Form: Symptom Log (12)

Generated On: 26 Nov 2020 10:51:05

[Symptom Day](#)

Audit	User	Time (GMT)
User entered 'Day 12 (Day 12)'	Karol Moore (b) (4) (b) (4)	09 Nov 2020 16:44:55

**US3312046**

**Folder: Covid-19 Assessment 13 Oct 2020**

**Form: Symptom Log (12)**

**Generated On: 26 Nov 2020 10:51:05**

[Date](#)

Audit	User	Time (GMT)
User entered '18 Oct 2020'	Karol Moore (b) (4) (b) (4)	09 Nov 2020 16:44:55



**US3312046**

**Folder: Covid-19 Assessment 13 Oct 2020**

**Form: Symptom Log (12)**

**Generated On: 26 Nov 2020 10:51:05**

[Assessment Not Done](#)

Audit	User	Time (GMT)
User entered '0'	Karol Moore (b) (4) (b) (4)	09 Nov 2020 16:44:55

US3312046

Folder: Covid-19 Assessment 13 Oct 2020

Form: Symptom Log (12)

Generated On: 26 Nov 2020 10:51:05

[O2 Saturation](#)

Audit	User	Time (GMT)
User entered '96'	Karol Moore (b) (4) (b) (4)	09 Nov 2020 16:44:55

**US3312046**

**Folder: Covid-19 Assessment 13 Oct 2020**

**Form: Symptom Log (12)**

**Generated On: 26 Nov 2020 10:51:05**

[O2 Saturation Units](#)

Audit	User	Time (GMT)
User entered '%'	System	09 Nov 2020 16:44:55

US3312046

Folder: Covid-19 Assessment 13 Oct 2020

Form: Symptom Log (12)

Generated On: 26 Nov 2020 10:51:05

[Temperature](#)

Audit	User	Time (GMT)
User entered '96.8' F	Karol Moore (b) (4) (b) (4)	09 Nov 2020 16:44:55

US3312046

Folder: Covid-19 Assessment 13 Oct 2020

Form: Symptom Log (12)

Generated On: 26 Nov 2020 10:51:05

[Chills](#)

Audit	User	Time (GMT)
User entered 'None (None)'	Karol Moore (b) (4) (b) (4)	09 Nov 2020 16:44:55

US3312046

Folder: Covid-19 Assessment 13 Oct 2020

Form: Symptom Log (12)

Generated On: 26 Nov 2020 10:51:05

[Cough](#)

Audit	User	Time (GMT)
User entered 'None (None)'	Karol Moore (b) (4) (b) (4)	09 Nov 2020 16:44:55

US3312046

Folder: Covid-19 Assessment 13 Oct 2020

Form: Symptom Log (12)

Generated On: 26 Nov 2020 10:51:05

[Shortness of Breath](#)

Audit	User	Time (GMT)
User entered 'None (None)'	Karol Moore (b) (4) (b) (4)	09 Nov 2020 16:44:55

US3312046

Folder: Covid-19 Assessment 13 Oct 2020

Form: Symptom Log (12)

Generated On: 26 Nov 2020 10:51:05

[Difficulty Breathing](#)

Audit	User	Time (GMT)
User entered 'None (None)'	Karol Moore (b) (4) (b) (4)	09 Nov 2020 16:44:55



US3312046

Folder: Covid-19 Assessment 13 Oct 2020

Form: Symptom Log (12)

Generated On: 26 Nov 2020 10:51:05

[Fatigue](#)

Audit	User	Time (GMT)
User entered 'Mild (Mild)'	Karol Moore (b) (4) (b) (4)	09 Nov 2020 16:44:55

US3312046

Folder: Covid-19 Assessment 13 Oct 2020

Form: Symptom Log (12)

Generated On: 26 Nov 2020 10:51:05

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
User entered 'None (None)'	Karol Moore (b) (4) (b) (4)	09 Nov 2020 16:44:55

US3312046

Folder: Covid-19 Assessment 13 Oct 2020

Form: Symptom Log (12)

Generated On: 26 Nov 2020 10:51:05

[Body Aches](#)

Audit	User	Time (GMT)
User entered 'Mild (Mild)'	Karol Moore (b) (4) (b) (4)	09 Nov 2020 16:44:55

US3312046

Folder: Covid-19 Assessment 13 Oct 2020

Form: Symptom Log (12)

Generated On: 26 Nov 2020 10:51:05

[Headache](#)

Audit	User	Time (GMT)
User entered 'None (None)'	Karol Moore (b) (4) (b) (4)	09 Nov 2020 16:44:55

US3312046

Folder: Covid-19 Assessment 13 Oct 2020

Form: Symptom Log (12)

Generated On: 26 Nov 2020 10:51:05

[New Loss of Taste](#)

Audit	User	Time (GMT)
User entered 'None (None)'	Karol Moore (b) (4) (b) (4)	09 Nov 2020 16:44:55

US3312046

Folder: Covid-19 Assessment 13 Oct 2020

Form: Symptom Log (12)

Generated On: 26 Nov 2020 10:51:05

[New Loss of Smell](#)

Audit	User	Time (GMT)
User entered 'None (None)'	Karol Moore (b) (4) (b) (4)	09 Nov 2020 16:44:55

US3312046

Folder: Covid-19 Assessment 13 Oct 2020

Form: Symptom Log (12)

Generated On: 26 Nov 2020 10:51:05

[Nasal Congestion](#)

Audit	User	Time (GMT)
User entered 'None (None)'	Karol Moore (b) (4) (b) (4)	09 Nov 2020 16:44:55

US3312046

Folder: Covid-19 Assessment 13 Oct 2020

Form: Symptom Log (12)

Generated On: 26 Nov 2020 10:51:05

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
User entered 'Mild (Mild)'	Karol Moore (b) (4) (b) (4)	09 Nov 2020 16:44:55



US3312046

Folder: Covid-19 Assessment 13 Oct 2020

Form: Symptom Log (12)

Generated On: 26 Nov 2020 10:51:05

[Nausea](#)

Audit	User	Time (GMT)
User entered 'Mild (Mild)'	Karol Moore (b) (4) (b) (4)	09 Nov 2020 16:44:55

US3312046

Folder: Covid-19 Assessment 13 Oct 2020

Form: Symptom Log (12)

Generated On: 26 Nov 2020 10:51:05

[Vomiting](#)

Audit	User	Time (GMT)
User entered 'None (None)'	Karol Moore (b) (4) (b) (4)	09 Nov 2020 16:44:55

US3312046

Folder: Covid-19 Assessment 13 Oct 2020

Form: Symptom Log (12)

Generated On: 26 Nov 2020 10:51:05

[Diarrhea](#)

Audit	User	Time (GMT)
User entered 'None (None)'	Karol Moore (b) (4) (b) (4)	09 Nov 2020 16:44:55

US3312046

Folder: Covid-19 Assessment 13 Oct 2020

Form: Symptom Log (12)

Generated On: 26 Nov 2020 10:51:05

[Sore Throat](#)

Audit	User	Time (GMT)
User entered 'None (None)'	Karol Moore (b) (4) (b) (4)	09 Nov 2020 16:44:55

US3312046

Folder: Covid-19 Assessment 13 Oct 2020

Form: Symptom Log (13)

Generated On: 26 Nov 2020 10:51:05

[Symptom Day](#)

Audit	User	Time (GMT)
User entered 'Day 13 (Day 13)'	Karol Moore (b) (4) (b) (4)	09 Nov 2020 16:45:22

**US3312046**

**Folder: Covid-19 Assessment 13 Oct 2020**

**Form: Symptom Log (13)**

**Generated On: 26 Nov 2020 10:51:05**

[Date](#)

Audit	User	Time (GMT)
User entered '19 Oct 2020'	Karol Moore (b) (4) (b) (4)	09 Nov 2020 16:45:22

US3312046

Folder: Covid-19 Assessment 13 Oct 2020

Form: Symptom Log (13)

Generated On: 26 Nov 2020 10:51:05

[Assessment Not Done](#)

Audit	User	Time (GMT)
User entered '0'	Karol Moore (b) (4) (b) (4)	09 Nov 2020 16:45:22

US3312046

Folder: Covid-19 Assessment 13 Oct 2020

Form: Symptom Log (13)

Generated On: 26 Nov 2020 10:51:05

[O2 Saturation](#)

Audit	User	Time (GMT)
User entered '96'	Karol Moore (b) (4) (b) (4)	09 Nov 2020 16:45:22



**US3312046**

**Folder: Covid-19 Assessment 13 Oct 2020**

**Form: Symptom Log (13)**

**Generated On: 26 Nov 2020 10:51:05**

[O2 Saturation Units](#)

Audit	User	Time (GMT)
User entered '%'	System	09 Nov 2020 16:45:22

US3312046

Folder: Covid-19 Assessment 13 Oct 2020

Form: Symptom Log (13)

Generated On: 26 Nov 2020 10:51:05

[Temperature](#)

Audit	User	Time (GMT)
User entered '96.8' F	Karol Moore (b) (4) (b) (4)	09 Nov 2020 16:45:22

US3312046

Folder: Covid-19 Assessment 13 Oct 2020

Form: Symptom Log (13)

Generated On: 26 Nov 2020 10:51:05

[Chills](#)

Audit	User	Time (GMT)
User entered 'None (None)'	Karol Moore (b) (4) (b) (4)	09 Nov 2020 16:45:22

US3312046

Folder: Covid-19 Assessment 13 Oct 2020

Form: Symptom Log (13)

Generated On: 26 Nov 2020 10:51:05

[Cough](#)

Audit	User	Time (GMT)
User entered 'None (None)'	Karol Moore (b) (4) (b) (4)	09 Nov 2020 16:45:22

US3312046

Folder: Covid-19 Assessment 13 Oct 2020

Form: Symptom Log (13)

Generated On: 26 Nov 2020 10:51:05

[Shortness of Breath](#)

Audit	User	Time (GMT)
User entered 'None (None)'	Karol Moore (b) (4) (b) (4)	09 Nov 2020 16:45:22

US3312046

Folder: Covid-19 Assessment 13 Oct 2020

Form: Symptom Log (13)

Generated On: 26 Nov 2020 10:51:05

[Difficulty Breathing](#)

Audit	User	Time (GMT)
User entered 'None (None)'	Karol Moore (b) (4) (b) (4)	09 Nov 2020 16:45:22

US3312046

Folder: Covid-19 Assessment 13 Oct 2020

Form: Symptom Log (13)

Generated On: 26 Nov 2020 10:51:05

[Fatigue](#)

Audit	User	Time (GMT)
User entered 'Mild (Mild)'	Karol Moore (b) (4) (b) (4)	09 Nov 2020 16:45:22

US3312046

Folder: Covid-19 Assessment 13 Oct 2020

Form: Symptom Log (13)

Generated On: 26 Nov 2020 10:51:05

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
User entered 'None (None)'	Karol Moore (b) (4) (b) (4)	09 Nov 2020 16:45:22



US3312046

Folder: Covid-19 Assessment 13 Oct 2020

Form: Symptom Log (13)

Generated On: 26 Nov 2020 10:51:05

[Body Aches](#)

Audit	User	Time (GMT)
User entered 'None (None)'	Karol Moore (b) (4) (b) (4)	09 Nov 2020 16:45:22

US3312046

Folder: Covid-19 Assessment 13 Oct 2020

Form: Symptom Log (13)

Generated On: 26 Nov 2020 10:51:05

[Headache](#)

Audit	User	Time (GMT)
User entered 'None (None)'	Karol Moore (b) (4) (b) (4)	09 Nov 2020 16:45:22

US3312046

Folder: Covid-19 Assessment 13 Oct 2020

Form: Symptom Log (13)

Generated On: 26 Nov 2020 10:51:05

[New Loss of Taste](#)

Audit	User	Time (GMT)
User entered 'None (None)'	Karol Moore (b) (4) (b) (4)	09 Nov 2020 16:45:22

US3312046

Folder: Covid-19 Assessment 13 Oct 2020

Form: Symptom Log (13)

Generated On: 26 Nov 2020 10:51:05

[New Loss of Smell](#)

Audit	User	Time (GMT)
User entered 'None (None)'	Karol Moore (b) (4) (b) (4)	09 Nov 2020 16:45:22

US3312046

Folder: Covid-19 Assessment 13 Oct 2020

Form: Symptom Log (13)

Generated On: 26 Nov 2020 10:51:05

[Nasal Congestion](#)

Audit	User	Time (GMT)
User entered 'None (None)'	Karol Moore (b) (4) (b) (4)	09 Nov 2020 16:45:22

US3312046

Folder: Covid-19 Assessment 13 Oct 2020

Form: Symptom Log (13)

Generated On: 26 Nov 2020 10:51:05

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
User entered 'Mild (Mild)'	Karol Moore (b) (4) (b) (4)	09 Nov 2020 16:45:22

US3312046

Folder: Covid-19 Assessment 13 Oct 2020

Form: Symptom Log (13)

Generated On: 26 Nov 2020 10:51:05

[Nausea](#)

Audit	User	Time (GMT)
User entered 'None (None)'	Karol Moore (b) (4) (b) (4)	09 Nov 2020 16:45:22

US3312046

Folder: Covid-19 Assessment 13 Oct 2020

Form: Symptom Log (13)

Generated On: 26 Nov 2020 10:51:05

[Vomiting](#)

Audit	User	Time (GMT)
User entered 'None (None)'	Karol Moore (b) (4) (b) (4)	09 Nov 2020 16:45:22



US3312046

Folder: Covid-19 Assessment 13 Oct 2020

Form: Symptom Log (13)

Generated On: 26 Nov 2020 10:51:05

[Diarrhea](#)

Audit	User	Time (GMT)
User entered 'None (None)'	Karol Moore (b) (4) (b) (4)	09 Nov 2020 16:45:22

US3312046

Folder: Covid-19 Assessment 13 Oct 2020

Form: Symptom Log (13)

Generated On: 26 Nov 2020 10:51:05

[Sore Throat](#)

Audit	User	Time (GMT)
User entered 'None (None)'	Karol Moore (b) (4) (b) (4)	09 Nov 2020 16:45:22

US3312046

Folder: Covid-19 Assessment 13 Oct 2020

Form: Symptom Log (14)

Generated On: 26 Nov 2020 10:51:05

[Symptom Day](#)

Audit	User	Time (GMT)
User entered 'Day 14 (Day 14)'	Karol Moore (b) (4) (b) (4)	09 Nov 2020 16:45:50

US3312046

Folder: Covid-19 Assessment 13 Oct 2020

Form: Symptom Log (14)

Generated On: 26 Nov 2020 10:51:05

[Date](#)

Audit	User	Time (GMT)
User entered '20 Oct 2020'	Karol Moore (b) (4) (b) (4)	09 Nov 2020 16:45:50

US3312046

Folder: Covid-19 Assessment 13 Oct 2020

Form: Symptom Log (14)

Generated On: 26 Nov 2020 10:51:05

[Assessment Not Done](#)

Audit	User	Time (GMT)
User entered '0'	Karol Moore (b) (4) (b) (4)	09 Nov 2020 16:45:50

US3312046

Folder: Covid-19 Assessment 13 Oct 2020

Form: Symptom Log (14)

Generated On: 26 Nov 2020 10:51:05

[O2 Saturation](#)

Audit	User	Time (GMT)
User entered '98'	Karol Moore (b) (4) (b) (4)	09 Nov 2020 16:45:50

**US3312046**

**Folder: Covid-19 Assessment 13 Oct 2020**

**Form: Symptom Log (14)**

**Generated On: 26 Nov 2020 10:51:05**

[O2 Saturation Units](#)

Audit	User	Time (GMT)
User entered '%'	System	09 Nov 2020 16:45:50

US3312046

Folder: Covid-19 Assessment 13 Oct 2020

Form: Symptom Log (14)

Generated On: 26 Nov 2020 10:51:05

[Temperature](#)

Audit	User	Time (GMT)
User entered '97.2' F	Karol Moore (b) (4) (b) (4)	09 Nov 2020 16:45:50



US3312046

Folder: Covid-19 Assessment 13 Oct 2020

Form: Symptom Log (14)

Generated On: 26 Nov 2020 10:51:05

[Chills](#)

Audit	User	Time (GMT)
User entered 'None (None)'	Karol Moore (b) (4) (b) (4)	09 Nov 2020 16:45:50

US3312046

Folder: Covid-19 Assessment 13 Oct 2020

Form: Symptom Log (14)

Generated On: 26 Nov 2020 10:51:05

[Cough](#)

Audit	User	Time (GMT)
User entered 'None (None)'	Karol Moore (b) (4) (b) (4)	09 Nov 2020 16:45:50

US3312046

Folder: Covid-19 Assessment 13 Oct 2020

Form: Symptom Log (14)

Generated On: 26 Nov 2020 10:51:05

[Shortness of Breath](#)

Audit	User	Time (GMT)
User entered 'None (None)'	Karol Moore (b) (4) (b) (4)	09 Nov 2020 16:45:50

US3312046

Folder: Covid-19 Assessment 13 Oct 2020

Form: Symptom Log (14)

Generated On: 26 Nov 2020 10:51:05

[Difficulty Breathing](#)

Audit	User	Time (GMT)
User entered 'None (None)'	Karol Moore (b) (4) (b) (4)	09 Nov 2020 16:45:50

US3312046

Folder: Covid-19 Assessment 13 Oct 2020

Form: Symptom Log (14)

Generated On: 26 Nov 2020 10:51:05

[Fatigue](#)

Audit	User	Time (GMT)
User entered 'Mild (Mild)'	Karol Moore (b) (4) (b) (4)	09 Nov 2020 16:45:50

US3312046

Folder: Covid-19 Assessment 13 Oct 2020

Form: Symptom Log (14)

Generated On: 26 Nov 2020 10:51:05

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
User entered 'None (None)'	Karol Moore (b) (4) (b) (4)	09 Nov 2020 16:45:50

US3312046

Folder: Covid-19 Assessment 13 Oct 2020

Form: Symptom Log (14)

Generated On: 26 Nov 2020 10:51:05

[Body Aches](#)

Audit	User	Time (GMT)
User entered 'None (None)'	Karol Moore (b) (4) (b) (4)	09 Nov 2020 16:45:50

US3312046

Folder: Covid-19 Assessment 13 Oct 2020

Form: Symptom Log (14)

Generated On: 26 Nov 2020 10:51:05

[Headache](#)

Audit	User	Time (GMT)
User entered 'None (None)'	Karol Moore (b) (4) (b) (4)	09 Nov 2020 16:45:50



US3312046

Folder: Covid-19 Assessment 13 Oct 2020

Form: Symptom Log (14)

Generated On: 26 Nov 2020 10:51:05

[New Loss of Taste](#)

Audit	User	Time (GMT)
User entered 'None (None)'	Karol Moore (b) (4) (b) (4)	09 Nov 2020 16:45:50

US3312046

Folder: Covid-19 Assessment 13 Oct 2020

Form: Symptom Log (14)

Generated On: 26 Nov 2020 10:51:05

[New Loss of Smell](#)

Audit	User	Time (GMT)
User entered 'None (None)'	Karol Moore (b) (4) (b) (4)	09 Nov 2020 16:45:50

US3312046

Folder: Covid-19 Assessment 13 Oct 2020

Form: Symptom Log (14)

Generated On: 26 Nov 2020 10:51:05

[Nasal Congestion](#)

Audit	User	Time (GMT)
User entered 'None (None)'	Karol Moore (b) (4) (b) (4)	09 Nov 2020 16:45:50

US3312046

Folder: Covid-19 Assessment 13 Oct 2020

Form: Symptom Log (14)

Generated On: 26 Nov 2020 10:51:05

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
User entered 'Mild (Mild)'	Karol Moore (b) (4) (b) (4)	09 Nov 2020 16:45:50

US3312046

Folder: Covid-19 Assessment 13 Oct 2020

Form: Symptom Log (14)

Generated On: 26 Nov 2020 10:51:05

[Nausea](#)

Audit	User	Time (GMT)
User entered 'None (None)'	Karol Moore (b) (4) (b) (4)	09 Nov 2020 16:45:50

US3312046

Folder: Covid-19 Assessment 13 Oct 2020

Form: Symptom Log (14)

Generated On: 26 Nov 2020 10:51:05

[Vomiting](#)

Audit	User	Time (GMT)
User entered 'None (None)'	Karol Moore (b) (4) (b) (4)	09 Nov 2020 16:45:50

US3312046

Folder: Covid-19 Assessment 13 Oct 2020

Form: Symptom Log (14)

Generated On: 26 Nov 2020 10:51:05

[Diarrhea](#)

Audit	User	Time (GMT)
User entered 'None (None)'	Karol Moore (b) (4) (b) (4)	09 Nov 2020 16:45:50

US3312046

Folder: Covid-19 Assessment 13 Oct 2020

Form: Symptom Log (14)

Generated On: 26 Nov 2020 10:51:05

[Sore Throat](#)

Audit	User	Time (GMT)
User entered 'None (None)'	Karol Moore (b) (4) (b) (4)	09 Nov 2020 16:45:50



**US3312046**

**Folder: Covid-19 Assessment 13 Oct 2020**

**Form: COVID Diagnostic Test**

**Generated On: 26 Nov 2020 10:51:05**

[Date of Visit](#)

Audit	User	Time (GMT)
User entered '16 Oct 2020'	Karol Moore (b) (4) (b) (4)	09 Nov 2020 16:46:06

**US3312046**

**Folder: Covid-19 Assessment 13 Oct 2020**

**Form: COVID Diagnostic Test**

**Generated On: 26 Nov 2020 10:51:05**

[Was the Subject Tested For SARS-CoV-2 by RT-PCR?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Karol Moore (b) (4) (b) (4)	09 Nov 2020 16:46:06

US3312046

Folder: Covid-19 Assessment 13 Oct 2020

Form: COVID Diagnostic Test

Generated On: 26 Nov 2020 10:51:05

Did Subject Test Positive For SARS-CoV-2 by RT-PCR?

