

US3552412 (Prod: Saint Louis University)

Generated By: KC Joubran

Generated On: 11 Aug 2021 22:53:07

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US3552412

Form: Participant Creation

Data signed: (b) (4) 21 Feb 2021 19:11:16

Generated On: 11 Aug 2021 22:53:07

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Participant ID

US3552412

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

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US3552412

Folder: Screening

Form: Visit Date

Data signed: (b) (4) 21 Feb 2021 19:11:19

Generated On: 11 Aug 2021 22:53:07

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

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Folder: Screening

Form: Demographics

Data signed: (b) (4) 21 Feb 2021 19:11:19

Generated On: 11 Aug 2021 22:53:07

Date of Birth (MMM yyyy)	(b) (6) 1991
Age	29
Age Units	YEARS
Age (Derived)	29
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

Data signed: (b) (4) 21 Feb 2021 19:11:19

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Date of Informed Consent ( <i>dd MMM yyyy</i> )	11 SEP 2020
Month and Year of Informed Consent (derived)	SEP 2020
Year of Informed Consent (derived)	2020
Protocol Version	Amendment 1 <input type="radio"/> Amendment 2 <input type="radio"/> Amendment 3 <input checked="" type="radio"/> Amendment 4 <input type="radio"/> Amendment 5 <input type="radio"/>
Was participant enrolled in the study?	Yes <input checked="" type="radio"/> No <input type="radio"/>
If No, indicate reason for screen fail	Withdrew Consent <input type="radio"/> Inclusion/Exclusion <input type="radio"/> Cohort Full <input type="radio"/> Other <input type="radio"/>
If reason for screen fail is Other, specify	
Was this participant screened previously?	Yes <input type="radio"/> No <input checked="" type="radio"/>
If Yes, previous participant number	
Enrollment Trigger	1

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Folder: Screening

Form: Inclusion/Exclusion Criteria Summary

Data signed: (b) (4) 21 Feb 2021 19:11:19

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Did the participant meet all eligibility criteria?

Yes ☒

No ☐

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Folder: Screening

Form: Medical History Summary

Data signed: (b) (4) 21 Feb 2021 19:11:19

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Were any significant conditions reported?

Yes ☒  
No ☐

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Folder: Screening

Form: Medical History (1)

Data signed: (b) (4) 21 Feb 2021 19:11:19

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Condition	MYOPIA
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)

Data signed: (b) (4) 21 Feb 2021 19:11:19

Generated On: 11 Aug 2021 22:53:07

Condition	BILATERAL LATTICE DEGENERATION
Start date (dd MMM yyyy)	UN UNK 2018
Start date completely unknown	False
Condition ongoing at study entry	Yes <input checked="" type="radio"/> No <input type="radio"/>
If No, please specify the stop date (dd MMM yyyy)	
Stop date completely unknown	False
Start Month and Year (derived)	JAN 2018
Start Year (derived)	2018
Stop Month and Year (derived)	
Stop Year (derived)	

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Folder: Screening

Form: Medical History (3)

Data signed: (b) (4) 21 Feb 2021 19:11:19

Generated On: 11 Aug 2021 22:53:07

Condition	HEADACHES
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 (4)

Data signed: (b) (4) 21 Feb 2021 19:11:19

Generated On: 11 Aug 2021 22:53:07

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

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Folder: Screening

Form: Medical History (5)

Data signed: (b) (4) 21 Feb 2021 19:11:19

Generated On: 11 Aug 2021 22:53:07

Condition	ACNE
Start date (dd MMM yyyy)	UN JUL 2020
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)	JUL 2020
Start Year (derived)	2020
Stop Month and Year (derived)	_____
Stop Year (derived)	_____

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Folder: Screening

Form: Vital Signs

Data signed: (b) (4) 21 Feb 2021 19:11:19

Generated On: 11 Aug 2021 22:53:07

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (dd MMM yyyy)	11 SEP 2020
Time of assessment (00:00-23:59)	12:55 (24 HR)
Vital Signs Date and Time (derived)	11 SEP 2020 12:55
Height (xxx.x)	66 in
Weight (xxx.x)	103.2 lb
BMI (xxx.x)	16.69174 kg/m <sup>2</sup>
BMI units	KG/M2
Temperature (xxx.x)	ND - Not Done
Route of measurement	Oral <input type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	ND - Not Done
Pulse units	BPM
Respiratory Rate (xxx)	ND - Not Done
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	ND - Not Done
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	ND - Not Done
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

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Folder: Screening

Form: Physical Examination

Data signed: (b) (4) 21 Feb 2021 19:11:19

Generated On: 11 Aug 2021 22:53:07

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

11 SEP 2020

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

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Folder: Screening

Form: Childbearing Potential

Data signed: (b) (4) 21 Feb 2021 19:11:19

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Date of assessment (dd MMM yyyy) 11 SEP 2020

Is the participant of childbearing potential? Yes ☒  
No ☐

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

If Partner medically sterile or Other, specify \_\_\_\_\_

If Surgically sterile, date of surgery (dd MMM yyyy) \_\_\_\_\_

Date of surgery unknown False

If Post-menopausal, date of last menstruation (dd MMM yyyy) \_\_\_\_\_

Date of last menstruation unknown False

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Folder: Screening

Form: Pregnancy Test

Data signed: (b) (4) 21 Feb 2021 19:11:19

Generated On: 11 Aug 2021 22:53:07

Was the pregnancy test performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of test ( <i>dd MMM yyyy</i> )	11 SEP 2020
Test performed	Urine <input checked="" type="radio"/>
	Serum <input type="radio"/>
Result	Positive <input type="radio"/>
	Negative <input checked="" type="radio"/>
Was FSH sample collected?	Yes <input type="radio"/>
	No <input checked="" type="radio"/>
Collection date	
Collection time	
Collection date and time (derived)	