Audit	User	Time (GMT)
User entered 'No (N)'	Karol Moore (b) (4) (b) (4)	09 Nov 2020 16:46:06

US3312046

Folder: Covid-19 Assessment 13 Oct 2020

Form: COVID Diagnostic Test

Generated On: 26 Nov 2020 10:51:05

[Date of Test](#)

Audit	User	Time (GMT)
User entered '16 Oct 2020'	Karol Moore (b) (4) (b) (4)	09 Nov 2020 16:46:06

US3312046

Folder: Covid-19 Assessment 13 Oct 2020

Form: COVID Diagnostic Test

Generated On: 26 Nov 2020 10:51:05

Type of Test Performed

Audit	User	Time (GMT)
User entered 'Nasopharyngeal Swab (Nasopharyngeal Swab)'	Karol Moore (b) (4) (b) (4)	09 Nov 2020 16:46:06

US3312046

Folder: Covid-19 Assessment 13 Oct 2020

Form: COVID Diagnostic Test

Generated On: 26 Nov 2020 10:51:05

[Other, specify](#)

Audit	User	Time (GMT)
User entered empty.	Karol Moore (b) (4) (b) (4)	09 Nov 2020 16:46:06

US3312046

Folder: Covid-19 Assessment 13 Oct 2020

Form: COVID Diagnostic Test

Generated On: 26 Nov 2020 10:51:05

[Was this diagnostic test performed at a lab other than the Study Central Lab?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Karol Moore (b) (4) (b) (4)	09 Nov 2020 16:46:06

**US3312046**

**Folder: Covid-19 Assessment 13 Oct 2020**

**Form: COVID Diagnostic Test**

**Generated On: 26 Nov 2020 10:51:05**

[Lab/ Institution Test Performed](#)

Audit	User	Time (GMT)
User entered empty.	Karol Moore (b) (4) (b) (4)	09 Nov 2020 16:46:06



US3312046

Folder: Covid-19 Assessment 13 Oct 2020

Form: COVID Diagnostic Test

Generated On: 26 Nov 2020 10:51:05

[CLIA Certified?](#)

Audit	User	Time (GMT)
User entered empty.	Karol Moore (b) (4) (b) (4)	09 Nov 2020 16:46:06

**US3312046**

**Folder: Covid-19 Assessment 13 Oct 2020**

**Form: COVID Diagnostic Test**

**Generated On: 26 Nov 2020 10:51:05**

[COVID-19 Positive \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '0'	System	09 Nov 2020 16:46:06

US3312046

Folder: Covid-19 Assessment 13 Oct 2020

Form: Generate Next COVID-19 Assessment

Generated On: 26 Nov 2020 10:51:05

[Generate Next COVID-19 Assessment](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Karol Moore (b) (4) (b) (4)	09 Nov 2020 16:31:43

**US3312046**

**Folder: Illness Visit (1)**

**Form: Saliva Collection (1)**

**Generated On: 26 Nov 2020 10:51:05**

[Visit](#)

Audit	User	Time (GMT)
User accepted default value 'Day 3 (Day 3)'	Karol Moore (b) (4) (b) (4)	09 Nov 2020 17:51:24

**US3312046**

**Folder: Illness Visit (1)**

**Form: Saliva Collection (1)**

**Generated On: 26 Nov 2020 10:51:05**

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Karol Moore (b) (4) (b) (4)	09 Nov 2020 17:51:24

US3312046

Folder: Illness Visit (1)

Form: Saliva Collection (1)

Generated On: 26 Nov 2020 10:51:05

[Date of Collection](#)

Audit	User	Time (GMT)
Query 'Per GCL Lab Reconciliation: Saliva: Sample dated 18OCT2020 is recorded under Illness Visit Day 3 visit in EDC, however the sample is reported with date 19OCT2020 in PPD Central lab. Please confirm the correct Date in the response and update EDC or PPD portal as appropriate. Thank you.' answered with 'CORRECT AS ENTERED. SITE SOURCE DOCS ARE CORRECT AS 18OCT2020' (Site from DM).	Karol Moore (b) (4) (b) (4)	17 Nov 2020 21:56:05
User opened query 'Per GCL Lab Reconciliation: Saliva: Sample dated 18OCT2020 is recorded under Illness Visit Day 3 visit in EDC, however the sample is reported with date 19OCT2020 in PPD Central lab. Please confirm the correct Date in the response and update EDC or PPD portal as appropriate. Thank you.' (Site from DM).	(b) (4), (b) (6)	12 Nov 2020 12:03:32
User entered '18 Oct 2020'	Karol Moore (b) (4) (b) (4)	09 Nov 2020 17:51:24

**US3312046**

**Folder: Illness Visit (1)**

**Form: Saliva Collection (2)**

**Generated On: 26 Nov 2020 10:51:05**

[Visit](#)

Audit	User	Time (GMT)
User accepted default value 'Day 5 (Day 5)'	Karol Moore (b) (4) (b) (4)	09 Nov 2020 17:51:24

**US3312046**

**Folder: Illness Visit (1)**

**Form: Saliva Collection (2)**

**Generated On: 26 Nov 2020 10:51:05**

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Karol Moore (b) (4) (b) (4)	09 Nov 2020 17:51:24



US3312046

Folder: Illness Visit (1)

Form: Saliva Collection (2)

Generated On: 26 Nov 2020 10:51:05

[Date of Collection](#)

Audit	User	Time (GMT)
Query 'Per GCL Lab Reconciliation: Saliva: Sample dated 20OCT2020 is recorded under Illness Visit Day 5 visit in EDC, however the sample is reported with date 21OCT2020 in PPD Central lab. Please confirm the correct Date in the response and update EDC or PPD portal as appropriate. Thank you.' answered with 'CORRECT AS ENTERED. SITE SOURCE DOCS ARE CORRECT AS 20OCT2020' (Site from DM).	Karol Moore (b) (4) (b) (4)	17 Nov 2020 21:56:24
User opened query 'Per GCL Lab Reconciliation: Saliva: Sample dated 20OCT2020 is recorded under Illness Visit Day 5 visit in EDC, however the sample is reported with date 21OCT2020 in PPD Central lab. Please confirm the correct Date in the response and update EDC or PPD portal as appropriate. Thank you.' (Site from DM).	(b) (4), (b) (6)	12 Nov 2020 12:04:10
User entered '20 Oct 2020'	Karol Moore (b) (4) (b) (4)	09 Nov 2020 17:51:24

**US3312046**

**Folder: Illness Visit (1)**

**Form: Saliva Collection (3)**

**Generated On: 26 Nov 2020 10:51:05**

[Visit](#)

Audit	User	Time (GMT)
User accepted default value 'Day 7 (Day 7)'	Karol Moore (b) (4) (b) (4)	09 Nov 2020 17:51:24

**US3312046**

**Folder: Illness Visit (1)**

**Form: Saliva Collection (3)**

**Generated On: 26 Nov 2020 10:51:05**

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
User entered 'NA (COVID-19 Negative) (NA)'	Karol Moore (b) (4) (b) (4)	09 Nov 2020 17:51:24

**US3312046**

**Folder: Illness Visit (1)**

**Form: Saliva Collection (3)**

**Generated On: 26 Nov 2020 10:51:05**

[Date of Collection](#)

Audit	User	Time (GMT)
User entered empty.	Karol Moore (b) (4) (b) (4)	09 Nov 2020 17:51:24

**US3312046**

**Folder: Illness Visit (1)**

**Form: Saliva Collection (4)**

**Generated On: 26 Nov 2020 10:51:05**

[Visit](#)

Audit	User	Time (GMT)
User accepted default value 'Day 9 (Day 9)'	Karol Moore (b) (4) (b) (4)	09 Nov 2020 17:51:24

**US3312046**

**Folder: Illness Visit (1)**

**Form: Saliva Collection (4)**

**Generated On: 26 Nov 2020 10:51:05**

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
User entered 'NA (COVID-19 Negative) (NA)'	Karol Moore (b) (4) (b) (4)	09 Nov 2020 17:51:24

**US3312046**

**Folder: Illness Visit (1)**

**Form: Saliva Collection (4)**

**Generated On: 26 Nov 2020 10:51:05**

[Date of Collection](#)

Audit	User	Time (GMT)
User entered empty.	Karol Moore (b) (4) (b) (4)	09 Nov 2020 17:51:24

**US3312046**

**Folder: Illness Visit (1)**

**Form: Saliva Collection (5)**

**Generated On: 26 Nov 2020 10:51:05**

[Visit](#)

Audit	User	Time (GMT)
User accepted default value 'Day 14 (Day 14)'	Karol Moore (b) (4) (b) (4)	09 Nov 2020 17:51:24



**US3312046**

**Folder: Illness Visit (1)**

**Form: Saliva Collection (5)**

**Generated On: 26 Nov 2020 10:51:05**

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
User entered 'NA (COVID-19 Negative) (NA)'	Karol Moore (b) (4) (b) (4)	09 Nov 2020 17:51:24

**US3312046**

**Folder: Illness Visit (1)**

**Form: Saliva Collection (5)**

**Generated On: 26 Nov 2020 10:51:05**

[Date of Collection](#)

Audit	User	Time (GMT)
User entered empty.	Karol Moore (b) (4) (b) (4)	09 Nov 2020 17:51:24

**US3312046**

**Folder: Illness Visit (1)**

**Form: Saliva Collection (6)**

**Generated On: 26 Nov 2020 10:51:05**

[Visit](#)

Audit	User	Time (GMT)
User accepted default value 'Day 21 (Day 21)'	Karol Moore (b) (4) (b) (4)	09 Nov 2020 17:51:24

**US3312046**

**Folder: Illness Visit (1)**

**Form: Saliva Collection (6)**

**Generated On: 26 Nov 2020 10:51:05**

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
User entered 'NA (COVID-19 Negative) (NA)'	Karol Moore (b) (4) (b) (4)	09 Nov 2020 17:51:24

**US3312046**

**Folder: Illness Visit (1)**

**Form: Saliva Collection (6)**

**Generated On: 26 Nov 2020 10:51:05**

[Date of Collection](#)

Audit	User	Time (GMT)
User entered empty.	Karol Moore (b) (4) (b) (4)	09 Nov 2020 17:51:24

**US3312046**

**Folder: Illness Visit (1)**

**Form: Saliva Collection (7)**

**Generated On: 26 Nov 2020 10:51:05**

[Visit](#)

Audit	User	Time (GMT)
User accepted default value 'Day 28 (Day 28)'	Karol Moore (b) (4) (b) (4)	09 Nov 2020 17:51:24

**US3312046**

**Folder: Illness Visit (1)**

**Form: Saliva Collection (7)**

**Generated On: 26 Nov 2020 10:51:05**

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
User entered 'NA (COVID-19 Negative) (NA)'	Karol Moore (b) (4) (b) (4)	09 Nov 2020 17:51:24

**US3312046**

**Folder: Illness Visit (1)**

**Form: Saliva Collection (7)**

**Generated On: 26 Nov 2020 10:51:05**

[Date of Collection](#)

Audit	User	Time (GMT)
User entered empty.	Karol Moore (b) (4) (b) (4)	09 Nov 2020 17:51:24



US3312046

Folder: Illness Visit Day 1 (1)

Form: Visit Date

Generated On: 26 Nov 2020 10:51:05

[Was this visit performed?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Karol Moore (b) (4) (b) (4)	09 Nov 2020 17:45:21

**US3312046**

**Folder: Illness Visit Day 1 (1)**

**Form: Visit Date**

**Generated On: 26 Nov 2020 10:51:05**

[Visit date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User entered '16 Oct 2020'	Karol Moore (b) (4) (b) (4)	09 Nov 2020 17:45:21

US3312046

Folder: Illness Visit Day 1 (1)

Form: Visit Date

Generated On: 26 Nov 2020 10:51:05

[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)	09 Nov 2020 17:45:21

**US3312046**

**Folder: Illness Visit Day 1 (1)**

**Form: Visit Date**

**Generated On: 26 Nov 2020 10:51:05**

[Folder OID](#)

Audit	User	Time (GMT)
User entered 'SICKD1'	System	09 Nov 2020 17:45:21

US3312046

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 10:51:05

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Karol Moore (b) (4) (b) (4)	09 Nov 2020 17:47:45

US3312046

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 10:51:05

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered '16 Oct 2020'	Karol Moore (b) (4) (b) (4)	09 Nov 2020 17:47:45

**US3312046**

**Folder: Illness Visit Day 1 (1)**

**Form: Vital Signs**

**Generated On: 26 Nov 2020 10:51:05**

**Time of assessment (00:00-23:59)**

Audit	User	Time (GMT)
User entered '09:40'	Karol Moore (b) (4) (b) (4)	09 Nov 2020 17:47:45

**US3312046**

**Folder: Illness Visit Day 1 (1)**

**Form: Vital Signs**

**Generated On: 26 Nov 2020 10:51:05**

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered '16 Oct 2020 09:40'	System	09 Nov 2020 17:47:45



**US3312046**

**Folder: Illness Visit Day 1 (1)**

**Form: Vital Signs**

**Generated On: 26 Nov 2020 10:51:05**

[Height \(xxx.x\)](#)

Audit	User	Time (GMT)
User entered '63' in	Karol Moore (b) (4)	09 Nov 2020 17:47:45
DataPoint set to visible.	(b) (4) System	09 Nov 2020 17:45:21

**US3312046**

**Folder: Illness Visit Day 1 (1)**

**Form: Vital Signs**

**Generated On: 26 Nov 2020 10:51:05**

[Weight \(.xxx.x\)](#)

Audit	User	Time (GMT)
User entered '140' lb	Karol Moore (b) (4)	09 Nov 2020 17:47:45
DataPoint set to visible.	(b) (4) System	09 Nov 2020 17:45:21

US3312046

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 10:51:05

Temperature (xxx.x)

Audit	User	Time (GMT)
User entered '97.2' F	Karol Moore (b) (4) (b) (4)	09 Nov 2020 17:47:45

**US3312046**

**Folder: Illness Visit Day 1 (1)**

**Form: Vital Signs**

**Generated On: 26 Nov 2020 10:51:05**

[Route of measurement](#)

Audit	User	Time (GMT)
User entered 'Oral (Oral)'	Karol Moore (b) (4) (b) (4)	09 Nov 2020 17:47:45

**US3312046**

**Folder: Illness Visit Day 1 (1)**

**Form: Vital Signs**

**Generated On: 26 Nov 2020 10:51:05**

[If Other, specify](#)

Audit	User	Time (GMT)
User entered empty.	Karol Moore (b) (4) (b) (4)	09 Nov 2020 17:47:45

**US3312046**

**Folder: Illness Visit Day 1 (1)**

**Form: Vital Signs**

**Generated On: 26 Nov 2020 10:51:05**

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
User entered '59'	Karol Moore (b) (4) (b) (4)	09 Nov 2020 17:47:45

**US3312046**

**Folder: Illness Visit Day 1 (1)**

**Form: Vital Signs**

**Generated On: 26 Nov 2020 10:51:05**

[Pulse units](#)

Audit	User	Time (GMT)
User entered 'bpm'	System	09 Nov 2020 17:47:45

US3312046

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 10:51:05

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
User entered '14'	Karol Moore (b) (4) (b) (4)	09 Nov 2020 17:47:45



**US3312046**

**Folder: Illness Visit Day 1 (1)**

**Form: Vital Signs**

**Generated On: 26 Nov 2020 10:51:05**

[Respiratory Rate units](#)

Audit	User	Time (GMT)
User entered 'breaths/min'	System	09 Nov 2020 17:47:45

US3312046

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 10:51:05

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
User entered '134'	Karol Moore (b) (4) (b) (4)	09 Nov 2020 17:47:45

**US3312046**

**Folder: Illness Visit Day 1 (1)**

**Form: Vital Signs**

**Generated On: 26 Nov 2020 10:51:05**

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	09 Nov 2020 17:47:45

US3312046

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 10:51:05

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
User entered '76'	Karol Moore (b) (4) (b) (4)	09 Nov 2020 17:47:45

**US3312046**

**Folder: Illness Visit Day 1 (1)**

**Form: Vital Signs**

**Generated On: 26 Nov 2020 10:51:05**

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	09 Nov 2020 17:47:45

**US3312046**

**Folder: Illness Visit Day 1 (1)**

**Form: Physical Examination**

**Generated On: 26 Nov 2020 10:51:05**

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Karol Moore (b) (4) (b) (4)	09 Nov 2020 17:47:56

**US3312046**

**Folder: Illness Visit Day 1 (1)**

**Form: Physical Examination**

**Generated On: 26 Nov 2020 10:51:05**

**Date of examination (dd MMM yyyy)**

Audit	User	Time (GMT)
User entered '16 Oct 2020'	Karol Moore (b) (4) (b) (4)	09 Nov 2020 17:47:56

US3312046

Folder: Illness Visit Day 1 (1)

Form: Blood Sample Collection for Immunologic Assessment of SARS-CoV-2 Infection

Generated On: 26 Nov 2020 10:51:05

[Was Blood Sample Taken for Immunologic Assessment of SARS\\_COV-2 Infection?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Karol Moore (b) (4) (b) (4)	09 Nov 2020 17:48:04



**US3312046**

**Folder: Illness Visit Day 1 (1)**

**Form: Blood Sample Collection for Immunologic Assessment of SARS-CoV-2 Infection**

**Generated On: 26 Nov 2020 10:51:05**

[Date of Collection](#)

Audit	User	Time (GMT)
User entered '16 Oct 2020'	Karol Moore (b) (4) (b) (4)	09 Nov 2020 17:48:04

US3312046

Folder: Convalescence Visit Day 28 (1)

Form: Visit Date

Generated On: 26 Nov 2020 10:51:05

[Was this visit performed?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Karol Moore (b) (4) (b) (4)	09 Nov 2020 17:48:11

US3312046

Folder: Convalescence Visit Day 28 (1)

Form: Visit Date

Generated On: 26 Nov 2020 10:51:05

[Visit date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User entered empty.	Karol Moore (b) (4) (b) (4)	09 Nov 2020 17:48:11

US3312046

Folder: Convalescence Visit Day 28 (1)

Form: Visit Date

Generated On: 26 Nov 2020 10:51:05

Was visit performed at the participant's home or at the clinic?

Audit	User	Time (GMT)
User entered empty.	Karol Moore (b) (4) (b) (4)	09 Nov 2020 17:48:11

**US3312046**

**Folder: Convalescence Visit Day 28 (1)**

**Form: Visit Date**

**Generated On: 26 Nov 2020 10:51:05**

[Folder OID](#)

Audit	User	Time (GMT)
User entered 'SICKD28'	System	09 Nov 2020 17:48:11

US3312046

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 10:51:05

Were vital signs assessed?

Audit	User	Time (GMT)
User entered 'No (N)'	Karol Moore (b) (4) (b) (4)	09 Nov 2020 17:48:15

US3312046

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 10:51:05

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered empty.	Karol Moore (b) (4) (b) (4)	09 Nov 2020 17:48:15

**US3312046**

**Folder: Convalescence Visit Day 28 (1)**

**Form: Vital Signs**

**Generated On: 26 Nov 2020 10:51:05**

**Time of assessment (00:00-23:59)**

Audit	User	Time (GMT)
User entered empty.	Karol Moore (b) (4) (b) (4)	09 Nov 2020 17:48:15



**US3312046**

**Folder: Convalescence Visit Day 28 (1)**

**Form: Vital Signs**

**Generated On: 26 Nov 2020 10:51:05**

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	09 Nov 2020 17:48:15

US3312046

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 10:51:05

Temperature (xxx.x)

Audit	User	Time (GMT)
User entered empty.	Karol Moore (b) (4) (b) (4)	09 Nov 2020 17:48:15

US3312046

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 10:51:05

[Route of measurement](#)

Audit	User	Time (GMT)
User entered empty.	Karol Moore (b) (4) (b) (4)	09 Nov 2020 17:48:15

US3312046

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 10:51:05

[If Other, specify](#)

Audit	User	Time (GMT)
User entered empty.	Karol Moore (b) (4) (b) (4)	09 Nov 2020 17:48:15

**US3312046**

**Folder: Convalescence Visit Day 28 (1)**

**Form: Vital Signs**

**Generated On: 26 Nov 2020 10:51:05**

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
User entered empty.	Karol Moore (b) (4) (b) (4)	09 Nov 2020 17:48:15

**US3312046**

**Folder: Convalescence Visit Day 28 (1)**

**Form: Vital Signs**

**Generated On: 26 Nov 2020 10:51:05**

[Pulse units](#)

Audit	User	Time (GMT)
User entered empty.	System	09 Nov 2020 17:48:15

US3312046

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 10:51:05

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
User entered empty.	Karol Moore (b) (4) (b) (4)	09 Nov 2020 17:48:15

**US3312046**

**Folder: Convalescence Visit Day 28 (1)**

**Form: Vital Signs**

**Generated On: 26 Nov 2020 10:51:05**

[Respiratory Rate units](#)

Audit	User	Time (GMT)
User entered empty.	System	09 Nov 2020 17:48:15



US3312046

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 10:51:05

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
User entered empty.	Karol Moore (b) (4) (b) (4)	09 Nov 2020 17:48:15

**US3312046**

**Folder: Convalescence Visit Day 28 (1)**

**Form: Vital Signs**

**Generated On: 26 Nov 2020 10:51:05**

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered empty.	System	09 Nov 2020 17:48:15

US3312046

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 10:51:05

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
User entered empty.	Karol Moore (b) (4) (b) (4)	09 Nov 2020 17:48:15

**US3312046**

**Folder: Convalescence Visit Day 28 (1)**

**Form: Vital Signs**

**Generated On: 26 Nov 2020 10:51:05**

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered empty.	System	09 Nov 2020 17:48:15

US3312046

Folder: Convalescence Visit Day 28 (1)

Form: Physical Examination

Generated On: 26 Nov 2020 10:51:05

Was the physical examination performed?

Audit	User	Time (GMT)
User entered 'No (N)'	Karol Moore (b) (4) (b) (4)	09 Nov 2020 17:48:18

US3312046

Folder: Convalescence Visit Day 28 (1)

Form: Physical Examination

Generated On: 26 Nov 2020 10:51:05

Date of examination (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered empty.	Karol Moore (b) (4) (b) (4)	09 Nov 2020 17:48:18

US3312046

Folder: Convalescence Visit Day 28 (1)

Form: Blood Sample Collection for Immunologic Assessment of SARS-CoV-2 Infection

Generated On: 26 Nov 2020 10:51:05

[Was Blood Sample Taken for Immunologic Assessment of SARS\\_COV-2 Infection?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Karol Moore (b) (4) (b) (4)	09 Nov 2020 17:48:25

US3312046

Folder: Convalescence Visit Day 28 (1)

Form: Blood Sample Collection for Immunologic Assessment of SARS-CoV-2 Infection

Generated On: 26 Nov 2020 10:51:05

[Date of Collection](#)

Audit	User	Time (GMT)
User entered empty.	Karol Moore (b) (4) (b) (4)	09 Nov 2020 17:48:25



**US3312046**

**Folder: Adverse Events**

**Form: Adverse Events Summary**

**Generated On: 26 Nov 2020 10:51:05**

[Did the participant experience any adverse events?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	14 Oct 2020 18:48:08

**US3312046**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 26 Nov 2020 10:51:05**

[AEID](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	15 Oct 2020 12:50:09
User entered 'USA-US300-2020-mRNA-1273-P301000005'	System	15 Oct 2020 12:50:05
User entered 'New'	(b) (4), (b) (6)	15 Oct 2020 12:50:05

US3312046

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 10:51:05

[Adverse event](#)

Audit	User	Time (GMT)
User closed query 'PV Query: Please consider updating the event term to the underlying cause/etiology of the infection.' (Site from Safety).	(b) (4), (b) (6)	17 Nov 2020 15:47:14
User coded data point as SOC: Infections and infestations, HLT: Viral infectious disorders, HLT: Viral infections NEC, PT: Viral pharyngitis, LLT: Viral pharyngitis - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	16 Nov 2020 16:39:44
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	16 Nov 2020 16:39:44
Query 'PV Query: Please consider updating the event term to the underlying cause/etiology of the infection.' answered with 'AE term updated' (Site from Safety).	(b) (4), (b) (6)	16 Nov 2020 16:37:37
Data point term sent to Coder	System	16 Nov 2020 16:25:26
Query 'For coding purposes, please enter the location for INFECTION in order that the term may be coded accurately and to the appropriate body site. Please make your changes to the reported term accordingly in the diagnosis field to enable coding.' canceled (Site from System).	Coder Import (b) (4) (b) (4)	16 Nov 2020 16:24:44
Data point term sent to Coder	System	16 Nov 2020 16:23:20
User entered 'viral pharyngitis' reason for change: Data Entry Error	(b) (4), (b) (6)	16 Nov 2020 16:22:30
User opened query 'PV Query: Please consider updating the event term to the underlying cause/etiology of the infection.' (Site from Safety).	(b) (4), (b) (6)	23 Oct 2020 16:25:49
User opened query 'For coding purposes, please enter the location for INFECTION in order that the term may be coded accurately and to the appropriate body site. Please make your changes to the reported term accordingly in the diagnosis field to enable coding.' (Site from System).	Coder Import (b) (4) (b) (4)	14 Oct 2020 23:14:15
Data point term sent to Coder	System	14 Oct 2020 18:50:17
User entered 'infection unknown origin'	(b) (4), (b) (6)	14 Oct 2020 18:49:34

**US3312046**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 26 Nov 2020 10:51:05**

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	14 Oct 2020 18:49:34

**US3312046**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 26 Nov 2020 10:51:05**

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	(b) (4), (b) (6)	14 Oct 2020 18:49:34

**US3312046**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 26 Nov 2020 10:51:05**

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	(b) (4), (b) (6)	14 Oct 2020 18:49:34

**US3312046**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 26 Nov 2020 10:51:05**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User entered '07 Oct 2020'	(b) (4), (b) (6)	14 Oct 2020 18:49:34

**US3312046**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 26 Nov 2020 10:51:05**

[Start time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	14 Oct 2020 18:49:34



**US3312046**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 26 Nov 2020 10:51:05**

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	14 Oct 2020 18:49:34

**US3312046**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 26 Nov 2020 10:51:05**

[Ongoing?](#)

Audit	User	Time (GMT)
User entered 'No (N)' reason for change: Data Entry Error	(b) (4), (b) (6)	16 Nov 2020 16:37:56
User entered 'Yes (Y)'	(b) (4), (b) (6)	14 Oct 2020 18:49:34

US3312046

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 10:51:05

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
User closed query 'PV Query: Please provide the event end date (recovered, returned to baseline, or, in the investigator's opinion, a new baseline has been achieved), when available.' (Site from Safety).	(b) (4), (b) (6)	17 Nov 2020 15:47:18
User closed query 'Outcome is not Recovered/Resolved, Recovered/Resolved with sequelae or Fatal, but End Date is provided. Please correct.' (Site from System).	(b) (4), (b) (6)	17 Nov 2020 08:18:44
Query 'Outcome is not Recovered/Resolved, Recovered/Resolved with sequelae or Fatal, but End Date is provided. Please correct.' answered with 'updated' (Site from System).	(b) (4), (b) (6)	16 Nov 2020 16:38:11
Query 'PV Query: Please provide the event end date (recovered, returned to baseline, or, in the investigator's opinion, a new baseline has been achieved), when available.' answered with 'updated' (Site from Safety).	(b) (4), (b) (6)	16 Nov 2020 16:38:06
User opened query 'Outcome is not Recovered/Resolved, Recovered/Resolved with sequelae or Fatal, but End Date is provided. Please correct.' (Site from System).	System	16 Nov 2020 16:37:56
User entered '15 Nov 2020' reason for change: Data Entry Error	(b) (4), (b) (6)	16 Nov 2020 16:37:56
User opened query 'PV Query: Please provide the event end date (recovered, returned to baseline, or, in the investigator's opinion, a new baseline has been achieved), when available.' (Site from Safety).	(b) (4), (b) (6)	23 Oct 2020 16:26:33
User entered empty.	(b) (4), (b) (6)	14 Oct 2020 18:49:34

**US3312046**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 26 Nov 2020 10:51:05**

[End time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	14 Oct 2020 18:49:34

**US3312046**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 26 Nov 2020 10:51:05**

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	14 Oct 2020 18:49:34

**US3312046**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 26 Nov 2020 10:51:05**

[Severity](#)

Audit	User	Time (GMT)
User entered 'Grade 2/Moderate (Grade 2/Moderate)'	(b) (4), (b) (6)	14 Oct 2020 18:49:34

US3312046

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 10:51:05

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	14 Oct 2020 18:49:34

**US3312046**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 26 Nov 2020 10:51:05**

[Death](#)

Audit	User	Time (GMT)
User entered '0'	(b) (4), (b) (6)	14 Oct 2020 18:49:34



**US3312046**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 26 Nov 2020 10:51:05**

[Life threatening](#)

Audit	User	Time (GMT)
User entered '0'	(b) (4), (b) (6)	14 Oct 2020 18:49:34

**US3312046**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 26 Nov 2020 10:51:05**

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User entered '1'	(b) (4), (b) (6)	14 Oct 2020 18:49:34

**US3312046**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 26 Nov 2020 10:51:05**

[Hospital Admission Date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User entered '07 Oct 2020'	(b) (4), (b) (6)	14 Oct 2020 18:49:34

**US3312046**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 26 Nov 2020 10:51:05**

[Hospital Discharge Date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User entered '09 Oct 2020'	(b) (4), (b) (6)	14 Oct 2020 18:49:34

**US3312046**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 26 Nov 2020 10:51:05**

[Admitted to ICU?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	(b) (4), (b) (6)	14 Oct 2020 18:49:34

**US3312046**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 26 Nov 2020 10:51:05**

[Number of Days in ICU](#)

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	14 Oct 2020 18:49:34

**US3312046**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 26 Nov 2020 10:51:05**

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User entered '0'	(b) (4), (b) (6)	14 Oct 2020 18:49:34

**US3312046**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 26 Nov 2020 10:51:05**

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User entered '0'	(b) (4), (b) (6)	14 Oct 2020 18:49:34



**US3312046**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 26 Nov 2020 10:51:05**

[Other medically important event](#)

Audit	User	Time (GMT)
User entered '0'	(b) (4), (b) (6)	14 Oct 2020 18:49:34

**US3312046**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 26 Nov 2020 10:51:05**

[Relationship to investigational product](#)

Audit	User	Time (GMT)
User entered 'Not Related (NOT RELATED)'	(b) (4), (b) (6)	14 Oct 2020 18:49:34

**US3312046**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 26 Nov 2020 10:51:05**

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
User entered 'Not Related (NOT RELATED)'	(b) (4), (b) (6)	14 Oct 2020 18:49:34

US3312046

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 10:51:05

Action taken with investigational product

Audit	User	Time (GMT)
User closed query 'PV Query: As the last dose of study drug was given on 09 Sep 2020, please update the action taken with study drug from none to not applicable.' (Site from Safety).	(b) (4), (b) (6)	10 Nov 2020 15:33:09
Query 'PV Query: As the last dose of study drug was given on 09 Sep 2020, please update the action taken with study drug from none to not applicable.' answered with 'UPDATED' (Site from Safety).	Karol Moore (b) (4)	09 Nov 2020 20:34:35
User entered 'Not Applicable (NOT APPLICABLE)' reason for change: Data Entry Error	(b) (4)	09 Nov 2020 20:34:28
User opened query 'PV Query: As the last dose of study drug was given on 09 Sep 2020, please update the action taken with study drug from none to not applicable.' (Site from Safety).	(b) (4), (b) (6)	23 Oct 2020 16:27:00
User entered 'None (NONE)'	(b) (4), (b) (6)	14 Oct 2020 18:49:34

**US3312046**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 26 Nov 2020 10:51:05**

[None](#)

Audit	User	Time (GMT)
User entered '0'	(b) (4), (b) (6)	14 Oct 2020 18:49:34

US3312046

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 10:51:05

[Concomitant Medication](#)

Audit	User	Time (GMT)
User closed query 'Per CDM: Concomitant Medication is checked, however no medication was added with an indication of "INFECTION UNKNOWN ORIGIN". Please review and clarify or update accordingly. ' (Site from DM).	(b) (4), (b) (6)	17 Nov 2020 08:18:56
Query 'Per CDM: Concomitant Medication is checked, however no medication was added with an indication of "INFECTION UNKNOWN ORIGIN". Please review and clarify or update accordingly. '	(b) (4), (b) (6)	16 Nov 2020 16:43:08
answered with 'CM updated' (Site from DM).		
User opened query 'Per CDM: Concomitant Medication is checked, however no medication was added with an indication of "INFECTION UNKNOWN ORIGIN". Please review and clarify or update accordingly. ' (Site from DM).	(b) (4), (b) (6)	22 Oct 2020 16:26:55
User entered 'I'	(b) (4), (b) (6)	14 Oct 2020 18:49:34

**US3312046**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 26 Nov 2020 10:51:05**

[Concomitant Procedure](#)

Audit	User	Time (GMT)
User entered '0'	(b) (4), (b) (6)	14 Oct 2020 18:49:34

**US3312046**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 26 Nov 2020 10:51:05**

[Outcome](#)

Audit	User	Time (GMT)
User closed query 'PV Query: Please provide the final event outcome, when available. If not expected to resolve, please confirm in your response. If resolution is expected, please keep query open until achieved.' (Site from Safety).	(b) (4), (b) (6)	17 Nov 2020 15:47:25
Query 'PV Query: Please provide the final event outcome, when available. If not expected to resolve, please confirm in your response. If resolution is expected, please keep query open until achieved.' answered with 'updated' (Site from Safety).	(b) (4), (b) (6)	16 Nov 2020 16:38:39
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)' reason for change: Data Entry Error	(b) (4), (b) (6)	16 Nov 2020 16:38:28
User opened query 'PV Query: Please provide the final event outcome, when available. If not expected to resolve, please confirm in your response. If resolution is expected, please keep query open until achieved.' (Site from Safety).	(b) (4), (b) (6)	23 Oct 2020 16:26:12
User entered 'Not Recovered/Not Resolved (NOT RECOVERED/NOT RESOLVED)'	(b) (4), (b) (6)	14 Oct 2020 18:49:34



**US3312046**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 26 Nov 2020 10:51:05**

[If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:](#)

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	14 Oct 2020 18:49:34

**US3312046**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 26 Nov 2020 10:51:05**

[Narrative](#)

Audit	User	Time (GMT)
User opened query 'PV Query: As the subject was admitted to the hospital please consider updating the severity of the event to Grade 4.' (Site from Safety).	(b) (4), (b) (6)	24 Nov 2020 13:03:04
Query 'PV Query: Since the subject was admitted for the event, please confirm that the severity of the event is Grade 3 at this time. If not, please explain.' canceled (Site from Safety).	(b) (4), (b) (6)	24 Nov 2020 13:02:58
Query 'PV Query: Please report if the subject had any risk factors for/exposures to infection.' canceled (Site from Safety).	(b) (4), (b) (6)	24 Nov 2020 13:01:03
Query 'PV Query: Please provide any relevant laboratory and diagnostic test results. Please include units and reference ranges if applicable.' canceled (Site from Safety).	(b) (4), (b) (6)	24 Nov 2020 13:01:01
User opened query 'PV Query: Since the subject was admitted for the event, please confirm that the severity of the event is Grade 3 at this time. If not, please explain.' (Site from Safety).	(b) (4), (b) (6)	19 Nov 2020 21:12:38
User opened query 'PV Query: Please report if the subject had any risk factors for/exposures to infection.' (Site from Safety).	(b) (4), (b) (6)	19 Nov 2020 21:12:21
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)	19 Nov 2020 21:12:13
Query 'PV Query: Please provide any relevant laboratory and diagnostic test results. Please include units and reference ranges if applicable.' canceled (Site from Safety).	(b) (4), (b) (6)	19 Nov 2020 21:04:51
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)	19 Nov 2020 21:04:03
User closed query 'PV Query: Please report if the subject had any risk factors for/exposures to infection.' (Site from Safety).	(b) (4), (b) (6)	17 Nov 2020 15:47:34
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)	17 Nov 2020 15:47:30

**US3312046**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 26 Nov 2020 10:51:05**

[Narrative](#)

Audit	User	Time (GMT)
Query 'PV Query: Please provide any relevant laboratory and diagnostic test results. Please include units and reference ranges if applicable.' answered with 'none provided in med record' (Site from Safety).	(b) (4), (b) (6)	16 Nov 2020 16:42:58
Query 'PV Query: Please report if the subject had any risk factors for/exposures to infection.' answered with 'No exposures/risk factors' (Site from Safety).	(b) (4), (b) (6)	16 Nov 2020 16:42:39

US3312046

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 10:51:05

[Narrative](#)

Audit	User	Time (GMT)
User entered 'SUBJECT CALLED 10/7/2020 TO REPORT SYMPTOMS OF LOW GRADE FEVER (100 DEGREES FARENHEIT), MILD SORE THROAT AND MILD NAUSEA THAT HAD BEGUN AT 0300 THAT DAY. SYMPTOMS DID NOT MEET ILLNESS VISIT CRITERIA AT THAT TIME AND SUBJECT WAS INSTRUCTED TO CALL BACK WITH WORSENING; D57 VISIT APPOINTMENT WAS RESCHEDULED TO A LATER DATE. ATTEMPTS TO FOLLOW-UP WITH SUBJECT TO ASSESS NEED FOR ILLNESS VISIT WERE UNSUCCESSFUL. ON 10/13/2020, SUBJECT REPORTED (VIA TELEPHONE) A HOSPITALIZATION FOR "INFECTION. " SUBJECT HAD GONE IN TO ER ON 10/7/2020, DUE TO FEVER (TEMPERATURE 101 DEGREES FARENHEIT), AND ADMITTED. PER SUBJECT'S VERBAL REPORT SHE RECEIVED IV HYDRATION, ACETAMINOPHEN AND IBUPROFEN AND WAS TESTED FOR COVID-19 AND INFLUENZA WHICH WERE BOTH NEGATIVE. AN ELEVATED TOTAL WBC WAS IDENTIFIED. AT TIME OF CALL, 10/13/2020, SUBJECT CONTINUED TO FEEL FATIGUED WITH LAST FEVER REPORTED ON 10/12/2020. SHE IS SCHEDULED TO FOLLOW-UP WITH PCP ON THE AFTERNOON OF 10/14/2020.  THIS IS AN SAE, HOSPITALIZATION, NOT RELATED TO IP. MEDICAL RECORDS WILL BE REQUESTED, UPON RECEIPT OF SIGNED MEDICAL RECORDS RELEASE FROM SUBJECT. Medical records reviewed, AE term updated to Viral pharyngitis, Subject has returned to baseline, AE closed. Per subject Covid test done in hospital was negative. Hospitalization (per med record) was more for observation since subject lives alone and was not comfortable being by herself' reason for change: Data Entry Error	(b) (4), (b) (6)	16 Nov 2020 16:41:54
User opened query 'PV Query: Please report if the subject had any risk factors for/exposures to infection.' (Site from Safety).	(b) (4), (b) (6)	23 Oct 2020 16:27:21

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 10:51:05

[Narrative](#)

Audit	User	Time (GMT)
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)	23 Oct 2020 16:26:03
User closed query 'AE Serious is Yes but SAE Narrative is missing. Please provide.' (Site from System).	System	14 Oct 2020 19:17:41
Query 'AE Serious is Yes but SAE Narrative is missing. Please provide.' answered by data change (Site from System).	System	14 Oct 2020 19:17:41
User entered 'Subject called 10/7/2020 to report symptoms of low grade fever (100 degrees Fahrenheit), mild sore throat and mild nausea that had begun at 0300 that day. Symptoms did not meet illness visit criteria at that time and subject was instructed to call back with worsening; D57 visit appointment was rescheduled to a later date. Attempts to follow-up with subject to assess need for illness visit were unsuccessful. On 10/13/2020, subject reported (via telephone) a hospitalization for "infection. " Subject had gone in to ER on 10/7/2020, due to fever (temperature 101 degrees Fahrenheit), and admitted. Per subject's verbal report she received IV hydration, acetaminophen and ibuprofen and was tested for COVID-19 and influenza which were both negative. An elevated total WBC was identified. At time of call, 10/13/2020, subject continued to feel fatigued with last fever reported on 10/12/2020. She is scheduled to follow-up with PCP on the afternoon of 10/14/2020. This is an SAE, hospitalization, not related to IP. Medical records will be requested, upon receipt of signed medical records release from subject.' reason for change: Data Entry Error	(b) (4), (b) (6)	14 Oct 2020 19:17:41
User opened query 'AE Serious is Yes but SAE Narrative is missing. Please provide.' (Site from System).	System	14 Oct 2020 18:49:34
User entered empty.	(b) (4), (b) (6)	14 Oct 2020 18:49:34

**US3312046**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 26 Nov 2020 10:51:05**

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered 'I'	System	14 Oct 2020 18:49:34

**US3312046**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 26 Nov 2020 10:51:05**

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered 'I'	System	14 Oct 2020 18:49:34

**US3312046**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 26 Nov 2020 10:51:05**

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '0'	System	14 Oct 2020 18:49:34



US3312046

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 10:51:05

[Adverse event](#)

Audit	User	Time (GMT)
User coded data point as SOC: General disorders and administration site conditions, HLGT: General system disorders NEC, HLT: Asthenic conditions, PT: Fatigue, LLT: Fatigue - version MedDRA\\23.0.	Coder Import (b) (4)	09 Nov 2020 20:44:36
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	(b) (4)	09 Nov 2020 20:44:36
Data point term sent to Coder	System	09 Nov 2020 20:28:48
User entered 'FATIGUE'	Karol Moore (b) (4)	09 Nov 2020 20:28:06
	(b) (4)	

**US3312046**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 26 Nov 2020 10:51:05**

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Karol Moore (b) (4) (b) (4)	09 Nov 2020 20:28:06

**US3312046**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 26 Nov 2020 10:51:05**

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Karol Moore (b) (4) (b) (4)	09 Nov 2020 20:28:06

**US3312046**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 26 Nov 2020 10:51:05**

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Karol Moore (b) (4) (b) (4)	09 Nov 2020 20:28:06

**US3312046**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 26 Nov 2020 10:51:05**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User entered '09 Oct 2020'	Karol Moore (b) (4) (b) (4)	09 Nov 2020 20:28:06

**US3312046**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 26 Nov 2020 10:51:05**

[Start time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
User entered empty.	Karol Moore (b) (4) (b) (4)	09 Nov 2020 20:28:06

**US3312046**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 26 Nov 2020 10:51:05**

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	09 Nov 2020 20:28:06

**US3312046**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 26 Nov 2020 10:51:05**

[Ongoing?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Karol Moore (b) (4) (b) (4)	09 Nov 2020 20:28:06



US3312046

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 10:51:05

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
User closed query 'Outcome is Recovered/Resolved, Recovered/Resolved with Sequelae or Fatal, but End Date is missing. Please provide.' (Site from System).	System	09 Nov 2020 20:34:02
Query 'Outcome is Recovered/Resolved, Recovered/Resolved with Sequelae or Fatal, but End Date is missing. Please provide.' answered by data change (Site from System).	System	09 Nov 2020 20:34:02
User opened query 'Outcome is Recovered/Resolved, Recovered/Resolved with Sequelae or Fatal, but End Date is missing. Please provide.' (Site from System).	System	09 Nov 2020 20:28:06
User entered empty.	Karol Moore (b) (4) (b) (4)	09 Nov 2020 20:28:06

**US3312046**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 26 Nov 2020 10:51:05**

[End time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
User entered empty.	Karol Moore (b) (4) (b) (4)	09 Nov 2020 20:28:06