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Folder: Screening

Form: Risk of Exposure

Data signed: (b) (4) 21 Feb 2021 19:11:19

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### Occupational Risk

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

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

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

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

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

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

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

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

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

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

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

**Other** Yes ☒ No ☐

Specify

PHYSICIAN ASSISTANT -  
(b) (6)  
SHOPPING, CHILD  
IN DAYCARE

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

**No Risk Identified** False

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EAB) (1725)

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Folder: Screening

Form: Risk of Exposure

Data signed: (b) (4) 21 Feb 2021 19:11:19

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<b>Resides in Nursing Home or Assisted Living Facility</b>	False
<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)	True
<b>Other</b>	False
<b>Specify</b>	

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Folder: Visit 1 Day 1

Form: Visit Date

Data signed: (b) (4) 21 Feb 2021 19:11:19

Generated On: 11 Aug 2021 22:53:07

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	11 SEP 2020
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	VISIT1

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Folder: Visit 1 Day 1

Form: Randomization

Data signed: (b) (4) 21 Feb 2021 19:11:19

Generated On: 11 Aug 2021 22:53:07

What was the date of randomization? (dd MMM yyyy) 11 SEP 2020

What was the participant's randomization number? 113394

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

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

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

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

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

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

Liver Disease Yes ☐ No ☒

Human Immunodeficiency Virus (HIV) infection Yes ☐ No ☒

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Data signed: (b) (4) 21 Feb 2021 19:11:19

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Height	ND - Not Done
Weight	ND - Not Done

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 21 Feb 2021 19:11:19

Generated On: 11 Aug 2021 22:53:07

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)	11 SEP 2020
Time of assessment (00:00-23:59)	12:55 (24 HR)
Vital Signs Date and Time (derived)	11 SEP 2020 12:55
Temperature (xxx.x)	97.6 F
Route of measurement	Oral <input checked="" type="radio"/> Axillary <input type="radio"/> Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	82 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	14 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	100 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	56 mmHg
Diastolic Blood Pressure units	MMHG

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 21 Feb 2021 19:11:19

Generated On: 11 Aug 2021 22:53:07

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)	11 SEP 2020
Time of assessment (00:00-23:59)	14:26 (24 HR)
Vital Signs Date and Time (derived)	11 SEP 2020 14:26
Temperature (xxx.x)	96.5 F
Route of measurement	Oral <input checked="" type="radio"/> Axillary <input type="radio"/> Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	69 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	97 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	68 mmHg
Diastolic Blood Pressure units	MMHG

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Folder: Visit 1 Day 1

Form: Physical Examination

Data signed: (b) (4) 21 Feb 2021 19:11:19

Generated On: 11 Aug 2021 22:53:07

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: Pregnancy Test

Data signed: (b) (4) 21 Feb 2021 19:11:19

Generated On: 11 Aug 2021 22:53:07

Was the pregnancy test performed? Yes ☐  
No ☒

Date of test (dd MMM yyyy) \_\_\_\_\_

Test performed Urine ☐  
Serum ☐

Result Positive ☐  
Negative ☐

Was FSH sample collected? Yes ☐  
No ☒

Collection date \_\_\_\_\_

Collection time \_\_\_\_\_

Collection date and time (derived) \_\_\_\_\_

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Folder: Visit 1 Day 1

Form: Exposure

Data signed: (b) (4) 21 Feb 2021 19:11:19

Generated On: 11 Aug 2021 22:53:07

Was study treatment given? Yes ☒ No ☐

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

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

What was the study treatment? MRNA-1273 OR PLACEBO

What was the treatment date? (dd MMM yyyy) 11 SEP 2020

What was the treatment time? (00:00-23:59) 13:56 (24 HR)

Treatment Date and Time (derived) 11 SEP 2020 13:56

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

What was the frequency of the study treatment dosing? ONCE

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

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Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Data signed: (b) (4) 21 Feb 2021 19:11:19

Generated On: 11 Aug 2021 22:53:07

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (dd MMM yyyy)	11 SEP 2020
Collection time (00:00-23:59)	13:21 (24 HR)
Collection date and time (derived)	11 SEP 2020 13:21

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Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab

Data signed: (b) (4) 21 Feb 2021 19:11:19

Generated On: 11 Aug 2021 22:53:07

Collection date (dd MMM yyyy)			11 SEP 2020
Lab Test	Was the sample collected?	Collection time (00:00 - 23:59)	Collection date and time (derived)
Nasopharyngeal Swab 1	Yes	13:25	11 SEP 2020 13:25
Nasopharyngeal Swab 2	No		

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Folder: Visit 1 Day 1

Form: Continuing

Data signed: (b) (4) 21 Feb 2021 19:11:19

Generated On: 11 Aug 2021 22:53:07

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: 11 Aug 2021 22:53:07

**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

96.5 °F

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

Yes ☐  
No ☒

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

PC Time Stamp 11 SEP 2020 14:29

PC Open Date & Time 11 SEP 2020 14:16

PC Close Date & Time 11 SEP 2020 16:46

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Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/2)

Generated On: 11 Aug 2021 22:53:07

**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

97.2 °F

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

Yes ☐

No ☒

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

PC Time Stamp

11 SEP 2020 21:40

PC Open Date & Time

11 SEP 2020 17:41

PC Close Date & Time

12 SEP 2020 11:59

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Folder: Diary Dose 1 (1)

Form: Temperature\_Day(2)