**US3312046**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 26 Nov 2020 10:51:05**

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	09 Nov 2020 20:28:06

**US3312046**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 26 Nov 2020 10:51:05**

[Severity](#)

Audit	User	Time (GMT)
User entered 'Grade 1/Mild (Grade 1/Mild)'	Karol Moore (b) (4) (b) (4)	09 Nov 2020 20:28:06

US3312046

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 10:51:05

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Karol Moore (b) (4) (b) (4)	09 Nov 2020 20:28:06

**US3312046**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 26 Nov 2020 10:51:05**

[Death](#)

Audit	User	Time (GMT)
User entered '0'	Karol Moore (b) (4) (b) (4)	09 Nov 2020 20:28:06

**US3312046**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 26 Nov 2020 10:51:05**

[Life threatening](#)

Audit	User	Time (GMT)
User entered '0'	Karol Moore (b) (4) (b) (4)	09 Nov 2020 20:28:06

**US3312046**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 26 Nov 2020 10:51:05**

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User entered '0'	Karol Moore (b) (4) (b) (4)	09 Nov 2020 20:28:06



US3312046

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 10:51:05

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered empty.	Karol Moore (b) (4) (b) (4)	09 Nov 2020 20:28:06

**US3312046**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 26 Nov 2020 10:51:05**

[Hospital Discharge Date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User entered empty.	Karol Moore (b) (4) (b) (4)	09 Nov 2020 20:28:06

**US3312046**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 26 Nov 2020 10:51:05**

[Admitted to ICU?](#)

Audit	User	Time (GMT)
User entered empty.	Karol Moore (b) (4) (b) (4)	09 Nov 2020 20:28:06

**US3312046**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 26 Nov 2020 10:51:05**

[Number of Days in ICU](#)

Audit	User	Time (GMT)
User entered empty.	Karol Moore (b) (4) (b) (4)	09 Nov 2020 20:28:06

**US3312046**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 26 Nov 2020 10:51:05**

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User entered '0'	Karol Moore (b) (4) (b) (4)	09 Nov 2020 20:28:06

**US3312046**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 26 Nov 2020 10:51:05**

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User entered '0'	Karol Moore (b) (4) (b) (4)	09 Nov 2020 20:28:06

**US3312046**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 26 Nov 2020 10:51:05**

[Other medically important event](#)

Audit	User	Time (GMT)
User entered '0'	Karol Moore (b) (4) (b) (4)	09 Nov 2020 20:28:06

**US3312046**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 26 Nov 2020 10:51:05**

[Relationship to investigational product](#)

Audit	User	Time (GMT)
User entered 'Not Related (NOT RELATED)'	Karol Moore (b) (4) (b) (4)	09 Nov 2020 20:28:06



**US3312046**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 26 Nov 2020 10:51:05**

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
User entered 'Not Related (NOT RELATED)'	Karol Moore (b) (4) (b) (4)	09 Nov 2020 20:28:06

**US3312046**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 26 Nov 2020 10:51:05**

[Action taken with investigational product](#)

Audit	User	Time (GMT)
User entered 'Not Applicable (NOT APPLICABLE)'	Karol Moore (b) (4)	09 Nov 2020 20:34:02
reason for change: Data Entry Error	(b) (4)	
User entered 'None (NONE)'	Karol Moore (b) (4)	09 Nov 2020 20:28:06
	(b) (4)	

**US3312046**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 26 Nov 2020 10:51:05**

[None](#)

Audit	User	Time (GMT)
User entered '1'	Karol Moore (b) (4) (b) (4)	09 Nov 2020 20:28:06

**US3312046**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 26 Nov 2020 10:51:05**

[Concomitant Medication](#)

Audit	User	Time (GMT)
User entered '0'	Karol Moore (b) (4) (b) (4)	09 Nov 2020 20:28:06

**US3312046**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 26 Nov 2020 10:51:05**

[Concomitant Procedure](#)

Audit	User	Time (GMT)
User entered '0'	Karol Moore (b) (4) (b) (4)	09 Nov 2020 20:28:06

**US3312046**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 26 Nov 2020 10:51:05**

[Outcome](#)

Audit	User	Time (GMT)
User entered 'Not Recovered/Not Resolved (NOT RECOVERED/NOT RESOLVED)' reason for change: Data Entry Error	Karol Moore (b) (4) (b) (4)	09 Nov 2020 20:34:02
User entered 'Recovered/Resolved with Sequelae (RECOVERED/RESOLVED WITH SEQUELAE)'	Karol Moore (b) (4) (b) (4)	09 Nov 2020 20:28:06

**US3312046**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 26 Nov 2020 10:51:05**

[If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:](#)

Audit	User	Time (GMT)
User closed query 'Outcome Recovered/Resolved with Sequelae, but specify the sequelae is missing. Please provide.' (Site from System).	System	09 Nov 2020 20:34:02
User opened query 'Outcome Recovered/Resolved with Sequelae, but specify the sequelae is missing. Please provide.' (Site from System).	System	09 Nov 2020 20:28:06
User entered empty.	Karol Moore (b) (4) (b) (4)	09 Nov 2020 20:28:06

**US3312046**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 26 Nov 2020 10:51:05**

[Narrative](#)

Audit	User	Time (GMT)
User entered empty.	Karol Moore (b) (4) (b) (4)	09 Nov 2020 20:28:06



**US3312046**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 26 Nov 2020 10:51:05**

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '0'	System	09 Nov 2020 20:28:06

**US3312046**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 26 Nov 2020 10:51:05**

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered 'I'	System	09 Nov 2020 20:28:06

US3312046

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 10:51:05

[Adverse event](#)

Audit	User	Time (GMT)
Query 'Per DM CLR: Please provide the specific location of Body Pain (eg, whole body, back muscle pain, arms, etc). Review and update Adverse Event condition as appropriate and ensure update is reconciled with any corresponding ConMed entries, if applicable. ' answered with 'NA. PER PROTOCOL, BODY ACHES REPORTED ON SYMPTOM LOG DURING CONVALESCENT PERIOD ARE "GENERALIZED BODY ACHES" AE. NAMES MUST MATCH SYMPTOM LOG' (Site from DM).	Karol Moore (b) (4) (b) (4)	23 Nov 2020 16:21:38
User opened query 'Per DM CLR: Please provide the specific location of Body Pain (eg, whole body, back muscle pain, arms, etc). Review and update Adverse Event condition as appropriate and ensure update is reconciled with any corresponding ConMed entries, if applicable. ' (Site from DM).	(b) (4), (b) (6) (b) (4)	23 Nov 2020 12:12:35
User coded data point as SOC: General disorders and administration site conditions, HLT: General system disorders NEC, HLT: Pain and discomfort NEC, PT: Pain, LLT: General body pain - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	09 Nov 2020 20:30:37
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	09 Nov 2020 20:30:37
Data point term sent to Coder	System	09 Nov 2020 20:29:49
User entered 'BODY ACHES'	Karol Moore (b) (4) (b) (4)	09 Nov 2020 20:28:56

**US3312046**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 26 Nov 2020 10:51:05**

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Karol Moore (b) (4) (b) (4)	09 Nov 2020 20:28:56

**US3312046**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 26 Nov 2020 10:51:05**

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Karol Moore (b) (4) (b) (4)	09 Nov 2020 20:28:56

**US3312046**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 26 Nov 2020 10:51:05**

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Karol Moore (b) (4) (b) (4)	09 Nov 2020 20:28:56

**US3312046**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 26 Nov 2020 10:51:05**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User entered '18 Oct 2020'	Karol Moore (b) (4) (b) (4)	09 Nov 2020 20:28:56

**US3312046**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 26 Nov 2020 10:51:05**

[Start time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
User entered empty.	Karol Moore (b) (4) (b) (4)	09 Nov 2020 20:28:56



**US3312046**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 26 Nov 2020 10:51:05**

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	09 Nov 2020 20:28:56

**US3312046**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 26 Nov 2020 10:51:05**

[Ongoing?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Karol Moore (b) (4) (b) (4)	09 Nov 2020 20:28:56

**US3312046**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 26 Nov 2020 10:51:05**

*If not Ongoing, end date (dd MMM yyyy)*

Audit	User	Time (GMT)
User entered '18 Oct 2020'	Karol Moore (b) (4) (b) (4)	09 Nov 2020 20:28:56

**US3312046**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 26 Nov 2020 10:51:05**

[End time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
User entered empty.	Karol Moore (b) (4) (b) (4)	09 Nov 2020 20:28:56

**US3312046**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 26 Nov 2020 10:51:05**

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	09 Nov 2020 20:28:56

**US3312046**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 26 Nov 2020 10:51:05**

[Severity](#)

Audit	User	Time (GMT)
User entered 'Grade 1/Mild (Grade 1/Mild)'	Karol Moore (b) (4) (b) (4)	09 Nov 2020 20:28:56

**US3312046**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 26 Nov 2020 10:51:05**

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Karol Moore (b) (4) (b) (4)	09 Nov 2020 20:28:56

**US3312046**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 26 Nov 2020 10:51:05**

[Death](#)

Audit	User	Time (GMT)
User entered '0'	Karol Moore (b) (4) (b) (4)	09 Nov 2020 20:28:56



**US3312046**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 26 Nov 2020 10:51:05**

[Life threatening](#)

Audit	User	Time (GMT)
User entered '0'	Karol Moore (b) (4) (b) (4)	09 Nov 2020 20:28:56

**US3312046**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 26 Nov 2020 10:51:05**

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User entered '0'	Karol Moore (b) (4) (b) (4)	09 Nov 2020 20:28:56

**US3312046**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 26 Nov 2020 10:51:05**

[Hospital Admission Date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User entered empty.	Karol Moore (b) (4) (b) (4)	09 Nov 2020 20:28:56

US3312046

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 10:51:05

Hospital Discharge Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered empty.	Karol Moore (b) (4) (b) (4)	09 Nov 2020 20:28:56

**US3312046**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 26 Nov 2020 10:51:05**

[Admitted to ICU?](#)

Audit	User	Time (GMT)
User entered empty.	Karol Moore (b) (4) (b) (4)	09 Nov 2020 20:28:56

**US3312046**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 26 Nov 2020 10:51:05**

[Number of Days in ICU](#)

Audit	User	Time (GMT)
User entered empty.	Karol Moore (b) (4) (b) (4)	09 Nov 2020 20:28:56

**US3312046**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 26 Nov 2020 10:51:05**

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User entered '0'	Karol Moore (b) (4) (b) (4)	09 Nov 2020 20:28:56

**US3312046**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 26 Nov 2020 10:51:05**

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User entered '0'	Karol Moore (b) (4) (b) (4)	09 Nov 2020 20:28:56



**US3312046**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 26 Nov 2020 10:51:05**

[Other medically important event](#)

Audit	User	Time (GMT)
User entered '0'	Karol Moore (b) (4) (b) (4)	09 Nov 2020 20:28:56

**US3312046**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 26 Nov 2020 10:51:05**

[Relationship to investigational product](#)

Audit	User	Time (GMT)
User entered 'Not Related (NOT RELATED)'	Karol Moore (b) (4) (b) (4)	09 Nov 2020 20:28:56

**US3312046**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 26 Nov 2020 10:51:05**

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
User entered 'Not Related (NOT RELATED)'	Karol Moore (b) (4) (b) (4)	09 Nov 2020 20:28:56

**US3312046**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 26 Nov 2020 10:51:05**

[Action taken with investigational product](#)

Audit	User	Time (GMT)
User entered 'Not Applicable (NOT APPLICABLE)'	Karol Moore (b) (4)	09 Nov 2020 20:33:35
reason for change: Data Entry Error	(b) (4)	
User entered 'None (NONE)'	Karol Moore (b) (4)	09 Nov 2020 20:28:56
	(b) (4)	

**US3312046**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 26 Nov 2020 10:51:05**

[None](#)

Audit	User	Time (GMT)
User entered '1'	Karol Moore (b) (4) (b) (4)	09 Nov 2020 20:28:56

**US3312046**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 26 Nov 2020 10:51:05**

[Concomitant Medication](#)

Audit	User	Time (GMT)
User entered '0'	Karol Moore (b) (4) (b) (4)	09 Nov 2020 20:28:56

**US3312046**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 26 Nov 2020 10:51:05**

[Concomitant Procedure](#)

Audit	User	Time (GMT)
User entered '0'	Karol Moore (b) (4) (b) (4)	09 Nov 2020 20:28:56

**US3312046**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 26 Nov 2020 10:51:05**

[Outcome](#)

Audit	User	Time (GMT)
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)'	Karol Moore (b) (4) (b) (4)	09 Nov 2020 20:28:56



**US3312046**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 26 Nov 2020 10:51:05**

[If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:](#)

Audit	User	Time (GMT)
User entered empty.	Karol Moore (b) (4) (b) (4)	09 Nov 2020 20:28:56

**US3312046**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 26 Nov 2020 10:51:05**

[Narrative](#)

Audit	User	Time (GMT)
User entered empty.	Karol Moore (b) (4) (b) (4)	09 Nov 2020 20:28:56

**US3312046**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 26 Nov 2020 10:51:05**

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '0'	System	09 Nov 2020 20:28:56

**US3312046**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 26 Nov 2020 10:51:05**

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered 'I'	System	09 Nov 2020 20:28:56

US3312046

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 26 Nov 2020 10:51:05

[Adverse event](#)

Audit	User	Time (GMT)
User coded data point as SOC: Respiratory, thoracic and mediastinal disorders, HLGT: Respiratory tract signs and symptoms, HLT: Upper respiratory tract signs and symptoms, PT: Rhinorrhoea, LLT: Runny nose - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	09 Nov 2020 20:47:36
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	09 Nov 2020 20:47:36
Data point term sent to Coder	System	09 Nov 2020 20:30:53
User entered 'RUNNY NOSE'	Karol Moore (b) (4) (b) (4)	09 Nov 2020 20:29:51

**US3312046**

**Folder: Adverse Events**

**Form: Adverse Events (4)**

**Generated On: 26 Nov 2020 10:51:05**

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Karol Moore (b) (4) (b) (4)	09 Nov 2020 20:29:51

**US3312046**

**Folder: Adverse Events**

**Form: Adverse Events (4)**

**Generated On: 26 Nov 2020 10:51:05**

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Karol Moore (b) (4) (b) (4)	09 Nov 2020 20:29:51

**US3312046**

**Folder: Adverse Events**

**Form: Adverse Events (4)**

**Generated On: 26 Nov 2020 10:51:05**

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Karol Moore (b) (4) (b) (4)	09 Nov 2020 20:29:51



US3312046

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 26 Nov 2020 10:51:05

Start date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered '18 Oct 2020'	Karol Moore (b) (4) (b) (4)	09 Nov 2020 20:29:51

**US3312046**

**Folder: Adverse Events**

**Form: Adverse Events (4)**

**Generated On: 26 Nov 2020 10:51:05**

[Start time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
User entered empty.	Karol Moore (b) (4) (b) (4)	09 Nov 2020 20:29:51

**US3312046**

**Folder: Adverse Events**

**Form: Adverse Events (4)**

**Generated On: 26 Nov 2020 10:51:05**

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	09 Nov 2020 20:29:51

**US3312046**

**Folder: Adverse Events**

**Form: Adverse Events (4)**

**Generated On: 26 Nov 2020 10:51:05**

[Ongoing?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Karol Moore (b) (4) (b) (4)	09 Nov 2020 20:29:51

**US3312046**

**Folder: Adverse Events**

**Form: Adverse Events (4)**

**Generated On: 26 Nov 2020 10:51:05**

*If not Ongoing, end date (dd MMM yyyy)*

Audit	User	Time (GMT)
User entered '20 Oct 2020'	Karol Moore (b) (4) (b) (4)	09 Nov 2020 20:29:51

**US3312046**

**Folder: Adverse Events**

**Form: Adverse Events (4)**

**Generated On: 26 Nov 2020 10:51:05**

[End time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
User entered empty.	Karol Moore (b) (4) (b) (4)	09 Nov 2020 20:29:51

**US3312046**

**Folder: Adverse Events**

**Form: Adverse Events (4)**

**Generated On: 26 Nov 2020 10:51:05**

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	09 Nov 2020 20:29:51

**US3312046**

**Folder: Adverse Events**

**Form: Adverse Events (4)**

**Generated On: 26 Nov 2020 10:51:05**

[Severity](#)

Audit	User	Time (GMT)
User entered 'Grade 1/Mild (Grade 1/Mild)'	Karol Moore (b) (4) (b) (4)	09 Nov 2020 20:29:51



US3312046

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 26 Nov 2020 10:51:05

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Karol Moore (b) (4) (b) (4)	09 Nov 2020 20:29:51

**US3312046**

**Folder: Adverse Events**

**Form: Adverse Events (4)**

**Generated On: 26 Nov 2020 10:51:05**

[Death](#)

Audit	User	Time (GMT)
User entered '0'	Karol Moore (b) (4) (b) (4)	09 Nov 2020 20:29:51

**US3312046**

**Folder: Adverse Events**

**Form: Adverse Events (4)**

**Generated On: 26 Nov 2020 10:51:05**

[Life threatening](#)

Audit	User	Time (GMT)
User entered '0'	Karol Moore (b) (4) (b) (4)	09 Nov 2020 20:29:51

**US3312046**

**Folder: Adverse Events**

**Form: Adverse Events (4)**

**Generated On: 26 Nov 2020 10:51:05**

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User entered '0'	Karol Moore (b) (4) (b) (4)	09 Nov 2020 20:29:51

US3312046

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 26 Nov 2020 10:51:05

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered empty.	Karol Moore (b) (4) (b) (4)	09 Nov 2020 20:29:51

**US3312046**

**Folder: Adverse Events**

**Form: Adverse Events (4)**

**Generated On: 26 Nov 2020 10:51:05**

[Hospital Discharge Date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User entered empty.	Karol Moore (b) (4) (b) (4)	09 Nov 2020 20:29:51

**US3312046**

**Folder: Adverse Events**

**Form: Adverse Events (4)**

**Generated On: 26 Nov 2020 10:51:05**

[Admitted to ICU?](#)

Audit	User	Time (GMT)
User entered empty.	Karol Moore (b) (4) (b) (4)	09 Nov 2020 20:29:51

**US3312046**

**Folder: Adverse Events**

**Form: Adverse Events (4)**

**Generated On: 26 Nov 2020 10:51:05**

[Number of Days in ICU](#)

Audit	User	Time (GMT)
User entered empty.	Karol Moore (b) (4) (b) (4)	09 Nov 2020 20:29:51



**US3312046**

**Folder: Adverse Events**

**Form: Adverse Events (4)**

**Generated On: 26 Nov 2020 10:51:05**

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User entered '0'	Karol Moore (b) (4) (b) (4)	09 Nov 2020 20:29:51

**US3312046**

**Folder: Adverse Events**

**Form: Adverse Events (4)**

**Generated On: 26 Nov 2020 10:51:05**

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User entered '0'	Karol Moore (b) (4) (b) (4)	09 Nov 2020 20:29:51

**US3312046**

**Folder: Adverse Events**

**Form: Adverse Events (4)**

**Generated On: 26 Nov 2020 10:51:05**

[Other medically important event](#)

Audit	User	Time (GMT)
User entered '0'	Karol Moore (b) (4) (b) (4)	09 Nov 2020 20:29:51

**US3312046**

**Folder: Adverse Events**

**Form: Adverse Events (4)**

**Generated On: 26 Nov 2020 10:51:05**

[Relationship to investigational product](#)

Audit	User	Time (GMT)
User entered 'Not Related (NOT RELATED)'	Karol Moore (b) (4) (b) (4)	09 Nov 2020 20:29:51

US3312046

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 26 Nov 2020 10:51:05

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
User entered 'Not Related (NOT RELATED)'	Karol Moore (b) (4) (b) (4)	09 Nov 2020 20:29:51

**US3312046**

**Folder: Adverse Events**

**Form: Adverse Events (4)**

**Generated On: 26 Nov 2020 10:51:05**

[Action taken with investigational product](#)

Audit	User	Time (GMT)
User entered 'Not Applicable (NOT APPLICABLE)'	Karol Moore (b) (4)	09 Nov 2020 20:33:23
reason for change: Data Entry Error	(b) (4)	
User entered 'None (NONE)'	Karol Moore (b) (4)	09 Nov 2020 20:29:51
	(b) (4)	

**US3312046**

**Folder: Adverse Events**

**Form: Adverse Events (4)**

**Generated On: 26 Nov 2020 10:51:05**

[None](#)

Audit	User	Time (GMT)
User entered 'I'	Karol Moore (b) (4) (b) (4)	09 Nov 2020 20:29:51

**US3312046**

**Folder: Adverse Events**

**Form: Adverse Events (4)**

**Generated On: 26 Nov 2020 10:51:05**

[Concomitant Medication](#)

Audit	User	Time (GMT)
User entered '0'	Karol Moore (b) (4) (b) (4)	09 Nov 2020 20:29:51



**US3312046**

**Folder: Adverse Events**

**Form: Adverse Events (4)**

**Generated On: 26 Nov 2020 10:51:05**

[Concomitant Procedure](#)

Audit	User	Time (GMT)
User entered '0'	Karol Moore (b) (4) (b) (4)	09 Nov 2020 20:29:51

**US3312046**

**Folder: Adverse Events**

**Form: Adverse Events (4)**

**Generated On: 26 Nov 2020 10:51:05**

[Outcome](#)

Audit	User	Time (GMT)
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)'	Karol Moore (b) (4) (b) (4)	09 Nov 2020 20:29:51

**US3312046**

**Folder: Adverse Events**

**Form: Adverse Events (4)**

**Generated On: 26 Nov 2020 10:51:05**

[If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:](#)

Audit	User	Time (GMT)
User entered empty.	Karol Moore (b) (4) (b) (4)	09 Nov 2020 20:29:51

**US3312046**

**Folder: Adverse Events**

**Form: Adverse Events (4)**

**Generated On: 26 Nov 2020 10:51:05**

[Narrative](#)

Audit	User	Time (GMT)
User entered empty.	Karol Moore (b) (4) (b) (4)	09 Nov 2020 20:29:51

**US3312046**

**Folder: Adverse Events**

**Form: Adverse Events (4)**

**Generated On: 26 Nov 2020 10:51:05**

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '0'	System	09 Nov 2020 20:29:51

**US3312046**

**Folder: Adverse Events**

**Form: Adverse Events (4)**

**Generated On: 26 Nov 2020 10:51:05**

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered 'I'	System	09 Nov 2020 20:29:51

US3312046

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 26 Nov 2020 10:51:05

[Adverse event](#)

Audit	User	Time (GMT)
User coded data point as SOC: Gastrointestinal disorders, HLGT: Gastrointestinal signs and symptoms, HLT: Nausea and vomiting symptoms, PT: Nausea, LLT: Nausea - version MedDRA\\23.0.	Coder Import (b) (4)	09 Nov 2020 20:32:37
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	09 Nov 2020 20:32:37
Data point term sent to Coder	System	09 Nov 2020 20:31:54
User entered 'NAUSEA'	Karol Moore (b) (4)	09 Nov 2020 20:30:57
	(b) (4)	

**US3312046**

**Folder: Adverse Events**

**Form: Adverse Events (5)**

**Generated On: 26 Nov 2020 10:51:05**

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Karol Moore (b) (4) (b) (4)	09 Nov 2020 20:30:57



**US3312046**

**Folder: Adverse Events**

**Form: Adverse Events (5)**

**Generated On: 26 Nov 2020 10:51:05**

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Karol Moore (b) (4) (b) (4)	09 Nov 2020 20:30:57

**US3312046**

**Folder: Adverse Events**

**Form: Adverse Events (5)**

**Generated On: 26 Nov 2020 10:51:05**

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Karol Moore (b) (4) (b) (4)	09 Nov 2020 20:30:57

**US3312046**

**Folder: Adverse Events**

**Form: Adverse Events (5)**

**Generated On: 26 Nov 2020 10:51:05**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User entered '07 Oct 2020'	Karol Moore (b) (4) (b) (4)	09 Nov 2020 20:30:57

**US3312046**

**Folder: Adverse Events**

**Form: Adverse Events (5)**

**Generated On: 26 Nov 2020 10:51:05**

[Start time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
User entered empty.	Karol Moore (b) (4) (b) (4)	09 Nov 2020 20:30:57

**US3312046**

**Folder: Adverse Events**

**Form: Adverse Events (5)**

**Generated On: 26 Nov 2020 10:51:05**

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	09 Nov 2020 20:30:57

**US3312046**

**Folder: Adverse Events**

**Form: Adverse Events (5)**

**Generated On: 26 Nov 2020 10:51:05**

[Ongoing?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Karol Moore (b) (4) (b) (4)	09 Nov 2020 20:30:57

US3312046

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 26 Nov 2020 10:51:05

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
User closed query 'Outcome is not Recovered/Resolved, Recovered/Resolved with sequelae or Fatal, but End Date is provided. Please correct.' (Site from System).	System	09 Nov 2020 20:31:18
Query 'Outcome is not Recovered/Resolved, Recovered/Resolved with sequelae or Fatal, but End Date is provided. Please correct.' answered by data change (Site from System).	System	09 Nov 2020 20:31:18
User opened query 'Outcome is not Recovered/Resolved, Recovered/Resolved with sequelae or Fatal, but End Date is provided. Please correct.' (Site from System).	System	09 Nov 2020 20:30:57
User entered '19 Oct 2020'	Karol Moore (b) (4) (b) (4)	09 Nov 2020 20:30:57

**US3312046**

**Folder: Adverse Events**

**Form: Adverse Events (5)**

**Generated On: 26 Nov 2020 10:51:05**

[End time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
User entered empty.	Karol Moore (b) (4) (b) (4)	09 Nov 2020 20:30:57



**US3312046**

**Folder: Adverse Events**

**Form: Adverse Events (5)**

**Generated On: 26 Nov 2020 10:51:05**

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	09 Nov 2020 20:30:57

**US3312046**

**Folder: Adverse Events**

**Form: Adverse Events (5)**

**Generated On: 26 Nov 2020 10:51:05**

[Severity](#)

Audit	User	Time (GMT)
User entered 'Grade 1/Mild (Grade 1/Mild)'	Karol Moore (b) (4) (b) (4)	09 Nov 2020 20:30:57

**US3312046**

**Folder: Adverse Events**

**Form: Adverse Events (5)**

**Generated On: 26 Nov 2020 10:51:05**

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Karol Moore (b) (4) (b) (4)	09 Nov 2020 20:30:57

**US3312046**

**Folder: Adverse Events**

**Form: Adverse Events (5)**

**Generated On: 26 Nov 2020 10:51:05**

[Death](#)

Audit	User	Time (GMT)
User entered '0'	Karol Moore (b) (4) (b) (4)	09 Nov 2020 20:30:57

**US3312046**

**Folder: Adverse Events**

**Form: Adverse Events (5)**

**Generated On: 26 Nov 2020 10:51:05**

[Life threatening](#)

Audit	User	Time (GMT)
User entered '0'	Karol Moore (b) (4) (b) (4)	09 Nov 2020 20:30:57

**US3312046**

**Folder: Adverse Events**

**Form: Adverse Events (5)**

**Generated On: 26 Nov 2020 10:51:05**

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User entered '0'	Karol Moore (b) (4) (b) (4)	09 Nov 2020 20:30:57

**US3312046**

**Folder: Adverse Events**

**Form: Adverse Events (5)**

**Generated On: 26 Nov 2020 10:51:05**

[Hospital Admission Date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User entered empty.	Karol Moore (b) (4) (b) (4)	09 Nov 2020 20:30:57

**US3312046**

**Folder: Adverse Events**

**Form: Adverse Events (5)**

**Generated On: 26 Nov 2020 10:51:05**

[Hospital Discharge Date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User entered empty.	Karol Moore (b) (4) (b) (4)	09 Nov 2020 20:30:57



**US3312046**

**Folder: Adverse Events**

**Form: Adverse Events (5)**

**Generated On: 26 Nov 2020 10:51:05**

[Admitted to ICU?](#)

Audit	User	Time (GMT)
User entered empty.	Karol Moore (b) (4) (b) (4)	09 Nov 2020 20:30:57

**US3312046**

**Folder: Adverse Events**

**Form: Adverse Events (5)**

**Generated On: 26 Nov 2020 10:51:05**

[Number of Days in ICU](#)

Audit	User	Time (GMT)
User entered empty.	Karol Moore (b) (4) (b) (4)	09 Nov 2020 20:30:57

**US3312046**

**Folder: Adverse Events**

**Form: Adverse Events (5)**

**Generated On: 26 Nov 2020 10:51:05**

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User entered '0'	Karol Moore (b) (4) (b) (4)	09 Nov 2020 20:30:57

**US3312046**

**Folder: Adverse Events**

**Form: Adverse Events (5)**

**Generated On: 26 Nov 2020 10:51:05**

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User entered '0'	Karol Moore (b) (4) (b) (4)	09 Nov 2020 20:30:57

**US3312046**

**Folder: Adverse Events**

**Form: Adverse Events (5)**

**Generated On: 26 Nov 2020 10:51:05**

[Other medically important event](#)

Audit	User	Time (GMT)
User entered '0'	Karol Moore (b) (4) (b) (4)	09 Nov 2020 20:30:57

**US3312046**

**Folder: Adverse Events**

**Form: Adverse Events (5)**

**Generated On: 26 Nov 2020 10:51:05**

[Relationship to investigational product](#)

Audit	User	Time (GMT)
User entered 'Not Related (NOT RELATED)'	Karol Moore (b) (4) (b) (4)	09 Nov 2020 20:30:57

**US3312046**

**Folder: Adverse Events**

**Form: Adverse Events (5)**

**Generated On: 26 Nov 2020 10:51:05**

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
User entered 'Not Related (NOT RELATED)'	Karol Moore (b) (4) (b) (4)	09 Nov 2020 20:30:57

**US3312046**

**Folder: Adverse Events**

**Form: Adverse Events (5)**

**Generated On: 26 Nov 2020 10:51:05**

[Action taken with investigational product](#)

Audit	User	Time (GMT)
User entered 'Not Applicable (NOT APPLICABLE)'	Karol Moore (b) (4)	09 Nov 2020 20:33:13
reason for change: Data Entry Error	(b) (4)	
User entered 'None (NONE)'	Karol Moore (b) (4)	09 Nov 2020 20:30:57
	(b) (4)	



**US3312046**

**Folder: Adverse Events**

**Form: Adverse Events (5)**

**Generated On: 26 Nov 2020 10:51:05**

[None](#)

Audit	User	Time (GMT)
User entered '1'	Karol Moore (b) (4) (b) (4)	09 Nov 2020 20:30:57

**US3312046**

**Folder: Adverse Events**

**Form: Adverse Events (5)**

**Generated On: 26 Nov 2020 10:51:05**

[Concomitant Medication](#)

Audit	User	Time (GMT)
User entered '0'	Karol Moore (b) (4) (b) (4)	09 Nov 2020 20:30:57

**US3312046**

**Folder: Adverse Events**

**Form: Adverse Events (5)**

**Generated On: 26 Nov 2020 10:51:05**

[Concomitant Procedure](#)

Audit	User	Time (GMT)
User entered '0'	Karol Moore (b) (4) (b) (4)	09 Nov 2020 20:30:57

**US3312046**

**Folder: Adverse Events**

**Form: Adverse Events (5)**

**Generated On: 26 Nov 2020 10:51:05**

[Outcome](#)

Audit	User	Time (GMT)
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)' reason for change: Data Entry Error	Karol Moore (b) (4) (b) (4)	09 Nov 2020 20:31:18
User entered 'Not Recovered/Not Resolved (NOT RECOVERED/NOT RESOLVED)'	Karol Moore (b) (4) (b) (4)	09 Nov 2020 20:30:57

**US3312046**

**Folder: Adverse Events**

**Form: Adverse Events (5)**

**Generated On: 26 Nov 2020 10:51:05**

[If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:](#)

Audit	User	Time (GMT)
User entered empty.	Karol Moore (b) (4) (b) (4)	09 Nov 2020 20:30:57

**US3312046**

**Folder: Adverse Events**

**Form: Adverse Events (5)**

**Generated On: 26 Nov 2020 10:51:05**

[Narrative](#)

Audit	User	Time (GMT)
User entered empty.	Karol Moore (b) (4) (b) (4)	09 Nov 2020 20:30:57

**US3312046**

**Folder: Adverse Events**

**Form: Adverse Events (5)**

**Generated On: 26 Nov 2020 10:51:05**

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '0'	System	09 Nov 2020 20:30:57

**US3312046**

**Folder: Adverse Events**

**Form: Adverse Events (5)**

**Generated On: 26 Nov 2020 10:51:05**

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered 'I'	System	09 Nov 2020 20:30:57



US3312046

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 26 Nov 2020 10:51:05

[Adverse event](#)

Audit	User	Time (GMT)
User coded data point as SOC: General disorders and administration site conditions, HLGT: Body temperature conditions, HLT: Febrile disorders, PT: Pyrexia, LLT: Fever - version MedDRA\\23.0.	Coder Import (b) (4)	09 Nov 2020 20:34:40
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	09 Nov 2020 20:34:40
Data point term sent to Coder	System	09 Nov 2020 20:33:59
User entered 'FEVER'	Karol Moore (b) (4)	09 Nov 2020 20:33:00
	(b) (4)	

**US3312046**

**Folder: Adverse Events**

**Form: Adverse Events (6)**

**Generated On: 26 Nov 2020 10:51:05**

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Karol Moore (b) (4) (b) (4)	09 Nov 2020 20:33:00

**US3312046**

**Folder: Adverse Events**

**Form: Adverse Events (6)**

**Generated On: 26 Nov 2020 10:51:05**

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Karol Moore (b) (4) (b) (4)	09 Nov 2020 20:33:00

**US3312046**

**Folder: Adverse Events**

**Form: Adverse Events (6)**

**Generated On: 26 Nov 2020 10:51:05**

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Karol Moore (b) (4) (b) (4)	09 Nov 2020 20:33:00

**US3312046**

**Folder: Adverse Events**

**Form: Adverse Events (6)**

**Generated On: 26 Nov 2020 10:51:05**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User entered '07 Oct 2020'	Karol Moore (b) (4) (b) (4)	09 Nov 2020 20:33:00

**US3312046**

**Folder: Adverse Events**

**Form: Adverse Events (6)**

**Generated On: 26 Nov 2020 10:51:05**

[Start time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
User entered empty.	Karol Moore (b) (4) (b) (4)	09 Nov 2020 20:33:00

**US3312046**

**Folder: Adverse Events**

**Form: Adverse Events (6)**

**Generated On: 26 Nov 2020 10:51:05**

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	09 Nov 2020 20:33:00

**US3312046**

**Folder: Adverse Events**

**Form: Adverse Events (6)**

**Generated On: 26 Nov 2020 10:51:05**

[Ongoing?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Karol Moore (b) (4) (b) (4)	09 Nov 2020 20:33:00



**US3312046**

**Folder: Adverse Events**

**Form: Adverse Events (6)**

**Generated On: 26 Nov 2020 10:51:05**

*If not Ongoing, end date (dd MMM yyyy)*

Audit	User	Time (GMT)
User entered '14 Oct 2020'	Karol Moore (b) (4) (b) (4)	09 Nov 2020 20:33:00

**US3312046**

**Folder: Adverse Events**

**Form: Adverse Events (6)**

**Generated On: 26 Nov 2020 10:51:05**

[End time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
User entered empty.	Karol Moore (b) (4) (b) (4)	09 Nov 2020 20:33:00

**US3312046**

**Folder: Adverse Events**

**Form: Adverse Events (6)**

**Generated On: 26 Nov 2020 10:51:05**

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	09 Nov 2020 20:33:00

**US3312046**

**Folder: Adverse Events**

**Form: Adverse Events (6)**

**Generated On: 26 Nov 2020 10:51:05**

[Severity](#)

Audit	User	Time (GMT)
User entered 'Grade 1/Mild (Grade 1/Mild)'	Karol Moore (b) (4) (b) (4)	09 Nov 2020 20:33:00

**US3312046**

**Folder: Adverse Events**

**Form: Adverse Events (6)**

**Generated On: 26 Nov 2020 10:51:05**

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Karol Moore (b) (4) (b) (4)	09 Nov 2020 20:33:00

**US3312046**

**Folder: Adverse Events**

**Form: Adverse Events (6)**

**Generated On: 26 Nov 2020 10:51:05**

[Death](#)

Audit	User	Time (GMT)
User entered '0'	Karol Moore (b) (4) (b) (4)	09 Nov 2020 20:33:00

**US3312046**

**Folder: Adverse Events**

**Form: Adverse Events (6)**

**Generated On: 26 Nov 2020 10:51:05**

[Life threatening](#)

Audit	User	Time (GMT)
User entered '0'	Karol Moore (b) (4) (b) (4)	09 Nov 2020 20:33:00

**US3312046**

**Folder: Adverse Events**

**Form: Adverse Events (6)**

**Generated On: 26 Nov 2020 10:51:05**

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User entered '0'	Karol Moore (b) (4) (b) (4)	09 Nov 2020 20:33:00



US3312046

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 26 Nov 2020 10:51:05

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered empty.	Karol Moore (b) (4) (b) (4)	09 Nov 2020 20:33:00

**US3312046**

**Folder: Adverse Events**

**Form: Adverse Events (6)**

**Generated On: 26 Nov 2020 10:51:05**

[Hospital Discharge Date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User entered empty.	Karol Moore (b) (4) (b) (4)	09 Nov 2020 20:33:00

**US3312046**

**Folder: Adverse Events**

**Form: Adverse Events (6)**

**Generated On: 26 Nov 2020 10:51:05**

[Admitted to ICU?](#)

Audit	User	Time (GMT)
User entered empty.	Karol Moore (b) (4) (b) (4)	09 Nov 2020 20:33:00

**US3312046**

**Folder: Adverse Events**

**Form: Adverse Events (6)**

**Generated On: 26 Nov 2020 10:51:05**

[Number of Days in ICU](#)

Audit	User	Time (GMT)
User entered empty.	Karol Moore (b) (4) (b) (4)	09 Nov 2020 20:33:00

**US3312046**

**Folder: Adverse Events**

**Form: Adverse Events (6)**

**Generated On: 26 Nov 2020 10:51:05**

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User entered '0'	Karol Moore (b) (4) (b) (4)	09 Nov 2020 20:33:00

**US3312046**

**Folder: Adverse Events**

**Form: Adverse Events (6)**

**Generated On: 26 Nov 2020 10:51:05**

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User entered '0'	Karol Moore (b) (4) (b) (4)	09 Nov 2020 20:33:00

**US3312046**

**Folder: Adverse Events**

**Form: Adverse Events (6)**

**Generated On: 26 Nov 2020 10:51:05**

[Other medically important event](#)

Audit	User	Time (GMT)
User entered '0'	Karol Moore (b) (4) (b) (4)	09 Nov 2020 20:33:00

**US3312046**

**Folder: Adverse Events**

**Form: Adverse Events (6)**

**Generated On: 26 Nov 2020 10:51:05**

[Relationship to investigational product](#)

Audit	User	Time (GMT)
User entered 'Not Related (NOT RELATED)'	Karol Moore (b) (4) (b) (4)	09 Nov 2020 20:33:00



**US3312046**

**Folder: Adverse Events**

**Form: Adverse Events (6)**

**Generated On: 26 Nov 2020 10:51:05**

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
User entered 'Not Related (NOT RELATED)'	Karol Moore (b) (4) (b) (4)	09 Nov 2020 20:33:00

**US3312046**

**Folder: Adverse Events**

**Form: Adverse Events (6)**

**Generated On: 26 Nov 2020 10:51:05**

[Action taken with investigational product](#)

Audit	User	Time (GMT)
User entered 'Not Applicable (NOT APPLICABLE)'	Karol Moore (b) (4) (b) (4)	09 Nov 2020 20:33:00

**US3312046**

**Folder: Adverse Events**

**Form: Adverse Events (6)**

**Generated On: 26 Nov 2020 10:51:05**

[None](#)

Audit	User	Time (GMT)
User entered 'I'	Karol Moore (b) (4) (b) (4)	09 Nov 2020 20:33:00

**US3312046**

**Folder: Adverse Events**

**Form: Adverse Events (6)**

**Generated On: 26 Nov 2020 10:51:05**

[Concomitant Medication](#)

Audit	User	Time (GMT)
User entered '0'	Karol Moore (b) (4) (b) (4)	09 Nov 2020 20:33:00

US3312046

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 26 Nov 2020 10:51:05

[Concomitant Procedure](#)

Audit	User	Time (GMT)
User entered '0'	Karol Moore (b) (4) (b) (4)	09 Nov 2020 20:33:00

**US3312046**

**Folder: Adverse Events**

**Form: Adverse Events (6)**

**Generated On: 26 Nov 2020 10:51:05**

[Outcome](#)

Audit	User	Time (GMT)
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)'	Karol Moore (b) (4) (b) (4)	09 Nov 2020 20:33:00

**US3312046**

**Folder: Adverse Events**

**Form: Adverse Events (6)**

**Generated On: 26 Nov 2020 10:51:05**

[If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:](#)

Audit	User	Time (GMT)
User entered empty.	Karol Moore (b) (4) (b) (4)	09 Nov 2020 20:33:00

**US3312046**

**Folder: Adverse Events**

**Form: Adverse Events (6)**

**Generated On: 26 Nov 2020 10:51:05**

[Narrative](#)

Audit	User	Time (GMT)
User entered empty.	Karol Moore (b) (4) (b) (4)	09 Nov 2020 20:33:00



**US3312046**

**Folder: Adverse Events**

**Form: Adverse Events (6)**

**Generated On: 26 Nov 2020 10:51:05**

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '0'	System	09 Nov 2020 20:33:00

**US3312046**

**Folder: Adverse Events**

**Form: Adverse Events (6)**

**Generated On: 26 Nov 2020 10:51:05**

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered 'I'	System	09 Nov 2020 20:33:00

US3312046

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 26 Nov 2020 10:51:05

[Adverse event](#)

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)	09 Nov 2020 20:36:35
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	09 Nov 2020 20:36:35
Data point term sent to Coder	System	09 Nov 2020 20:36:03
User entered 'HEADACHE'	Karol Moore (b) (4) (b) (4)	09 Nov 2020 20:35:34

**US3312046**

**Folder: Adverse Events**

**Form: Adverse Events (7)**

**Generated On: 26 Nov 2020 10:51:05**

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Karol Moore (b) (4) (b) (4)	09 Nov 2020 20:35:34

**US3312046**

**Folder: Adverse Events**

**Form: Adverse Events (7)**

**Generated On: 26 Nov 2020 10:51:05**

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Karol Moore (b) (4) (b) (4)	09 Nov 2020 20:35:34

**US3312046**

**Folder: Adverse Events**

**Form: Adverse Events (7)**

**Generated On: 26 Nov 2020 10:51:05**

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Karol Moore (b) (4) (b) (4)	09 Nov 2020 20:35:34

**US3312046**

**Folder: Adverse Events**

**Form: Adverse Events (7)**

**Generated On: 26 Nov 2020 10:51:05**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User entered '07 Oct 2020'	Karol Moore (b) (4) (b) (4)	09 Nov 2020 20:35:34

**US3312046**

**Folder: Adverse Events**

**Form: Adverse Events (7)**

**Generated On: 26 Nov 2020 10:51:05**

**Start time (00:00-23:59)**

Audit	User	Time (GMT)
User entered empty.	Karol Moore (b) (4) (b) (4)	09 Nov 2020 20:35:34