Generated On: 11 Aug 2021 22:53:07

**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

97.2 °F

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

Yes ☐

No ☒

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

PC Time Stamp

12 SEP 2020 21:18

PC Open Date & Time

12 SEP 2020 12:00

PC Close Date & Time

13 SEP 2020 11:59

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Folder: Diary Dose 1 (1)

Form: Temperature\_Day(3)

Generated On: 11 Aug 2021 22:53:07

**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

97.4 °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

13 SEP 2020 21:45

PC Open Date & Time

13 SEP 2020 12:00

PC Close Date & Time

14 SEP 2020 11:59

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Folder: Diary Dose 1 (1)

Form: Temperature\_Day(4)

Generated On: 11 Aug 2021 22:53:07

**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

14 SEP 2020 21:37

PC Open Date & Time

14 SEP 2020 12:00

PC Close Date & Time

15 SEP 2020 11:59

US3552412

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(5)

Generated On: 11 Aug 2021 22:53:07

**TIMEPOINT**

DAY 5

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.8 °F

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

Yes ☐

No ☒

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

PC Time Stamp

15 SEP 2020 21:18

PC Open Date & Time

15 SEP 2020 12:00

PC Close Date & Time

16 SEP 2020 11:59

US3552412

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(6)

Generated On: 11 Aug 2021 22:53:07

**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

97.1 °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

16 SEP 2020 21:59

PC Open Date & Time

16 SEP 2020 12:00

PC Close Date & Time

17 SEP 2020 11:59

US3552412

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(7)

Generated On: 11 Aug 2021 22:53:07

**TIMEPOINT**

DAY 7

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.1 °F

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

Yes ☐

No ☒

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

PC Time Stamp

17 SEP 2020 22:02

PC Open Date & Time

17 SEP 2020 12:00

PC Close Date & Time

18 SEP 2020 11:59

US3552412

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 11 Aug 2021 22:53:07

**TIMEPOINT**

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

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

Please select one response below

None ☒

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

Please select one response below

None ☒

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

PC Time Stamp

11 SEP 2020 14:30

PC Open Date & Time

11 SEP 2020 14:16

PC Close Date & Time

11 SEP 2020 16:46

US3552412

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 11 Aug 2021 22:53:07

**TIMEPOINT**

DAY 1, AFTER VACCINATION  
(AT HOME)

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

Please select one response below

None ☐

Does not interfere with activity ☒

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

Any use of prescription pain  
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

Please select one response below

None ☒

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

PC Time Stamp

11 SEP 2020 21:41

PC Open Date & Time

11 SEP 2020 17:41

PC Close Date & Time

12 SEP 2020 11:59

US3552412

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 11 Aug 2021 22:53:07

**TIMEPOINT**

DAY 2

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

None ☐

Please select one response below

Does not interfere with activity ☒

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

Any use of prescription pain  
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

PC Time Stamp

12 SEP 2020 21:16

PC Open Date & Time

12 SEP 2020 12:00

PC Close Date & Time

13 SEP 2020 11:59

US3552412

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 11 Aug 2021 22:53:07

**TIMEPOINT**

DAY 3

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

None ☐

Please select one response below

Does not interfere with activity ☒

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

Any use of prescription pain  
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

PC Time Stamp

13 SEP 2020 21:44

PC Open Date & Time

13 SEP 2020 12:00

PC Close Date & Time

14 SEP 2020 11:59

US3552412

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 11 Aug 2021 22:53:07

**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

14 SEP 2020 21:38

PC Open Date & Time

14 SEP 2020 12:00

PC Close Date & Time

15 SEP 2020 11:59

US3552412

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 11 Aug 2021 22:53:07

**TIMEPOINT**

DAY 5

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

PC Time Stamp

15 SEP 2020 21:18

PC Open Date & Time

15 SEP 2020 12:00

PC Close Date & Time

16 SEP 2020 11:59

US3552412

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(6)

Generated On: 11 Aug 2021 22:53:07

**TIMEPOINT**

DAY 6

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

PC Time Stamp

16 SEP 2020 21:59

PC Open Date & Time

16 SEP 2020 12:00

PC Close Date & Time

17 SEP 2020 11:59

US3552412

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 11 Aug 2021 22:53:07

**TIMEPOINT**

DAY 7

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

PC Time Stamp

17 SEP 2020 22:01

PC Open Date & Time

17 SEP 2020 12:00

PC Close Date & Time

18 SEP 2020 11:59

US3552412

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 11 Aug 2021 22:53:07

**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 ☐

US3552412

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 11 Aug 2021 22:53:07

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

No ☒

Yes ☐

PC Time stamp	11 SEP 2020 14:30
PC Open Date & Time	11 SEP 2020 14:16
PC Close Date & Time	11 SEP 2020 16:46

US3552412

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 11 Aug 2021 22:53:07

**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 ☐

US3552412

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 11 Aug 2021 22:53:07

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

No ☒

Yes ☐

PC Time stamp	11 SEP 2020 21:39
PC Open Date & Time	11 SEP 2020 17:41
PC Close Date & Time	12 SEP 2020 11:59

US3552412

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 11 Aug 2021 22:53:07

**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 ☒

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EAB) (1725)

US3552412

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 11 Aug 2021 22:53:07

Yes <input type="checkbox"/>	
PC Time stamp	12 SEP 2020 21:17
PC Open Date & Time	12 SEP 2020 12:00
PC Close Date & Time	13 SEP 2020 11:59

US3552412

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 11 Aug 2021 22:53:07

**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 ☒

US3552412

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 11 Aug 2021 22:53:07

Yes <input type="checkbox"/>	
PC Time stamp	13 SEP 2020 21:44
PC Open Date & Time	13 SEP 2020 12:00
PC Close Date & Time	14 SEP 2020 11:59