**US3312046**

**Folder: Adverse Events**

**Form: Adverse Events (7)**

**Generated On: 26 Nov 2020 10:51:05**

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	09 Nov 2020 20:35:34

**US3312046**

**Folder: Adverse Events**

**Form: Adverse Events (7)**

**Generated On: 26 Nov 2020 10:51:05**

[Ongoing?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Karol Moore (b) (4) (b) (4)	09 Nov 2020 20:35:34

**US3312046**

**Folder: Adverse Events**

**Form: Adverse Events (7)**

**Generated On: 26 Nov 2020 10:51:05**

*If not Ongoing, end date (dd MMM yyyy)*

Audit	User	Time (GMT)
User entered '07 Oct 2020'	Karol Moore (b) (4) (b) (4)	09 Nov 2020 20:35:34

**US3312046**

**Folder: Adverse Events**

**Form: Adverse Events (7)**

**Generated On: 26 Nov 2020 10:51:05**

[End time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
User entered empty.	Karol Moore (b) (4) (b) (4)	09 Nov 2020 20:35:34

**US3312046**

**Folder: Adverse Events**

**Form: Adverse Events (7)**

**Generated On: 26 Nov 2020 10:51:05**

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	09 Nov 2020 20:35:34

**US3312046**

**Folder: Adverse Events**

**Form: Adverse Events (7)**

**Generated On: 26 Nov 2020 10:51:05**

[Severity](#)

Audit	User	Time (GMT)
User entered 'Grade 1/Mild (Grade 1/Mild)'	Karol Moore (b) (4) (b) (4)	09 Nov 2020 20:35:34

**US3312046**

**Folder: Adverse Events**

**Form: Adverse Events (7)**

**Generated On: 26 Nov 2020 10:51:05**

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Karol Moore (b) (4) (b) (4)	09 Nov 2020 20:35:34

**US3312046**

**Folder: Adverse Events**

**Form: Adverse Events (7)**

**Generated On: 26 Nov 2020 10:51:05**

[Death](#)

Audit	User	Time (GMT)
User entered '0'	Karol Moore (b) (4) (b) (4)	09 Nov 2020 20:35:34



**US3312046**

**Folder: Adverse Events**

**Form: Adverse Events (7)**

**Generated On: 26 Nov 2020 10:51:05**

[Life threatening](#)

Audit	User	Time (GMT)
User entered '0'	Karol Moore (b) (4) (b) (4)	09 Nov 2020 20:35:34

**US3312046**

**Folder: Adverse Events**

**Form: Adverse Events (7)**

**Generated On: 26 Nov 2020 10:51:05**

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User entered '0'	Karol Moore (b) (4) (b) (4)	09 Nov 2020 20:35:34

**US3312046**

**Folder: Adverse Events**

**Form: Adverse Events (7)**

**Generated On: 26 Nov 2020 10:51:05**

[Hospital Admission Date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User entered empty.	Karol Moore (b) (4) (b) (4)	09 Nov 2020 20:35:34

**US3312046**

**Folder: Adverse Events**

**Form: Adverse Events (7)**

**Generated On: 26 Nov 2020 10:51:05**

[Hospital Discharge Date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User entered empty.	Karol Moore (b) (4) (b) (4)	09 Nov 2020 20:35:34

**US3312046**

**Folder: Adverse Events**

**Form: Adverse Events (7)**

**Generated On: 26 Nov 2020 10:51:05**

[Admitted to ICU?](#)

Audit	User	Time (GMT)
User entered empty.	Karol Moore (b) (4) (b) (4)	09 Nov 2020 20:35:34

**US3312046**

**Folder: Adverse Events**

**Form: Adverse Events (7)**

**Generated On: 26 Nov 2020 10:51:05**

[Number of Days in ICU](#)

Audit	User	Time (GMT)
User entered empty.	Karol Moore (b) (4) (b) (4)	09 Nov 2020 20:35:34

**US3312046**

**Folder: Adverse Events**

**Form: Adverse Events (7)**

**Generated On: 26 Nov 2020 10:51:05**

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User entered '0'	Karol Moore (b) (4) (b) (4)	09 Nov 2020 20:35:34

**US3312046**

**Folder: Adverse Events**

**Form: Adverse Events (7)**

**Generated On: 26 Nov 2020 10:51:05**

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User entered '0'	Karol Moore (b) (4) (b) (4)	09 Nov 2020 20:35:34



**US3312046**

**Folder: Adverse Events**

**Form: Adverse Events (7)**

**Generated On: 26 Nov 2020 10:51:05**

[Other medically important event](#)

Audit	User	Time (GMT)
User entered '0'	Karol Moore (b) (4) (b) (4)	09 Nov 2020 20:35:34

**US3312046**

**Folder: Adverse Events**

**Form: Adverse Events (7)**

**Generated On: 26 Nov 2020 10:51:05**

[Relationship to investigational product](#)

Audit	User	Time (GMT)
User entered 'Not Related (NOT RELATED)'	Karol Moore (b) (4) (b) (4)	09 Nov 2020 20:35:34

**US3312046**

**Folder: Adverse Events**

**Form: Adverse Events (7)**

**Generated On: 26 Nov 2020 10:51:05**

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
User entered 'Not Related (NOT RELATED)'	Karol Moore (b) (4) (b) (4)	09 Nov 2020 20:35:34

**US3312046**

**Folder: Adverse Events**

**Form: Adverse Events (7)**

**Generated On: 26 Nov 2020 10:51:05**

[Action taken with investigational product](#)

Audit	User	Time (GMT)
User entered 'Not Applicable (NOT APPLICABLE)'	Karol Moore (b) (4) (b) (4)	09 Nov 2020 20:35:34

**US3312046**

**Folder: Adverse Events**

**Form: Adverse Events (7)**

**Generated On: 26 Nov 2020 10:51:05**

[None](#)

Audit	User	Time (GMT)
User entered 'I'	Karol Moore (b) (4) (b) (4)	09 Nov 2020 20:35:34

**US3312046**

**Folder: Adverse Events**

**Form: Adverse Events (7)**

**Generated On: 26 Nov 2020 10:51:05**

[Concomitant Medication](#)

Audit	User	Time (GMT)
User entered '0'	Karol Moore (b) (4) (b) (4)	09 Nov 2020 20:35:34

**US3312046**

**Folder: Adverse Events**

**Form: Adverse Events (7)**

**Generated On: 26 Nov 2020 10:51:05**

[Concomitant Procedure](#)

Audit	User	Time (GMT)
User entered '0'	Karol Moore (b) (4) (b) (4)	09 Nov 2020 20:35:34

**US3312046**

**Folder: Adverse Events**

**Form: Adverse Events (7)**

**Generated On: 26 Nov 2020 10:51:05**

[Outcome](#)

Audit	User	Time (GMT)
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)'	Karol Moore (b) (4) (b) (4)	09 Nov 2020 20:35:34



**US3312046**

**Folder: Adverse Events**

**Form: Adverse Events (7)**

**Generated On: 26 Nov 2020 10:51:05**

[If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:](#)

Audit	User	Time (GMT)
User entered empty.	Karol Moore (b) (4) (b) (4)	09 Nov 2020 20:35:34

**US3312046**

**Folder: Adverse Events**

**Form: Adverse Events (7)**

**Generated On: 26 Nov 2020 10:51:05**

[Narrative](#)

Audit	User	Time (GMT)
User entered empty.	Karol Moore (b) (4) (b) (4)	09 Nov 2020 20:35:34

**US3312046**

**Folder: Adverse Events**

**Form: Adverse Events (7)**

**Generated On: 26 Nov 2020 10:51:05**

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '0'	System	09 Nov 2020 20:35:34

**US3312046**

**Folder: Adverse Events**

**Form: Adverse Events (7)**

**Generated On: 26 Nov 2020 10:51:05**

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered 'I'	System	09 Nov 2020 20:35:34

US3312046

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 26 Nov 2020 10:51:05

[Adverse event](#)

Audit	User	Time (GMT)
User coded data point as SOC: Gastrointestinal disorders, HLGT: Gastrointestinal signs and symptoms, HLT: Nausea and vomiting symptoms, PT: Vomiting, LLT: Vomiting - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	09 Nov 2020 20:37:38
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	09 Nov 2020 20:37:38
Data point term sent to Coder	System	09 Nov 2020 20:37:04
User entered 'VOMITING'	Karol Moore (b) (4) (b) (4)	09 Nov 2020 20:36:11

**US3312046**

**Folder: Adverse Events**

**Form: Adverse Events (8)**

**Generated On: 26 Nov 2020 10:51:05**

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Karol Moore (b) (4) (b) (4)	09 Nov 2020 20:36:11

**US3312046**

**Folder: Adverse Events**

**Form: Adverse Events (8)**

**Generated On: 26 Nov 2020 10:51:05**

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Karol Moore (b) (4) (b) (4)	09 Nov 2020 20:36:11

**US3312046**

**Folder: Adverse Events**

**Form: Adverse Events (8)**

**Generated On: 26 Nov 2020 10:51:05**

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Karol Moore (b) (4) (b) (4)	09 Nov 2020 20:36:11



**US3312046**

**Folder: Adverse Events**

**Form: Adverse Events (8)**

**Generated On: 26 Nov 2020 10:51:05**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User entered '07 Oct 2020'	Karol Moore (b) (4) (b) (4)	09 Nov 2020 20:36:11

**US3312046**

**Folder: Adverse Events**

**Form: Adverse Events (8)**

**Generated On: 26 Nov 2020 10:51:05**

[Start time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
User entered empty.	Karol Moore (b) (4) (b) (4)	09 Nov 2020 20:36:11

**US3312046**

**Folder: Adverse Events**

**Form: Adverse Events (8)**

**Generated On: 26 Nov 2020 10:51:05**

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	09 Nov 2020 20:36:11

**US3312046**

**Folder: Adverse Events**

**Form: Adverse Events (8)**

**Generated On: 26 Nov 2020 10:51:05**

[Ongoing?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Karol Moore (b) (4) (b) (4)	09 Nov 2020 20:36:11

**US3312046**

**Folder: Adverse Events**

**Form: Adverse Events (8)**

**Generated On: 26 Nov 2020 10:51:05**

**If not Ongoing, end date (*dd MMM yyyy*)**

Audit	User	Time (GMT)
User entered '07 Oct 2020'	Karol Moore (b) (4) (b) (4)	09 Nov 2020 20:36:11

**US3312046**

**Folder: Adverse Events**

**Form: Adverse Events (8)**

**Generated On: 26 Nov 2020 10:51:05**

[End time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
User entered empty.	Karol Moore (b) (4) (b) (4)	09 Nov 2020 20:36:11

**US3312046**

**Folder: Adverse Events**

**Form: Adverse Events (8)**

**Generated On: 26 Nov 2020 10:51:05**

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	09 Nov 2020 20:36:11

**US3312046**

**Folder: Adverse Events**

**Form: Adverse Events (8)**

**Generated On: 26 Nov 2020 10:51:05**

[Severity](#)

Audit	User	Time (GMT)
User entered 'Grade 1/Mild (Grade 1/Mild)'	Karol Moore (b) (4) (b) (4)	09 Nov 2020 20:36:11



**US3312046**

**Folder: Adverse Events**

**Form: Adverse Events (8)**

**Generated On: 26 Nov 2020 10:51:05**

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Karol Moore (b) (4) (b) (4)	09 Nov 2020 20:36:11

**US3312046**

**Folder: Adverse Events**

**Form: Adverse Events (8)**

**Generated On: 26 Nov 2020 10:51:05**

[Death](#)

Audit	User	Time (GMT)
User entered '0'	Karol Moore (b) (4) (b) (4)	09 Nov 2020 20:36:11

**US3312046**

**Folder: Adverse Events**

**Form: Adverse Events (8)**

**Generated On: 26 Nov 2020 10:51:05**

[Life threatening](#)

Audit	User	Time (GMT)
User entered '0'	Karol Moore (b) (4) (b) (4)	09 Nov 2020 20:36:11

**US3312046**

**Folder: Adverse Events**

**Form: Adverse Events (8)**

**Generated On: 26 Nov 2020 10:51:05**

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User entered '0'	Karol Moore (b) (4) (b) (4)	09 Nov 2020 20:36:11

**US3312046**

**Folder: Adverse Events**

**Form: Adverse Events (8)**

**Generated On: 26 Nov 2020 10:51:05**

[Hospital Admission Date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User entered empty.	Karol Moore (b) (4) (b) (4)	09 Nov 2020 20:36:11

**US3312046**

**Folder: Adverse Events**

**Form: Adverse Events (8)**

**Generated On: 26 Nov 2020 10:51:05**

[Hospital Discharge Date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User entered empty.	Karol Moore (b) (4) (b) (4)	09 Nov 2020 20:36:11

**US3312046**

**Folder: Adverse Events**

**Form: Adverse Events (8)**

**Generated On: 26 Nov 2020 10:51:05**

[Admitted to ICU?](#)

Audit	User	Time (GMT)
User entered empty.	Karol Moore (b) (4) (b) (4)	09 Nov 2020 20:36:11

**US3312046**

**Folder: Adverse Events**

**Form: Adverse Events (8)**

**Generated On: 26 Nov 2020 10:51:05**

[Number of Days in ICU](#)

Audit	User	Time (GMT)
User entered empty.	Karol Moore (b) (4) (b) (4)	09 Nov 2020 20:36:11



**US3312046**

**Folder: Adverse Events**

**Form: Adverse Events (8)**

**Generated On: 26 Nov 2020 10:51:05**

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User entered '0'	Karol Moore (b) (4) (b) (4)	09 Nov 2020 20:36:11

**US3312046**

**Folder: Adverse Events**

**Form: Adverse Events (8)**

**Generated On: 26 Nov 2020 10:51:05**

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User entered '0'	Karol Moore (b) (4) (b) (4)	09 Nov 2020 20:36:11

**US3312046**

**Folder: Adverse Events**

**Form: Adverse Events (8)**

**Generated On: 26 Nov 2020 10:51:05**

[Other medically important event](#)

Audit	User	Time (GMT)
User entered '0'	Karol Moore (b) (4) (b) (4)	09 Nov 2020 20:36:11

**US3312046**

**Folder: Adverse Events**

**Form: Adverse Events (8)**

**Generated On: 26 Nov 2020 10:51:05**

[Relationship to investigational product](#)

Audit	User	Time (GMT)
User entered 'Not Related (NOT RELATED)'	Karol Moore (b) (4) (b) (4)	09 Nov 2020 20:36:11

US3312046

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 26 Nov 2020 10:51:05

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
User entered 'Not Related (NOT RELATED)'	Karol Moore (b) (4) (b) (4)	09 Nov 2020 20:36:11

**US3312046**

**Folder: Adverse Events**

**Form: Adverse Events (8)**

**Generated On: 26 Nov 2020 10:51:05**

[Action taken with investigational product](#)

Audit	User	Time (GMT)
User entered 'None (NONE)'	Karol Moore (b) (4) (b) (4)	09 Nov 2020 20:36:11

**US3312046**

**Folder: Adverse Events**

**Form: Adverse Events (8)**

**Generated On: 26 Nov 2020 10:51:05**

[None](#)

Audit	User	Time (GMT)
User entered 'I'	Karol Moore (b) (4) (b) (4)	09 Nov 2020 20:36:11

US3312046

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 26 Nov 2020 10:51:05

[Concomitant Medication](#)

Audit	User	Time (GMT)
User entered '0'	Karol Moore (b) (4) (b) (4)	09 Nov 2020 20:36:11



US3312046

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 26 Nov 2020 10:51:05

[Concomitant Procedure](#)

Audit	User	Time (GMT)
User entered '0'	Karol Moore (b) (4) (b) (4)	09 Nov 2020 20:36:11

**US3312046**

**Folder: Adverse Events**

**Form: Adverse Events (8)**

**Generated On: 26 Nov 2020 10:51:05**

[Outcome](#)

Audit	User	Time (GMT)
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)'	Karol Moore (b) (4) (b) (4)	09 Nov 2020 20:36:11

**US3312046**

**Folder: Adverse Events**

**Form: Adverse Events (8)**

**Generated On: 26 Nov 2020 10:51:05**

[If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:](#)

Audit	User	Time (GMT)
User entered empty.	Karol Moore (b) (4) (b) (4)	09 Nov 2020 20:36:11

**US3312046**

**Folder: Adverse Events**

**Form: Adverse Events (8)**

**Generated On: 26 Nov 2020 10:51:05**

[Narrative](#)

Audit	User	Time (GMT)
User entered empty.	Karol Moore (b) (4) (b) (4)	09 Nov 2020 20:36:11

**US3312046**

**Folder: Adverse Events**

**Form: Adverse Events (8)**

**Generated On: 26 Nov 2020 10:51:05**

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '0'	System	09 Nov 2020 20:36:11

**US3312046**

**Folder: Adverse Events**

**Form: Adverse Events (8)**

**Generated On: 26 Nov 2020 10:51:05**

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered 'I'	System	09 Nov 2020 20:36:11

US3312046

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 26 Nov 2020 10:51:05

[Adverse event](#)

Audit	User	Time (GMT)
User coded data point as SOC: Respiratory, thoracic and mediastinal disorders, HLGT: Respiratory tract signs and symptoms, HLT: Upper respiratory tract signs and symptoms, PT: Oropharyngeal pain, LLT: Sore throat - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	09 Nov 2020 20:37:36
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	09 Nov 2020 20:37:36
Data point term sent to Coder	System	09 Nov 2020 20:37:05
User entered 'SORE THROAT'	Karol Moore (b) (4) (b) (4)	09 Nov 2020 20:36:44

**US3312046**

**Folder: Adverse Events**

**Form: Adverse Events (9)**

**Generated On: 26 Nov 2020 10:51:05**

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Karol Moore (b) (4) (b) (4)	09 Nov 2020 20:36:44



**US3312046**

**Folder: Adverse Events**

**Form: Adverse Events (9)**

**Generated On: 26 Nov 2020 10:51:05**

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Karol Moore (b) (4) (b) (4)	09 Nov 2020 20:36:44

**US3312046**

**Folder: Adverse Events**

**Form: Adverse Events (9)**

**Generated On: 26 Nov 2020 10:51:05**

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Karol Moore (b) (4) (b) (4)	09 Nov 2020 20:36:44

**US3312046**

**Folder: Adverse Events**

**Form: Adverse Events (9)**

**Generated On: 26 Nov 2020 10:51:05**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User entered '07 Oct 2020'	Karol Moore (b) (4) (b) (4)	09 Nov 2020 20:36:44

**US3312046**

**Folder: Adverse Events**

**Form: Adverse Events (9)**

**Generated On: 26 Nov 2020 10:51:05**

[Start time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
User entered empty.	Karol Moore (b) (4) (b) (4)	09 Nov 2020 20:36:44

**US3312046**

**Folder: Adverse Events**

**Form: Adverse Events (9)**

**Generated On: 26 Nov 2020 10:51:05**

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	09 Nov 2020 20:36:44

**US3312046**

**Folder: Adverse Events**

**Form: Adverse Events (9)**

**Generated On: 26 Nov 2020 10:51:05**

[Ongoing?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Karol Moore (b) (4) (b) (4)	09 Nov 2020 20:36:44

**US3312046**

**Folder: Adverse Events**

**Form: Adverse Events (9)**

**Generated On: 26 Nov 2020 10:51:05**

**If not Ongoing, end date (*dd MMM yyyy*)**

Audit	User	Time (GMT)
User entered '16 Oct 2020'	Karol Moore (b) (4) (b) (4)	09 Nov 2020 20:36:44

**US3312046**

**Folder: Adverse Events**

**Form: Adverse Events (9)**

**Generated On: 26 Nov 2020 10:51:05**

[End time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
User entered empty.	Karol Moore (b) (4) (b) (4)	09 Nov 2020 20:36:44



**US3312046**

**Folder: Adverse Events**

**Form: Adverse Events (9)**

**Generated On: 26 Nov 2020 10:51:05**

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	09 Nov 2020 20:36:44

**US3312046**

**Folder: Adverse Events**

**Form: Adverse Events (9)**

**Generated On: 26 Nov 2020 10:51:05**

[Severity](#)

Audit	User	Time (GMT)
User entered 'Grade 1/Mild (Grade 1/Mild)'	Karol Moore (b) (4) (b) (4)	09 Nov 2020 20:36:44

**US3312046**

**Folder: Adverse Events**

**Form: Adverse Events (9)**

**Generated On: 26 Nov 2020 10:51:05**

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Karol Moore (b) (4) (b) (4)	09 Nov 2020 20:36:44

**US3312046**

**Folder: Adverse Events**

**Form: Adverse Events (9)**

**Generated On: 26 Nov 2020 10:51:05**

[Death](#)

Audit	User	Time (GMT)
User entered '0'	Karol Moore (b) (4) (b) (4)	09 Nov 2020 20:36:44

**US3312046**

**Folder: Adverse Events**

**Form: Adverse Events (9)**

**Generated On: 26 Nov 2020 10:51:05**

[Life threatening](#)

Audit	User	Time (GMT)
User entered '0'	Karol Moore (b) (4) (b) (4)	09 Nov 2020 20:36:44

**US3312046**

**Folder: Adverse Events**

**Form: Adverse Events (9)**

**Generated On: 26 Nov 2020 10:51:05**

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User entered '0'	Karol Moore (b) (4) (b) (4)	09 Nov 2020 20:36:44

**US3312046**

**Folder: Adverse Events**

**Form: Adverse Events (9)**

**Generated On: 26 Nov 2020 10:51:05**

[Hospital Admission Date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User entered empty.	Karol Moore (b) (4) (b) (4)	09 Nov 2020 20:36:44

**US3312046**

**Folder: Adverse Events**

**Form: Adverse Events (9)**

**Generated On: 26 Nov 2020 10:51:05**

[Hospital Discharge Date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User entered empty.	Karol Moore (b) (4) (b) (4)	09 Nov 2020 20:36:44



**US3312046**

**Folder: Adverse Events**

**Form: Adverse Events (9)**

**Generated On: 26 Nov 2020 10:51:05**

[Admitted to ICU?](#)