US3552412

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 11 Aug 2021 22:53:07

**TIMEPOINT**

DAY 4

**HEADACHE**

None ☒

No interference with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

**FATIGUE**

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

**MUSCLE ACHES ALL OVER BODY**

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

**JOINT ACHES IN SEVERAL JOINTS**

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

**NAUSEA/VOMITING**

None ☒

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

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

Prevents daily activity, requires  
outpatient IV hydration ☐

**CHILLS**

None ☒

No interference with activity ☐

Some interference with activity  
not requiring medical attention ☐

Prevents daily activity and  
requires medical attention ☐

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

No ☒

PRODUCTION RELEASE (v12.003

53 of 2459

EAB) (1725)

US3552412

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 11 Aug 2021 22:53:07

Yes <input type="checkbox"/>	
PC Time stamp	14 SEP 2020 21:38
PC Open Date & Time	14 SEP 2020 12:00
PC Close Date & Time	15 SEP 2020 11:59

US3552412

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 11 Aug 2021 22:53:07

TIMEPOINT

DAY 5

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires  
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity  
not requiring medical attention ☐

Prevents daily activity and  
requires medical attention ☐

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

No ☒

PRODUCTION RELEASE (v12.003

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EAB) (1725)

US3552412

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 11 Aug 2021 22:53:07

Yes <input type="checkbox"/>	
PC Time stamp	15 SEP 2020 21:18
PC Open Date & Time	15 SEP 2020 12:00
PC Close Date & Time	16 SEP 2020 11:59

US3552412

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 11 Aug 2021 22:53:07

TIMEPOINT

DAY 6

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires  
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity  
not requiring medical attention ☐

Prevents daily activity and  
requires medical attention ☐

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

No ☒

PRODUCTION RELEASE (v12.003  
EAB) (1725)

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US3552412

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 11 Aug 2021 22:53:07

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

US3552412

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 11 Aug 2021 22:53:07

**TIMEPOINT**

DAY 7

**HEADACHE**

None ☒

No interference with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

**FATIGUE**

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

**MUSCLE ACHES ALL OVER BODY**

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

**JOINT ACHES IN SEVERAL JOINTS**

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

**NAUSEA/VOMITING**

None ☒

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

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

Prevents daily activity, requires  
outpatient IV hydration ☐

**CHILLS**

None ☒

No interference with activity ☐

Some interference with activity  
not requiring medical attention ☐

Prevents daily activity and  
requires medical attention ☐

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

No ☒

PRODUCTION RELEASE (v12.003

59 of 2459

EAB) (1725)

US3552412

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 11 Aug 2021 22:53:07

Yes <input type="checkbox"/>	
PC Time stamp	17 SEP 2020 22:02
PC Open Date & Time	17 SEP 2020 12:00
PC Close Date & Time	18 SEP 2020 11:59

US3552412

Folder: Safety Call Day 8 (1)

Form: Safety Call

Data signed: (b) (4) 21 Feb 2021 19:11:19

Generated On: 11 Aug 2021 22:53:07

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

18 SEP 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

*If Contact Not Made, please provide Comments*

US3552412

Folder: Safety Call Day 8 (1)

Form: Continuing

Data signed: (b) (4) 21 Feb 2021 19:11:19

Generated On: 11 Aug 2021 22:53:07

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3552412

Folder: Safety Call Day 15 (1)

Form: Safety Call

Data signed: (b) (4) 21 Feb 2021 19:11:19

Generated On: 11 Aug 2021 22:53:07

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

25 SEP 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

*If Contact Not Made, please provide Comments*

US3552412

Folder: Safety Call Day 15 (1)

Form: Continuing

Data signed: (b) (4) 21 Feb 2021 19:11:19

Generated On: 11 Aug 2021 22:53:07

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3552412

Folder: Safety Call Day 22 (1)

Form: Safety Call

Data signed: (b) (4) 21 Feb 2021 19:11:19

Generated On: 11 Aug 2021 22:53:07

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

02 OCT 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

*If Contact Not Made, please provide Comments*

US3552412

Folder: Safety Call Day 22 (1)

Form: Continuing

Data signed: (b) (4) 21 Feb 2021 19:11:19

Generated On: 11 Aug 2021 22:53:07

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3552412

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Data signed: (b) (4) 21 Feb 2021 19:11:19

Generated On: 11 Aug 2021 22:53:07

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	09 OCT 2020
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	VISIT2

US3552412

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 21 Feb 2021 19:11:19

Generated On: 11 Aug 2021 22:53:07

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 OCT 2020
Time of assessment (00:00-23:59)	08:38 (24 HR)
Vital Signs Date and Time (derived)	09 OCT 2020 08:38
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)	90 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	12 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	90 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	60 mmHg
Diastolic Blood Pressure units	MMHG

US3552412

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 21 Feb 2021 19:11:19

Generated On: 11 Aug 2021 22:53:07

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 OCT 2020
Time of assessment (00:00-23:59)	10:02 (24 HR)
Vital Signs Date and Time (derived)	09 OCT 2020 10:02
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)	72 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	14 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	97 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	62 mmHg
Diastolic Blood Pressure units	MMHG

US3552412

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Data signed: (b) (4) 21 Feb 2021 19:11:19

Generated On: 11 Aug 2021 22:53:07

---

Was the physical examination performed?

Yes ☒

No ☐

---

Date of examination (dd MMM yyyy)

09 OCT 2020

---

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

---

US3552412

Folder: Visit 2 Day 29 (1)

Form: Pregnancy Test

Data signed: (b) (4) 21 Feb 2021 19:11:19

Generated On: 11 Aug 2021 22:53:07

Was the pregnancy test performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of test ( <i>dd MMM yyyy</i> )	09 OCT 2020
Test performed	Urine <input checked="" type="radio"/>
	Serum <input type="radio"/>
Result	Positive <input type="radio"/>
	Negative <input checked="" type="radio"/>
Was FSH sample collected?	Yes <input type="radio"/>
	No <input checked="" type="radio"/>
Collection date	
Collection time	
Collection date and time (derived)	

US3552412

Folder: Visit 2 Day 29 (1)

Form: Exposure

Data signed: (b) (4) 21 Feb 2021 19:11:19

Generated On: 11 Aug 2021 22:53:07

Was study treatment given? Yes ☒ No ☐

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

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

What was the study treatment? MRNA-1273 OR PLACEBO

What was the treatment date? (dd MMM yyyy) 09 OCT 2020

What was the treatment time? (00:00-23:59) 09:32 (24 HR)

Treatment Date and Time (derived) 09 OCT 2020 09:32

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

What was the frequency of the study treatment dosing? ONCE

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

US3552412

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 21 Feb 2021 19:11:19

Generated On: 11 Aug 2021 22:53:07

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (dd MMM yyyy)	09 OCT 2020
Collection time (00:00-23:59)	09:01 (24 HR)
Collection date and time (derived)	09 OCT 2020 09:01

US3552412

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab

Data signed: (b) (4) 21 Feb 2021 19:11:19

Generated On: 11 Aug 2021 22:53:07

Collection date (dd MMM yyyy)			09 OCT 2020
Lab Test	Was the sample collected?	Collection time (00:00 - 23:59)	Collection date and time (derived)
Nasopharyngeal Swab 1	Yes	09:08	09 OCT 2020 09:08
Nasopharyngeal Swab 2	No		

US3552412

Folder: Visit 2 Day 29 (1)

Form: Continuing

Data signed: (b) (4) 21 Feb 2021 19:11:19

Generated On: 11 Aug 2021 22:53:07

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3552412

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/1)

Generated On: 11 Aug 2021 22:53:07

**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

97.8 °F

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

Yes ☐

No ☒

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

PC Time Stamp

09 OCT 2020 10:02

PC Open Date & Time

09 OCT 2020 09:52

PC Close Date & Time

09 OCT 2020 12:22

US3552412

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/2)

Generated On: 11 Aug 2021 22:53:07

**TIMEPOINT**

DAY 1, AFTER VACCINATION  
(AT HOME)

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

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

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

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

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

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

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

Was **TEMPERATURE** taken? Yes ☒ No ☐

Please record your **TEMPERATURE** in °F 100.0 °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):

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

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

PC Time Stamp 09 OCT 2020 18:46

PC Open Date & Time 09 OCT 2020 13:17

PC Close Date & Time 10 OCT 2020 11:59

US3552412

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(2)

Generated On: 11 Aug 2021 22:53:07

**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 <b>TEMPERATURE</b> taken?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Please record your <b>TEMPERATURE</b> in °F	99.0 °F
Was any <b>MEDICATION TAKEN</b> today for pain or fever?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>

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

To <b>TREAT</b> pain or fever that has already occurred	True
To <b>PREVENT</b> pain or fever from occurring	False

PC Time Stamp	10 OCT 2020 19:33
PC Open Date & Time	10 OCT 2020 12:00
PC Close Date & Time	11 OCT 2020 11:59

US3552412

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(3)

Generated On: 11 Aug 2021 22:53:07

**TIMEPOINT**

DAY 3

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.3 °F

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

Yes ☐

No ☒

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

PC Time Stamp

11 OCT 2020 20:05

PC Open Date & Time

11 OCT 2020 12:00

PC Close Date & Time

12 OCT 2020 11:59

US3552412

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(4)

Generated On: 11 Aug 2021 22:53:07

**TIMEPOINT**

DAY 4

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.1 °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 OCT 2020 19:23

PC Open Date & Time

12 OCT 2020 12:00

PC Close Date & Time

13 OCT 2020 11:59

US3552412

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(5)

Generated On: 11 Aug 2021 22:53:07

**TIMEPOINT**

DAY 5

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.5 °F

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

Yes ☐

No ☒

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

PC Time Stamp

13 OCT 2020 21:19

PC Open Date & Time

13 OCT 2020 12:00

PC Close Date & Time

14 OCT 2020 11:59

US3552412

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(6)

Generated On: 11 Aug 2021 22:53:07

**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.

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.1 °F

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

Yes ☐

No ☒

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

PC Time Stamp

15 OCT 2020 07:15

PC Open Date & Time

14 OCT 2020 12:00

PC Close Date & Time

15 OCT 2020 11:59

US3552412

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(7)

Generated On: 11 Aug 2021 22:53:07

**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.

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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 <b>TEMPERATURE</b> taken?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Please record your <b>TEMPERATURE</b> in °F	97.3 °F
Was any <b>MEDICATION TAKEN</b> today for pain or fever?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>

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

To <b>TREAT</b> pain or fever that has already occurred	True
To <b>PREVENT</b> pain or fever from occurring	False

PC Time Stamp	15 OCT 2020 21:12
PC Open Date & Time	15 OCT 2020 12:00
PC Close Date & Time	16 OCT 2020 11:59

US3552412

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(8)

Generated On: 11 Aug 2021 22:53:07

**TIMEPOINT**

DAY 8

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

16 OCT 2020 22:12

PC Open Date & Time

16 OCT 2020 12:00

PC Close Date & Time

17 OCT 2020 11:59

US3552412

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/1)