Audit	User	Time (GMT)
User entered empty.	Karol Moore (b) (4) (b) (4)	09 Nov 2020 20:36:44

**US3312046**

**Folder: Adverse Events**

**Form: Adverse Events (9)**

**Generated On: 26 Nov 2020 10:51:05**

[Number of Days in ICU](#)

Audit	User	Time (GMT)
User entered empty.	Karol Moore (b) (4) (b) (4)	09 Nov 2020 20:36:44

**US3312046**

**Folder: Adverse Events**

**Form: Adverse Events (9)**

**Generated On: 26 Nov 2020 10:51:05**

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User entered '0'	Karol Moore (b) (4) (b) (4)	09 Nov 2020 20:36:44

**US3312046**

**Folder: Adverse Events**

**Form: Adverse Events (9)**

**Generated On: 26 Nov 2020 10:51:05**

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User entered '0'	Karol Moore (b) (4) (b) (4)	09 Nov 2020 20:36:44

**US3312046**

**Folder: Adverse Events**

**Form: Adverse Events (9)**

**Generated On: 26 Nov 2020 10:51:05**

[Other medically important event](#)

Audit	User	Time (GMT)
User entered '0'	Karol Moore (b) (4) (b) (4)	09 Nov 2020 20:36:44

**US3312046**

**Folder: Adverse Events**

**Form: Adverse Events (9)**

**Generated On: 26 Nov 2020 10:51:05**

[Relationship to investigational product](#)

Audit	User	Time (GMT)
User entered 'Not Related (NOT RELATED)'	Karol Moore (b) (4) (b) (4)	09 Nov 2020 20:36:44

**US3312046**

**Folder: Adverse Events**

**Form: Adverse Events (9)**

**Generated On: 26 Nov 2020 10:51:05**

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
User entered 'Not Related (NOT RELATED)'	Karol Moore (b) (4) (b) (4)	09 Nov 2020 20:36:44

**US3312046**

**Folder: Adverse Events**

**Form: Adverse Events (9)**

**Generated On: 26 Nov 2020 10:51:05**

[Action taken with investigational product](#)

Audit	User	Time (GMT)
User entered 'Not Applicable (NOT APPLICABLE)'	Karol Moore (b) (4) (b) (4)	09 Nov 2020 20:36:44



**US3312046**

**Folder: Adverse Events**

**Form: Adverse Events (9)**

**Generated On: 26 Nov 2020 10:51:05**

[None](#)

Audit	User	Time (GMT)
User entered '0'	Karol Moore (b) (4) (b) (4)	09 Nov 2020 20:36:44

**US3312046**

**Folder: Adverse Events**

**Form: Adverse Events (9)**

**Generated On: 26 Nov 2020 10:51:05**

[Concomitant Medication](#)

Audit	User	Time (GMT)
User entered 'I'	Karol Moore (b) (4) (b) (4)	09 Nov 2020 20:36:44

**US3312046**

**Folder: Adverse Events**

**Form: Adverse Events (9)**

**Generated On: 26 Nov 2020 10:51:05**

[Concomitant Procedure](#)

Audit	User	Time (GMT)
User entered '0'	Karol Moore (b) (4) (b) (4)	09 Nov 2020 20:36:44

**US3312046**

**Folder: Adverse Events**

**Form: Adverse Events (9)**

**Generated On: 26 Nov 2020 10:51:05**

[Outcome](#)

Audit	User	Time (GMT)
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)'	Karol Moore (b) (4) (b) (4)	09 Nov 2020 20:36:44

**US3312046**

**Folder: Adverse Events**

**Form: Adverse Events (9)**

**Generated On: 26 Nov 2020 10:51:05**

[If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:](#)

Audit	User	Time (GMT)
User entered empty.	Karol Moore (b) (4) (b) (4)	09 Nov 2020 20:36:44

**US3312046**

**Folder: Adverse Events**

**Form: Adverse Events (9)**

**Generated On: 26 Nov 2020 10:51:05**

[Narrative](#)

Audit	User	Time (GMT)
User entered empty.	Karol Moore (b) (4) (b) (4)	09 Nov 2020 20:36:44

**US3312046**

**Folder: Adverse Events**

**Form: Adverse Events (9)**

**Generated On: 26 Nov 2020 10:51:05**

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '0'	System	09 Nov 2020 20:36:44

**US3312046**

**Folder: Adverse Events**

**Form: Adverse Events (9)**

**Generated On: 26 Nov 2020 10:51:05**

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered 'I'	System	09 Nov 2020 20:36:44



US3312046

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Generated On: 26 Nov 2020 10:51:05

Were any prior/concomitant medications and/or vaccinations taken?

Audit	User	Time (GMT)
User closed query 'Per ETRTR: Please update ConMeds page according to Medication dosed for SAE "Infection Unknown Origin", thanks.' (Site from CRA).	(b) (4), (b) (6)	18 Nov 2020 14:33:52
Query 'Per ETRTR: Please update ConMeds page according to Medication dosed for SAE "Infection Unknown Origin", thanks.' answered with 'UPDATED ' (Site from CRA).	Karol Moore (b) (4) (b) (4)	17 Nov 2020 21:57:40
User opened query 'Per ETRTR: Please update ConMeds page according to Medication dosed for SAE "Infection Unknown Origin", thanks.' (Site from CRA).	(b) (4), (b) (6)	16 Oct 2020 16:47:35
User entered 'Yes (Y)'	Karol Moore (b) (4) (b) (4)	14 Aug 2020 17:55:57

US3312046

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 10:51:05

[Name of Medication](#)

Audit	User	Time (GMT)
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)	14 Aug 2020 18:10:21
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	14 Aug 2020 18:10:21
Data point term sent to Coder	System	14 Aug 2020 17:57:42
User entered 'acetominophen'	Karol Moore (b) (4) (b) (4)	14 Aug 2020 17:56:51

US3312046

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 10:51:05

[Prophylaxis](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Karol Moore (b) (4) (b) (4)	14 Aug 2020 17:56:51

US3312046

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 10:51:05

[Indication](#)

Audit	User	Time (GMT)
User entered 'lower back pain'	Karol Moore (b) (4) (b) (4)	14 Aug 2020 17:56:51

US3312046

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 26 Nov 2020 10:51:05**

[Dose per administration](#)

Audit	User	Time (GMT)
User entered '1000'	Karol Moore (b) (4) (b) (4)	14 Aug 2020 17:56:51

US3312046

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 10:51:05

[Dose unit](#)

Audit	User	Time (GMT)
User entered 'mg (mg)'	Karol Moore (b) (4) (b) (4)	14 Aug 2020 17:56:51

US3312046

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 26 Nov 2020 10:51:05**

If dose unit is Other, specify

Audit	User	Time (GMT)
User entered empty.	Karol Moore (b) (4) (b) (4)	14 Aug 2020 17:56:51

US3312046

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 10:51:05

[Frequency](#)

Audit	User	Time (GMT)
User entered 'as needed (PRN)'	Karol Moore (b) (4) (b) (4)	14 Aug 2020 17:56:51



**US3312046**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 26 Nov 2020 10:51:05**

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User entered empty.	Karol Moore (b) (4) (b) (4)	14 Aug 2020 17:56:51

US3312046

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 26 Nov 2020 10:51:05**

[Route of administration](#)

Audit	User	Time (GMT)
User entered 'Oral (ORAL)'	Karol Moore (b) (4) (b) (4)	14 Aug 2020 17:56:51

US3312046

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 26 Nov 2020 10:51:05**

If route of administration is Other, specify

Audit	User	Time (GMT)
User entered empty.	Karol Moore (b) (4) (b) (4)	14 Aug 2020 17:56:51

US3312046

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 10:51:05

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' canceled (Site from System).	(b) (4), (b) (6)	15 Aug 2020 19:04:20
User opened query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' (Site from System).	System	14 Aug 2020 17:56:51
User entered 'un UNK 2000'	Karol Moore (b) (4) (b) (4)	14 Aug 2020 17:56:51

**US3312046**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 26 Nov 2020 10:51:05**

[Start date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	Karol Moore (b) (4) (b) (4)	14 Aug 2020 17:56:51

**US3312046**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 26 Nov 2020 10:51:05**

[Ongoing?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Karol Moore (b) (4) (b) (4)	14 Aug 2020 17:56:51

US3312046

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 26 Nov 2020 10:51:05**

*If not Ongoing, End date (dd MMM yyyy)*

Audit	User	Time (GMT)
User entered empty.	Karol Moore (b) (4) (b) (4)	14 Aug 2020 17:56:51

US3312046

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 26 Nov 2020 10:51:05**

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Karol Moore (b) (4) (b) (4)	14 Aug 2020 17:56:51



**US3312046**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 26 Nov 2020 10:51:05**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	14 Aug 2020 17:56:51

**US3312046**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 26 Nov 2020 10:51:05**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	14 Aug 2020 17:56:51

**US3312046**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 26 Nov 2020 10:51:05**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	14 Aug 2020 17:56:51

US3312046

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 10:51:05

[Name of Medication](#)

Audit	User	Time (GMT)
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)	18 Sep 2020 19:39:39
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	18 Sep 2020 19:39:39
Data point term sent to Coder	System	18 Sep 2020 19:38:55
User entered 'ACETAMINOPHEN'	Christa Estrada (b) (4)	18 Sep 2020 19:38:41
	(b) (4)	

**US3312046**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 26 Nov 2020 10:51:05**

[Prophylaxis](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Christa Estrada (b) (4) (b) (4)	18 Sep 2020 19:38:41

US3312046

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 10:51:05

[Indication](#)

Audit	User	Time (GMT)
User closed query 'Per DM CLR: Please note that there is no AE that matches this Con Med indication during this timeframe. If the INJECTION SITE PAIN is considered a solicited local or systemic adverse reaction, and meets any of the following criteria:results in a visit to a healthcare provider (MAAE), leads to withdrawal from the study of study vaccination, or otherwise meets the definition of an SAE, please add an entry and applicable details to the AE ecrf as appropriate. Otherwise, please confirm in query response that the solicited adverse reaction of INJECTION SITE PAIN did not meet the AE reporting criteria. ' (Site from DM).	(b) (4), (b) (6)	23 Oct 2020 13:41:31
Query 'Per DM CLR: Please note that there is no AE that matches this Con Med indication during this timeframe. If the INJECTION SITE PAIN is considered a solicited local or systemic adverse reaction, and meets any of the following criteria:results in a visit to a healthcare provider (MAAE), leads to withdrawal from the study of study vaccination, or otherwise meets the definition of an SAE, please add an entry and applicable details to the AE ecrf as appropriate. Otherwise, please confirm in query response that the solicited adverse reaction of INJECTION SITE PAIN did not meet the AE reporting criteria. ' answered with 'did not meet AE criteria ' (Site from DM).	(b) (4), (b) (6)	22 Oct 2020 12:05:45
User opened query 'Per DM CLR: Please note that there is no AE that matches this Con Med indication during this timeframe. If the INJECTION SITE PAIN is considered a solicited local or systemic adverse reaction, and meets any of the following criteria:results in a visit to a healthcare provider (MAAE), leads to withdrawal from the study of study vaccination, or otherwise meets the definition of an SAE, please add an entry and applicable details to the AE ecrf as appropriate. Otherwise, please confirm in query response that the solicited adverse reaction of INJECTION SITE PAIN did not meet the AE reporting criteria. ' (Site from DM).	(b) (4), (b) (6)	16 Oct 2020 05:18:18
v6.020 DTW (1102)		2309 of 2431

**US3312046**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 26 Nov 2020 10:51:05**

[Indication](#)

Audit	User	Time (GMT)
User entered 'INJECTION SITE PAIN'	Christa Estrada (b) (4) (b) (4)	18 Sep 2020 19:38:41

**US3312046**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 26 Nov 2020 10:51:05**

[Dose per administration](#)

Audit	User	Time (GMT)
User entered '1000'	Christa Estrada (b) (4) (b) (4)	18 Sep 2020 19:38:41



US3312046

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 10:51:05

[Dose unit](#)

Audit	User	Time (GMT)
User entered 'mg (mg)'	Christa Estrada (b) (4) (b) (4)	18 Sep 2020 19:38:41

**US3312046**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 26 Nov 2020 10:51:05**

If dose unit is Other, specify

Audit	User	Time (GMT)
User entered empty.	Christa Estrada (b) (4) (b) (4)	18 Sep 2020 19:38:41

**US3312046**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 26 Nov 2020 10:51:05**

[Frequency](#)

Audit	User	Time (GMT)
User entered 'as needed (PRN)'	Christa Estrada (b) (4) (b) (4)	18 Sep 2020 19:38:41

**US3312046**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 26 Nov 2020 10:51:05**

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User entered empty.	Christa Estrada (b) (4) (b) (4)	18 Sep 2020 19:38:41

**US3312046**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 26 Nov 2020 10:51:05**

[Route of administration](#)

Audit	User	Time (GMT)
User entered 'Oral (ORAL)'	Christa Estrada (b) (4) (b) (4)	18 Sep 2020 19:38:41

**US3312046**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 26 Nov 2020 10:51:05**

If route of administration is Other, specify

Audit	User	Time (GMT)
User entered empty.	Christa Estrada (b) (4) (b) (4)	18 Sep 2020 19:38:41

US3312046

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 10:51:05

Start date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered '11 Sep 2020'	Christa Estrada (b) (4) (b) (4)	18 Sep 2020 19:38:41

**US3312046**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 26 Nov 2020 10:51:05**

[Start date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	Christa Estrada (b) (4) (b) (4)	18 Sep 2020 19:38:41



**US3312046**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 26 Nov 2020 10:51:05**

[Ongoing?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Christa Estrada (b) (4) (b) (4)	18 Sep 2020 19:38:41

**US3312046**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 26 Nov 2020 10:51:05**

**If not Ongoing, End date (*dd MMM yyyy*)**

Audit	User	Time (GMT)
User entered '12 Sep 2020'	Christa Estrada (b) (4) (b) (4)	18 Sep 2020 19:38:41

**US3312046**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 26 Nov 2020 10:51:05**

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Christa Estrada (b) (4) (b) (4)	18 Sep 2020 19:38:41

**US3312046**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 26 Nov 2020 10:51:05**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	18 Sep 2020 19:38:41

**US3312046**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 26 Nov 2020 10:51:05**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	18 Sep 2020 19:38:41

**US3312046**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 26 Nov 2020 10:51:05**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	18 Sep 2020 19:38:41

US3312046

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 10:51:05

[Name of Medication](#)

Audit	User	Time (GMT)
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)	16 Nov 2020 16:44:45
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	16 Nov 2020 16:44:45
Data point term sent to Coder	System	16 Nov 2020 16:43:48
Coding entries removed.	(b) (4), (b) (6)	16 Nov 2020 16:43:47
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)	06 Nov 2020 15:12:17
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 Nov 2020 15:12:17
Data point term sent to Coder	System	06 Nov 2020 15:11:20
User entered 'ACETAMINOPHEN'	Monica Atwood (b) (4) (b) (4)	06 Nov 2020 15:10:50

**US3312046**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 26 Nov 2020 10:51:05**

[Prophylaxis](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Monica Atwood (b) (4) (b) (4)	06 Nov 2020 15:10:50



**US3312046**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 26 Nov 2020 10:51:05**

[Indication](#)

Audit	User	Time (GMT)
User entered 'viral pharyngitis' reason for change:	(b) (4), (b) (6)	16 Nov 2020 16:43:47
Data Entry Error		
User entered 'SORE THROAT'	Monica Atwood (b) (4)	06 Nov 2020 15:10:50
	(b) (4)	

US3312046

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 26 Nov 2020 10:51:05**

[Dose per administration](#)

Audit	User	Time (GMT)
User entered '1000'	Monica Atwood (b) (4) (b) (4)	06 Nov 2020 15:10:50

US3312046

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 26 Nov 2020 10:51:05**

[Dose unit](#)

Audit	User	Time (GMT)
User entered 'mg (mg)'	Monica Atwood (b) (4) (b) (4)	06 Nov 2020 15:10:50

US3312046

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 26 Nov 2020 10:51:05**

If dose unit is Other, specify

Audit	User	Time (GMT)
User entered empty.	Monica Atwood (b) (4) (b) (4)	06 Nov 2020 15:10:50

**US3312046**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 26 Nov 2020 10:51:05**

[Frequency](#)

Audit	User	Time (GMT)
User entered 'as needed (PRN)'	Monica Atwood (b) (4) (b) (4)	06 Nov 2020 15:10:50

US3312046

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 26 Nov 2020 10:51:05**

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User entered empty.	Monica Atwood (b) (4) (b) (4)	06 Nov 2020 15:10:50

**US3312046**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 26 Nov 2020 10:51:05**

[Route of administration](#)

Audit	User	Time (GMT)
User entered 'Oral (ORAL)'	Monica Atwood (b) (4) (b) (4)	06 Nov 2020 15:10:50

**US3312046**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 26 Nov 2020 10:51:05**

If route of administration is Other, specify

Audit	User	Time (GMT)
User entered empty.	Monica Atwood (b) (4) (b) (4)	06 Nov 2020 15:10:50



**US3312046**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 26 Nov 2020 10:51:05**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User entered '07 Oct 2020'	Monica Atwood (b) (4) (b) (4)	06 Nov 2020 15:10:50

**US3312046**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 26 Nov 2020 10:51:05**

[Start date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	Monica Atwood (b) (4) (b) (4)	06 Nov 2020 15:10:50

**US3312046**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 26 Nov 2020 10:51:05**

[Ongoing?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Monica Atwood (b) (4) (b) (4)	06 Nov 2020 15:10:50

**US3312046**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 26 Nov 2020 10:51:05**

**If not Ongoing, End date (*dd MMM yyyy*)**

Audit	User	Time (GMT)
User entered '17 Oct 2020'	Monica Atwood (b) (4) (b) (4)	06 Nov 2020 15:10:50

**US3312046**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 26 Nov 2020 10:51:05**

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Monica Atwood (b) (4) (b) (4)	06 Nov 2020 15:10:50

**US3312046**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 26 Nov 2020 10:51:05**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	06 Nov 2020 15:10:50

**US3312046**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 26 Nov 2020 10:51:05**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	06 Nov 2020 15:10:50

**US3312046**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 26 Nov 2020 10:51:05**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	06 Nov 2020 15:10:50



US3312046

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 10:51:05

Name of Medication

Audit	User	Time (GMT)
User coded data point as ATC: MUSCULO-SKELETAL SYSTEM, ATC: ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, ATC: ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, NON-STEROIDS, ATC: PROPIONIC ACID DERIVATIVES, PRODUCT: IBUPROFEN - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	17 Nov 2020 07:55:57
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	17 Nov 2020 07:55:57
Data point term sent to Coder	System	16 Nov 2020 16:44:49
Coding entries removed.	(b) (4), (b) (6)	16 Nov 2020 16:44:00
User coded data point as ATC: MUSCULO-SKELETAL SYSTEM, ATC: ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, ATC: ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, NON-STEROIDS, ATC: PROPIONIC ACID DERIVATIVES, PRODUCT: IBUPROFEN - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	06 Nov 2020 15:29:17
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 Nov 2020 15:29:17
Data point term sent to Coder	System	06 Nov 2020 15:13:32
User entered 'IBUPROFEN'	Monica Atwood (b) (4) (b) (4)	06 Nov 2020 15:13:11

**US3312046**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 26 Nov 2020 10:51:05**

[Prophylaxis](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Monica Atwood (b) (4) (b) (4)	06 Nov 2020 15:13:11

**US3312046**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 26 Nov 2020 10:51:05**

[Indication](#)

Audit	User	Time (GMT)
User entered 'viral pharyngitis' reason for change:	(b) (4), (b) (6)	16 Nov 2020 16:44:00
Data Entry Error		
User entered 'SORE THROAT'	Monica Atwood (b) (4)	06 Nov 2020 15:13:11
	(b) (4)	

**US3312046**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 26 Nov 2020 10:51:05**

[Dose per administration](#)

Audit	User	Time (GMT)
User entered '200'	Monica Atwood (b) (4) (b) (4)	06 Nov 2020 15:13:11

US3312046

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 10:51:05

[Dose unit](#)

Audit	User	Time (GMT)
User entered 'mg (mg)'	Monica Atwood (b) (4) (b) (4)	06 Nov 2020 15:13:11

US3312046

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 10:51:05

If dose unit is Other, specify

Audit	User	Time (GMT)
User entered empty.	Monica Atwood (b) (4) (b) (4)	06 Nov 2020 15:13:11

**US3312046**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 26 Nov 2020 10:51:05**

[Frequency](#)

Audit	User	Time (GMT)
User entered 'as needed (PRN)'	Monica Atwood (b) (4) (b) (4)	06 Nov 2020 15:13:11

US3312046

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 26 Nov 2020 10:51:05**

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User entered empty.	Monica Atwood (b) (4) (b) (4)	06 Nov 2020 15:13:11



**US3312046**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 26 Nov 2020 10:51:05**

[Route of administration](#)

Audit	User	Time (GMT)
User entered 'Oral (ORAL)'	Monica Atwood (b) (4) (b) (4)	06 Nov 2020 15:13:11

US3312046

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 26 Nov 2020 10:51:05**

If route of administration is Other, specify

Audit	User	Time (GMT)
User entered empty.	Monica Atwood (b) (4) (b) (4)	06 Nov 2020 15:13:11

**US3312046**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 26 Nov 2020 10:51:05**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User entered '07 Oct 2020'	Monica Atwood (b) (4) (b) (4)	06 Nov 2020 15:13:11

**US3312046**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 26 Nov 2020 10:51:05**

[Start date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	Monica Atwood (b) (4) (b) (4)	06 Nov 2020 15:13:11

**US3312046**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 26 Nov 2020 10:51:05**

[Ongoing?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Monica Atwood (b) (4) (b) (4)	06 Nov 2020 15:13:11