Generated On: 11 Aug 2021 22:53:07

**TIMEPOINT**

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

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

Please select one response below

None ☒

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

Please select one response below

None ☒

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

PC Time Stamp

09 OCT 2020 10:03

PC Open Date & Time

09 OCT 2020 09:52

PC Close Date & Time

09 OCT 2020 12:22

US3552412

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/2)

Generated On: 11 Aug 2021 22:53:07

**TIMEPOINT**

DAY 1, AFTER VACCINATION  
(AT HOME)

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

Please select one response below

None ☐

Does not interfere with activity ☒

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

Any use of prescription pain  
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

Please select one response below

None ☒

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

PC Time Stamp

09 OCT 2020 18:47

PC Open Date & Time

09 OCT 2020 13:17

PC Close Date & Time

10 OCT 2020 11:59

US3552412

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(2)

Generated On: 11 Aug 2021 22:53:07

**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 ☐

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

50

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 - **UNDERARM GLAND SWELLING OR  
TENDERNESS.**

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

PC Time Stamp

10 OCT 2020 19:30

PC Open Date & Time

10 OCT 2020 12:00

PC Close Date & Time

11 OCT 2020 11:59

US3552412

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(3)

Generated On: 11 Aug 2021 22:53:07

**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

11 OCT 2020 20:05

PC Open Date & Time

11 OCT 2020 12:00

PC Close Date & Time

12 OCT 2020 11:59

US3552412

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(4)

Generated On: 11 Aug 2021 22:53:07

TIMEPOINT	DAY 4
Please record - <b>PAIN AT INJECTION SITE.</b>	None <input type="radio"/>
Please select one response below	Does not interfere with activity <input checked="" type="radio"/>
	Repeated use of over-the-counter pain reliever > 24 hours or interferes with activity <input type="radio"/>
	Any use of prescription pain reliever or prevents daily activity <input type="radio"/>
Is there any <b>REDNESS AT INJECTION SITE?</b>	Yes <input type="radio"/>
	No <input checked="" type="radio"/>
Is there any <b>SWELLING/HARDNESS AT INJECTION SITE?</b>	Yes <input type="radio"/>
	No <input checked="" type="radio"/>
Please record - <b>UNDERARM GLAND SWELLING OR TENDERNESS.</b>	None <input checked="" type="radio"/>
Please select one response below	Does not interfere with activity <input type="radio"/>
	Repeated use of over-the-counter pain reliever > 24 hours or interferes with some activity <input type="radio"/>
	Any use of prescription pain reliever or prevents daily activity <input type="radio"/>
PC Time Stamp	12 OCT 2020 19:24
PC Open Date & Time	12 OCT 2020 12:00
PC Close Date & Time	13 OCT 2020 11:59

US3552412

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(5)

Generated On: 11 Aug 2021 22:53:07

**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 OCT 2020 21:18

PC Open Date & Time

13 OCT 2020 12:00

PC Close Date & Time

14 OCT 2020 11:59

US3552412

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(6)

Generated On: 11 Aug 2021 22:53:07

TIMEPOINT	DAY 6
Please record - <b>PAIN AT INJECTION SITE.</b>	None <input checked="" type="radio"/>
Please select one response below	
Does not interfere with activity	<input type="radio"/>
Repeated use of over-the-counter pain reliever > 24 hours or interferes with activity	<input type="radio"/>
Any use of prescription pain reliever or prevents daily activity	<input type="radio"/>
Is there any <b>REDNESS AT INJECTION SITE?</b>	Yes <input type="radio"/>
	No <input checked="" type="radio"/>
Is there any <b>SWELLING/HARDNESS AT INJECTION SITE?</b>	Yes <input type="radio"/>
	No <input checked="" type="radio"/>
Please record - <b>UNDERARM GLAND SWELLING OR TENDERNESS.</b>	None <input checked="" type="radio"/>
Please select one response below	
Does not interfere with activity	<input type="radio"/>
Repeated use of over-the-counter pain reliever > 24 hours or interferes with some activity	<input type="radio"/>
Any use of prescription pain reliever or prevents daily activity	<input type="radio"/>
PC Time Stamp	15 OCT 2020 07:15
PC Open Date & Time	14 OCT 2020 12:00
PC Close Date & Time	15 OCT 2020 11:59

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Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(7)

Generated On: 11 Aug 2021 22:53:07

**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 OCT 2020 21:12

PC Open Date & Time

15 OCT 2020 12:00

PC Close Date & Time

16 OCT 2020 11:59

US3552412

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 11 Aug 2021 22:53:07

**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 ☐

US3552412

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 11 Aug 2021 22:53:07

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

No ☒

Yes ☐

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PC Open Date & Time	09 OCT 2020 09:52
PC Close Date & Time	09 OCT 2020 12:22

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Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 11 Aug 2021 22:53:07

**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 ☐

US3552412

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 11 Aug 2021 22:53:07

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

No ☒

Yes ☐

PC Time stamp	09 OCT 2020 18:45
PC Open Date & Time	09 OCT 2020 13:17
PC Close Date & Time	10 OCT 2020 11:59

US3552412

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 11 Aug 2021 22:53:07

**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 ☒

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EAB) (1725)

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Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 11 Aug 2021 22:53:07

Yes <input type="checkbox"/>	
PC Time stamp	10 OCT 2020 19:26
PC Open Date & Time	10 OCT 2020 12:00
PC Close Date & Time	11 OCT 2020 11:59

US3552412

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 11 Aug 2021 22:53:07

**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 ☒

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Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 11 Aug 2021 22:53:07

Yes <input type="checkbox"/>	
PC Time stamp	11 OCT 2020 20:06
PC Open Date & Time	11 OCT 2020 12:00
PC Close Date & Time	12 OCT 2020 11:59

US3552412

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 11 Aug 2021 22:53:07

TIMEPOINT

DAY 4

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☐

No interference with activity ☒

Some interference with activity ☐

Significant; prevents daily  
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires  
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity  
not requiring medical attention ☐

Prevents daily activity and  
requires medical attention ☐

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

No ☒

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Folder: Diary Dose 2 (1)

Form: General\_Day(4)

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Yes <input type="checkbox"/>	
PC Time stamp	12 OCT 2020 19:24
PC Open Date & Time	12 OCT 2020 12:00
PC Close Date & Time	13 OCT 2020 11:59

US3552412

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 11 Aug 2021 22:53:07

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 ☒

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Folder: Diary Dose 2 (1)

Form: General\_Day(5)

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Yes <input type="checkbox"/>	
PC Time stamp	13 OCT 2020 21:18
PC Open Date & Time	13 OCT 2020 12:00
PC Close Date & Time	14 OCT 2020 11:59

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Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 11 Aug 2021 22:53:07

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 ☒

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Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 11 Aug 2021 22:53:07

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

US3552412

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 11 Aug 2021 22:53:07

**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 ☒

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Folder: Diary Dose 2 (1)

Form: General\_Day(7)

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Yes <input type="checkbox"/>	
PC Time stamp	15 OCT 2020 21:12
PC Open Date & Time	15 OCT 2020 12:00
PC Close Date & Time	16 OCT 2020 11:59

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Folder: Diary Dose 2 (1)

Form: Headache\_Day(8)

Generated On: 11 Aug 2021 22:53:07

**TIMEPOINT**

DAY 8

Select one response below to indicate the intensity of your

None ☒

**HEADACHE**

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 ☐

PC Time Stamp 16 OCT 2020 22:12

PC Open Date & Time 16 OCT 2020 12:00

PC Close Date & Time 17 OCT 2020 11:59

US3552412

Folder: Diary Dose 2 (1)

Form: Nausea\_Day(8)

Generated On: 11 Aug 2021 22:53:07

**TIMEPOINT**

DAY 8

Select one response below to indicate the level of your

**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 ☐

PC Time stamp 16 OCT 2020 22:12

PC Open Date & Time 16 OCT 2020 12:00

PC Close Date & Time 17 OCT 2020 11:59

US3552412

Folder: Diary Dose 2 (1)

Form: Medical Attention\_Day(8)

Generated On: 11 Aug 2021 22:53:07

<b>TIMEPOINT</b>	DAY 8
Did you receive any <b>MEDICAL ATTENTION</b> (doctor visit, <b>other</b> ) for any illness or symptoms?	No <input checked="" type="radio"/> Yes <input type="radio"/>
PC Time stamp	16 OCT 2020 22:12
PC Open Date & Time	16 OCT 2020 12:00
PC Close Date & Time	17 OCT 2020 11:59

US3552412

Folder: Safety Call Day 36 (1)

Form: Safety Call

Data signed: (b) (4) 21 Feb 2021 19:11:19

Generated On: 11 Aug 2021 22:53:07

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

16 OCT 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

*If Contact Not Made, please provide Comments*

US3552412

Folder: Safety Call Day 36 (1)

Form: Continuing

Data signed: (b) (4) 21 Feb 2021 19:11:19

Generated On: 11 Aug 2021 22:53:07

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3552412

Folder: Safety Call Day 43 (1)

Form: Safety Call

Data signed: (b) (4) 21 Feb 2021 19:11:19

Generated On: 11 Aug 2021 22:53:07

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

23 OCT 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

*If Contact Not Made, please provide Comments*

US3552412

Folder: Safety Call Day 43 (1)

Form: Continuing

Data signed: (b) (4) 21 Feb 2021 19:11:19

Generated On: 11 Aug 2021 22:53:07

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3552412

Folder: Safety Call Day 50 (1)

Form: Safety Call

Data signed: (b) (4) 21 Feb 2021 19:11:19

Generated On: 11 Aug 2021 22:53:07

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

30 OCT 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

*If Contact Not Made, please provide Comments*

US3552412

Folder: Safety Call Day 50 (1)

Form: Continuing

Data signed: (b) (4) 21 Feb 2021 19:11:19

Generated On: 11 Aug 2021 22:53:07

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3552412

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Data signed: (b) (4) 21 Feb 2021 19:11:20

Generated On: 11 Aug 2021 22:53:07

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	10 NOV 2020
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	VISIT3

US3552412

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Data signed: (b) (4) 21 Feb 2021 19:11:20

Generated On: 11 Aug 2021 22:53:07

Were vital signs assessed? Yes ☐  
No ☒

Date of assessment (dd MMM yyyy) \_\_\_\_\_

Time of assessment (00:00-23:59) \_\_\_\_\_

Vital Signs Date and Time (derived) \_\_\_\_\_

Temperature (xxx.x) \_\_\_\_\_

Route of measurement Oral ☐  
Axillary ☐  
Other ☐

If Other, specify \_\_\_\_\_

Pulse (xxx) \_\_\_\_\_

Pulse units \_\_\_\_\_

Respiratory Rate (xxx) \_\_\_\_\_

Respiratory Rate units \_\_\_\_\_

Systolic Blood Pressure (xxx) \_\_\_\_\_

Systolic Blood Pressure units \_\_\_\_\_

Diastolic Blood Pressure (xxx) \_\_\_\_\_

Diastolic Blood Pressure units \_\_\_\_\_

Height (derived) \_\_\_\_\_

Weight (derived) \_\_\_\_\_

US3552412

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Data signed: (b) (4) 21 Feb 2021 19:11:20