**US3312046**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 26 Nov 2020 10:51:05**

**If not Ongoing, End date (*dd MMM yyyy*)**

Audit	User	Time (GMT)
User entered '17 Oct 2020'	Monica Atwood (b) (4) (b) (4)	06 Nov 2020 15:13:11

US3312046

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 10:51:05

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Monica Atwood (b) (4) (b) (4)	06 Nov 2020 15:13:11

**US3312046**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 26 Nov 2020 10:51:05**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	06 Nov 2020 15:13:11



**US3312046**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 26 Nov 2020 10:51:05**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	06 Nov 2020 15:13:11

**US3312046**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 26 Nov 2020 10:51:05**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	06 Nov 2020 15:13:11

**US3312046**

**Folder: SAE USA-US300-2020-MRNA-1273-P301000005**

**Form: Safety Report Form**

**Generated On: 26 Nov 2020 10:51:05**

[SAEID](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	15 Oct 2020 12:50:31
User entered 'USA-US300-2020-MRNA-1273-P301000005'	System	15 Oct 2020 12:50:05

**US3312046**

**Folder: SAE USA-US300-2020-MRNA-1273-P301000005**

**Form: Safety Report Form**

**Generated On: 26 Nov 2020 10:51:05**

**Serious**

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	15 Oct 2020 12:50:31
User entered 'Yes (Y)'	System	15 Oct 2020 12:50:05

**US3312046**

**Folder: SAE USA-US300-2020-MRNA-1273-P301000005**

**Form: Safety Report Form**

**Generated On: 26 Nov 2020 10:51:05**

[Death](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	15 Oct 2020 12:50:31
User entered 'No (N)'	System	15 Oct 2020 12:50:05

**US3312046**

**Folder: SAE USA-US300-2020-MRNA-1273-P301000005**

**Form: Safety Report Form**

**Generated On: 26 Nov 2020 10:51:05**

[Life threatening](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	15 Oct 2020 12:50:31
User entered 'No (N)'	System	15 Oct 2020 12:50:05

**US3312046**

**Folder: SAE USA-US300-2020-MRNA-1273-P301000005**

**Form: Safety Report Form**

**Generated On: 26 Nov 2020 10:51:05**

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	15 Oct 2020 12:50:31
User entered 'Yes (Y)'	System	15 Oct 2020 12:50:05

**US3312046**

**Folder: SAE USA-US300-2020-MRNA-1273-P301000005**

**Form: Safety Report Form**

**Generated On: 26 Nov 2020 10:51:05**

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	15 Oct 2020 12:50:31
User entered 'No (N)'	System	15 Oct 2020 12:50:05



**US3312046**

**Folder: SAE USA-US300-2020-MRNA-1273-P301000005**

**Form: Safety Report Form**

**Generated On: 26 Nov 2020 10:51:05**

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	15 Oct 2020 12:50:31
User entered 'No (N)'	System	15 Oct 2020 12:50:05

**US3312046**

**Folder: SAE USA-US300-2020-MRNA-1273-P301000005**

**Form: Safety Report Form**

**Generated On: 26 Nov 2020 10:51:05**

[Other medically important event](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	15 Oct 2020 12:50:31
User entered 'No (N)'	System	15 Oct 2020 12:50:05

**US3312046**

**Folder: SAE USA-US300-2020-MRNA-1273-P301000005**

**Form: Safety Report Form**

**Generated On: 26 Nov 2020 10:51:05**

[Investigator's First Name](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	15 Oct 2020 12:50:31
User entered 'Carlos'	System	15 Oct 2020 12:50:05

**US3312046**

**Folder: SAE USA-US300-2020-MRNA-1273-P301000005**

**Form: Safety Report Form**

**Generated On: 26 Nov 2020 10:51:05**

[Investigator's Last Name](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	15 Oct 2020 12:50:31
User entered 'Fierro'	System	15 Oct 2020 12:50:05

**US3312046**

**Folder: SAE USA-US300-2020-MRNA-1273-P301000005**

**Form: Safety Report Form**

**Generated On: 26 Nov 2020 10:51:05**

[Site Address: Street](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	15 Oct 2020 12:50:31
User entered '16300 College Blvd'	System	15 Oct 2020 12:50:05

**US3312046**

**Folder: SAE USA-US300-2020-MRNA-1273-P301000005**

**Form: Safety Report Form**

**Generated On: 26 Nov 2020 10:51:05**

[Site Address: City](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	15 Oct 2020 12:50:31
User entered 'Shawnee'	System	15 Oct 2020 12:50:05

**US3312046**

**Folder: SAE USA-US300-2020-MRNA-1273-P301000005**

**Form: Safety Report Form**

**Generated On: 26 Nov 2020 10:51:05**

[Site Address: State](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	15 Oct 2020 12:50:31
User entered 'KS'	System	15 Oct 2020 12:50:05

**US3312046**

**Folder: SAE USA-US300-2020-MRNA-1273-P301000005**

**Form: Safety Report Form**

**Generated On: 26 Nov 2020 10:51:05**

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	15 Oct 2020 12:50:31
User entered '66219'	System	15 Oct 2020 12:50:05



**US3312046**

**Folder: SAE USA-US300-2020-MRNA-1273-P301000005**

**Form: Safety Report Form**

**Generated On: 26 Nov 2020 10:51:05**

[Investigator Country](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	17 Nov 2020 15:47:45
User entered 'US'	System	15 Oct 2020 12:50:36

**US3312046**

**Folder: SAE USA-US300-2020-MRNA-1273-P301000005**

**Form: Safety Report Form**

**Generated On: 26 Nov 2020 10:51:05**

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '3'	System	17 Nov 2020 15:49:16
User entered '2'	System	10 Nov 2020 15:30:43
User entered '1'	System	15 Oct 2020 12:50:36

**US3312046**

**Folder: SAE USA-US300-2020-MRNA-1273-P301000005**

**Form: Safety Report Form**

**Generated On: 26 Nov 2020 10:51:05**

[SAEID](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	15 Oct 2020 12:50:31
User entered 'USA-US300-2020-MRNA-1273-P301000005'	System	15 Oct 2020 12:50:05

**US3312046**

**Folder: SAE USA-US300-2020-MRNA-1273-P301000005**

**Form: Safety Report Form**

**Generated On: 26 Nov 2020 10:51:05**

**Serious**

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	15 Oct 2020 12:50:31
User entered 'Yes (Y)'	System	15 Oct 2020 12:50:05

**US3312046**

**Folder: SAE USA-US300-2020-MRNA-1273-P301000005**

**Form: Safety Report Form**

**Generated On: 26 Nov 2020 10:51:05**

[Death](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	15 Oct 2020 12:50:31
User entered 'No (N)'	System	15 Oct 2020 12:50:05

**US3312046**

**Folder: SAE USA-US300-2020-MRNA-1273-P301000005**

**Form: Safety Report Form**

**Generated On: 26 Nov 2020 10:51:05**

[Life threatening](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	15 Oct 2020 12:50:31
User entered 'No (N)'	System	15 Oct 2020 12:50:05

**US3312046**

**Folder: SAE USA-US300-2020-MRNA-1273-P301000005**

**Form: Safety Report Form**

**Generated On: 26 Nov 2020 10:51:05**

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	15 Oct 2020 12:50:31
User entered 'Yes (Y)'	System	15 Oct 2020 12:50:05

**US3312046**

**Folder: SAE USA-US300-2020-MRNA-1273-P301000005**

**Form: Safety Report Form**

**Generated On: 26 Nov 2020 10:51:05**

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	15 Oct 2020 12:50:31
User entered 'No (N)'	System	15 Oct 2020 12:50:05



**US3312046**

**Folder: SAE USA-US300-2020-MRNA-1273-P301000005**

**Form: Safety Report Form**

**Generated On: 26 Nov 2020 10:51:05**

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	15 Oct 2020 12:50:31
User entered 'No (N)'	System	15 Oct 2020 12:50:05

**US3312046**

**Folder: SAE USA-US300-2020-MRNA-1273-P301000005**

**Form: Safety Report Form**

**Generated On: 26 Nov 2020 10:51:05**

[Other medically important event](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	15 Oct 2020 12:50:31
User entered 'No (N)'	System	15 Oct 2020 12:50:05

**US3312046**

**Folder: SAE USA-US300-2020-MRNA-1273-P301000005**

**Form: Safety Report Form**

**Generated On: 26 Nov 2020 10:51:05**

[Investigator's First Name](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	15 Oct 2020 12:50:31
User entered 'Carlos'	System	15 Oct 2020 12:50:05

**US3312046**

**Folder: SAE USA-US300-2020-MRNA-1273-P301000005**

**Form: Safety Report Form**

**Generated On: 26 Nov 2020 10:51:05**

[Investigator's Last Name](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	15 Oct 2020 12:50:31
User entered 'Fierro'	System	15 Oct 2020 12:50:05

**US3312046**

**Folder: SAE USA-US300-2020-MRNA-1273-P301000005**

**Form: Safety Report Form**

**Generated On: 26 Nov 2020 10:51:05**

[Site Address: Street](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	15 Oct 2020 12:50:31
User entered '16300 College Blvd'	System	15 Oct 2020 12:50:05

**US3312046**

**Folder: SAE USA-US300-2020-MRNA-1273-P301000005**

**Form: Safety Report Form**

**Generated On: 26 Nov 2020 10:51:05**

[Site Address: City](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	15 Oct 2020 12:50:31
User entered 'Shawnee'	System	15 Oct 2020 12:50:05

**US3312046**

**Folder: SAE USA-US300-2020-MRNA-1273-P301000005**

**Form: Safety Report Form**

**Generated On: 26 Nov 2020 10:51:05**

[Site Address: State](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	15 Oct 2020 12:50:31
User entered 'KS'	System	15 Oct 2020 12:50:05

**US3312046**

**Folder: SAE USA-US300-2020-MRNA-1273-P301000005**

**Form: Safety Report Form**

**Generated On: 26 Nov 2020 10:51:05**

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	15 Oct 2020 12:50:31
User entered '66219'	System	15 Oct 2020 12:50:05



**US3312046**

**Folder: SAE USA-US300-2020-MRNA-1273-P301000005**

**Form: Safety Report Form**

**Generated On: 26 Nov 2020 10:51:05**

[Investigator Country](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	17 Nov 2020 15:47:45
User entered 'US'	System	15 Oct 2020 12:50:36

**US3312046**

**Folder: SAE USA-US300-2020-MRNA-1273-P301000005**

**Form: Safety Report Form**

**Generated On: 26 Nov 2020 10:51:05**

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '3'	System	17 Nov 2020 15:49:16
User entered '2'	System	10 Nov 2020 15:30:43
User entered '1'	System	15 Oct 2020 12:50:36

**US3312046**

**Folder: SAE USA-US300-2020-MRNA-1273-P301000005**

**Form: Safety Report Form (1)**

**Generated On: 26 Nov 2020 10:51:05**

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User entered '15/Oct/2020 12:50'	System	15 Oct 2020 12:50:36

US3312046

Folder: SAE USA-US300-2020-MRNA-1273-P301000005

Form: Safety Report Form (1)

Generated On: 26 Nov 2020 10:51:05

**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.**

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	17 Nov 2020 15:47:45
User entered 'I'	(b) (4), (b) (6)	15 Oct 2020 12:50:36

**US3312046**

**Folder: SAE USA-US300-2020-MRNA-1273-P301000005**

**Form: Safety Report Form**

**Generated On: 26 Nov 2020 10:51:05**

[SAEID](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	15 Oct 2020 12:50:31
User entered 'USA-US300-2020-MRNA-1273-P301000005'	System	15 Oct 2020 12:50:05

**US3312046**

**Folder: SAE USA-US300-2020-MRNA-1273-P301000005**

**Form: Safety Report Form**

**Generated On: 26 Nov 2020 10:51:05**

**Serious**

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	15 Oct 2020 12:50:31
User entered 'Yes (Y)'	System	15 Oct 2020 12:50:05

**US3312046**

**Folder: SAE USA-US300-2020-MRNA-1273-P301000005**

**Form: Safety Report Form**

**Generated On: 26 Nov 2020 10:51:05**

[Death](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	15 Oct 2020 12:50:31
User entered 'No (N)'	System	15 Oct 2020 12:50:05

**US3312046**

**Folder: SAE USA-US300-2020-MRNA-1273-P301000005**

**Form: Safety Report Form**

**Generated On: 26 Nov 2020 10:51:05**

[Life threatening](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	15 Oct 2020 12:50:31
User entered 'No (N)'	System	15 Oct 2020 12:50:05



**US3312046**

**Folder: SAE USA-US300-2020-MRNA-1273-P301000005**

**Form: Safety Report Form**

**Generated On: 26 Nov 2020 10:51:05**

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	15 Oct 2020 12:50:31
User entered 'Yes (Y)'	System	15 Oct 2020 12:50:05

**US3312046**

**Folder: SAE USA-US300-2020-MRNA-1273-P301000005**

**Form: Safety Report Form**

**Generated On: 26 Nov 2020 10:51:05**

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	15 Oct 2020 12:50:31
User entered 'No (N)'	System	15 Oct 2020 12:50:05

**US3312046**

**Folder: SAE USA-US300-2020-MRNA-1273-P301000005**

**Form: Safety Report Form**

**Generated On: 26 Nov 2020 10:51:05**

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	15 Oct 2020 12:50:31
User entered 'No (N)'	System	15 Oct 2020 12:50:05

**US3312046**

**Folder: SAE USA-US300-2020-MRNA-1273-P301000005**

**Form: Safety Report Form**

**Generated On: 26 Nov 2020 10:51:05**

[Other medically important event](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	15 Oct 2020 12:50:31
User entered 'No (N)'	System	15 Oct 2020 12:50:05

**US3312046**

**Folder: SAE USA-US300-2020-MRNA-1273-P301000005**

**Form: Safety Report Form**

**Generated On: 26 Nov 2020 10:51:05**

[Investigator's First Name](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	15 Oct 2020 12:50:31
User entered 'Carlos'	System	15 Oct 2020 12:50:05

**US3312046**

**Folder: SAE USA-US300-2020-MRNA-1273-P301000005**

**Form: Safety Report Form**

**Generated On: 26 Nov 2020 10:51:05**

[Investigator's Last Name](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	15 Oct 2020 12:50:31
User entered 'Fierro'	System	15 Oct 2020 12:50:05

**US3312046**

**Folder: SAE USA-US300-2020-MRNA-1273-P301000005**

**Form: Safety Report Form**

**Generated On: 26 Nov 2020 10:51:05**

[Site Address: Street](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	15 Oct 2020 12:50:31
User entered '16300 College Blvd'	System	15 Oct 2020 12:50:05

**US3312046**

**Folder: SAE USA-US300-2020-MRNA-1273-P301000005**

**Form: Safety Report Form**

**Generated On: 26 Nov 2020 10:51:05**

[Site Address: City](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	15 Oct 2020 12:50:31
User entered 'Shawnee'	System	15 Oct 2020 12:50:05



**US3312046**

**Folder: SAE USA-US300-2020-MRNA-1273-P301000005**

**Form: Safety Report Form**

**Generated On: 26 Nov 2020 10:51:05**

[Site Address: State](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	15 Oct 2020 12:50:31
User entered 'KS'	System	15 Oct 2020 12:50:05

**US3312046**

**Folder: SAE USA-US300-2020-MRNA-1273-P301000005**

**Form: Safety Report Form**

**Generated On: 26 Nov 2020 10:51:05**

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	15 Oct 2020 12:50:31
User entered '66219'	System	15 Oct 2020 12:50:05

**US3312046**

**Folder: SAE USA-US300-2020-MRNA-1273-P301000005**

**Form: Safety Report Form**

**Generated On: 26 Nov 2020 10:51:05**

[Investigator Country](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	17 Nov 2020 15:47:45
User entered 'US'	System	15 Oct 2020 12:50:36

**US3312046**

**Folder: SAE USA-US300-2020-MRNA-1273-P301000005**

**Form: Safety Report Form**

**Generated On: 26 Nov 2020 10:51:05**

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '3'	System	17 Nov 2020 15:49:16
User entered '2'	System	10 Nov 2020 15:30:43
User entered '1'	System	15 Oct 2020 12:50:36

**US3312046**

**Folder: SAE USA-US300-2020-MRNA-1273-P301000005**

**Form: Safety Report Form (2)**

**Generated On: 26 Nov 2020 10:51:05**

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User entered '10/Nov/2020 10:30'	System	10 Nov 2020 15:30:43

US3312046

Folder: SAE USA-US300-2020-MRNA-1273-P301000005

Form: Safety Report Form (2)

Generated On: 26 Nov 2020 10:51:05

**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.**

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	17 Nov 2020 15:47:45
User entered 'I'	(b) (4), (b) (6)	10 Nov 2020 15:30:43

**US3312046**

**Folder: SAE USA-US300-2020-MRNA-1273-P301000005**

**Form: Safety Report Form**

**Generated On: 26 Nov 2020 10:51:05**

[SAEID](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	15 Oct 2020 12:50:31
User entered 'USA-US300-2020-MRNA-1273-P301000005'	System	15 Oct 2020 12:50:05

**US3312046**

**Folder: SAE USA-US300-2020-MRNA-1273-P301000005**

**Form: Safety Report Form**

**Generated On: 26 Nov 2020 10:51:05**

**Serious**

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	15 Oct 2020 12:50:31
User entered 'Yes (Y)'	System	15 Oct 2020 12:50:05



**US3312046**

**Folder: SAE USA-US300-2020-MRNA-1273-P301000005**

**Form: Safety Report Form**

**Generated On: 26 Nov 2020 10:51:05**

[Death](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	15 Oct 2020 12:50:31
User entered 'No (N)'	System	15 Oct 2020 12:50:05

**US3312046**

**Folder: SAE USA-US300-2020-MRNA-1273-P301000005**

**Form: Safety Report Form**

**Generated On: 26 Nov 2020 10:51:05**

[Life threatening](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	15 Oct 2020 12:50:31
User entered 'No (N)'	System	15 Oct 2020 12:50:05

**US3312046**

**Folder: SAE USA-US300-2020-MRNA-1273-P301000005**

**Form: Safety Report Form**

**Generated On: 26 Nov 2020 10:51:05**

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	15 Oct 2020 12:50:31
User entered 'Yes (Y)'	System	15 Oct 2020 12:50:05

**US3312046**

**Folder: SAE USA-US300-2020-MRNA-1273-P301000005**

**Form: Safety Report Form**

**Generated On: 26 Nov 2020 10:51:05**

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	15 Oct 2020 12:50:31
User entered 'No (N)'	System	15 Oct 2020 12:50:05

**US3312046**

**Folder: SAE USA-US300-2020-MRNA-1273-P301000005**

**Form: Safety Report Form**

**Generated On: 26 Nov 2020 10:51:05**

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	15 Oct 2020 12:50:31
User entered 'No (N)'	System	15 Oct 2020 12:50:05

**US3312046**

**Folder: SAE USA-US300-2020-MRNA-1273-P301000005**

**Form: Safety Report Form**

**Generated On: 26 Nov 2020 10:51:05**

[Other medically important event](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	15 Oct 2020 12:50:31
User entered 'No (N)'	System	15 Oct 2020 12:50:05

**US3312046**

**Folder: SAE USA-US300-2020-MRNA-1273-P301000005**

**Form: Safety Report Form**

**Generated On: 26 Nov 2020 10:51:05**

[Investigator's First Name](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	15 Oct 2020 12:50:31
User entered 'Carlos'	System	15 Oct 2020 12:50:05

**US3312046**

**Folder: SAE USA-US300-2020-MRNA-1273-P301000005**

**Form: Safety Report Form**

**Generated On: 26 Nov 2020 10:51:05**

[Investigator's Last Name](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	15 Oct 2020 12:50:31
User entered 'Fierro'	System	15 Oct 2020 12:50:05



**US3312046**

**Folder: SAE USA-US300-2020-MRNA-1273-P301000005**

**Form: Safety Report Form**

**Generated On: 26 Nov 2020 10:51:05**

[Site Address: Street](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	15 Oct 2020 12:50:31
User entered '16300 College Blvd'	System	15 Oct 2020 12:50:05

**US3312046**

**Folder: SAE USA-US300-2020-MRNA-1273-P301000005**

**Form: Safety Report Form**

**Generated On: 26 Nov 2020 10:51:05**

[Site Address: City](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	15 Oct 2020 12:50:31
User entered 'Shawnee'	System	15 Oct 2020 12:50:05

**US3312046**

**Folder: SAE USA-US300-2020-MRNA-1273-P301000005**

**Form: Safety Report Form**

**Generated On: 26 Nov 2020 10:51:05**

[Site Address: State](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	15 Oct 2020 12:50:31
User entered 'KS'	System	15 Oct 2020 12:50:05

**US3312046**

**Folder: SAE USA-US300-2020-MRNA-1273-P301000005**

**Form: Safety Report Form**

**Generated On: 26 Nov 2020 10:51:05**

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	15 Oct 2020 12:50:31
User entered '66219'	System	15 Oct 2020 12:50:05

**US3312046**

**Folder: SAE USA-US300-2020-MRNA-1273-P301000005**

**Form: Safety Report Form**

**Generated On: 26 Nov 2020 10:51:05**

[Investigator Country](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	17 Nov 2020 15:47:45
User entered 'US'	System	15 Oct 2020 12:50:36

**US3312046**

**Folder: SAE USA-US300-2020-MRNA-1273-P301000005**

**Form: Safety Report Form**

**Generated On: 26 Nov 2020 10:51:05**

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '3'	System	17 Nov 2020 15:49:16
User entered '2'	System	10 Nov 2020 15:30:43
User entered '1'	System	15 Oct 2020 12:50:36

**US3312046**

**Folder: SAE USA-US300-2020-MRNA-1273-P301000005**

**Form: Safety Report Form (3)**

**Generated On: 26 Nov 2020 10:51:05**

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User entered '17/Nov/2020 15:49'	System	17 Nov 2020 15:49:16

US3312046

Folder: SAE USA-US300-2020-MRNA-1273-P301000005

Form: Safety Report Form (3)

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**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.**

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