Generated On: 11 Aug 2021 22:53:07

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.*

US3552412

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 21 Feb 2021 19:11:20

Generated On: 11 Aug 2021 22:53:07

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (dd MMM yyyy)	10 NOV 2020
Collection time (00:00-23:59)	15:12 (24 HR)
Collection date and time (derived)	10 NOV 2020 15:12

US3552412

Folder: Visit 3 Day 57 (1)

Form: Continuing

Data signed: (b) (4) 21 Feb 2021 19:11:19

Generated On: 11 Aug 2021 22:53:07

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3552412

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:53:07

**TIMEPOINT**

DAY 64

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

12 NOV 2020 19:09:26

Patient Cloud Open Date & Time

11 NOV 2020 00:01

Patient Cloud Close Date & Time

15 NOV 2020 23:59

US3552412

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:53:07

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 <input type="radio"/> Yes <input checked="" type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input checked="" type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input checked="" type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input checked="" type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input checked="" type="radio"/>
Date and time of submission	18 NOV 2020 21:24:48
Patient Cloud Open Date & Time	18 NOV 2020 00:01
Patient Cloud Close Date & Time	22 NOV 2020 23:59

US3552412

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:53:07

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="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"/>

**US3552412**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:53:07**

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

[Patient Cloud Close Date & Time](#)

26 NOV 2020 23:59

US3552412

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:53:07

<b>TIMEPOINT</b>	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 checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	03 DEC 2020 12:09:01
Patient Cloud Open Date & Time	29 NOV 2020 00:01
Patient Cloud Close Date & Time	03 DEC 2020 23:59

US3552412

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:53:07

<b>TIMEPOINT</b>	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 checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	09 DEC 2020 17:56:34
Patient Cloud Open Date & Time	06 DEC 2020 00:01
Patient Cloud Close Date & Time	10 DEC 2020 23:59

US3552412

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:53:07

TIMEPOINT	DAY 96
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	16 DEC 2020 13:28:20
Patient Cloud Open Date & Time	13 DEC 2020 00:01
Patient Cloud Close Date & Time	17 DEC 2020 23:59

US3552412

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:53:07

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="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"/>

**US3552412**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:53:07**

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

[Patient Cloud Close Date & Time](#)

24 DEC 2020 23:59

US3552412

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:53:07

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 checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	28 DEC 2020 10:01:25
Patient Cloud Open Date & Time	27 DEC 2020 00:01
Patient Cloud Close Date & Time	31 DEC 2020 23:59

US3552412

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:53:07

**TIMEPOINT**

DAY 117

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

04 JAN 2021 06:22:17

Patient Cloud Open Date & Time

03 JAN 2021 00:01

Patient Cloud Close Date & Time

07 JAN 2021 23:59

US3552412

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:53:07

<b>TIMEPOINT</b>	DAY 124
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	11 JAN 2021 08:18:19
Patient Cloud Open Date & Time	10 JAN 2021 00:01
Patient Cloud Close Date & Time	14 JAN 2021 23:59

US3552412

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:53:07

**TIMEPOINT**

DAY 131

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

21 JAN 2021 13:47:35

Patient Cloud Open Date & Time

17 JAN 2021 00:01

Patient Cloud Close Date & Time

21 JAN 2021 23:59

US3552412

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:53:07

<b>TIMEPOINT</b>	DAY 138
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	25 JAN 2021 06:27:18
Patient Cloud Open Date & Time	24 JAN 2021 00:01
Patient Cloud Close Date & Time	28 JAN 2021 23:59

US3552412

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:53:07

**TIMEPOINT**

DAY 145

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

31 JAN 2021 20:44:07

Patient Cloud Open Date & Time

31 JAN 2021 00:01

Patient Cloud Close Date & Time

04 FEB 2021 23:59

US3552412

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:53:07

**TIMEPOINT**

DAY 152

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

08 FEB 2021 06:18:12

Patient Cloud Open Date & Time

07 FEB 2021 00:01

Patient Cloud Close Date & Time

11 FEB 2021 23:59

US3552412

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:53:07

<b>TIMEPOINT</b>	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 checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	15 FEB 2021 20:57:29
Patient Cloud Open Date & Time	14 FEB 2021 00:01
Patient Cloud Close Date & Time	18 FEB 2021 23:59

US3552412

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:53:07

<b>TIMEPOINT</b>	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 checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	22 FEB 2021 07:22:01
Patient Cloud Open Date & Time	21 FEB 2021 00:01
Patient Cloud Close Date & Time	25 FEB 2021 23:59

US3552412

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:53:07

**TIMEPOINT**

DAY 173

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

01 MAR 2021 06:19:25

Patient Cloud Open Date & Time

28 FEB 2021 00:01

Patient Cloud Close Date & Time

04 MAR 2021 23:59

US3552412

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:53:07

**TIMEPOINT**

DAY 180

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

08 MAR 2021 09:18:52

Patient Cloud Open Date & Time

07 MAR 2021 00:01

Patient Cloud Close Date & Time

11 MAR 2021 23:59

US3552412

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:53:07

<b>TIMEPOINT</b>	DAY 187
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	15 MAR 2021 15:46:49
Patient Cloud Open Date & Time	14 MAR 2021 00:01
Patient Cloud Close Date & Time	18 MAR 2021 23:59

US3552412

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:53:07

TIMEPOINT	DAY 194
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	22 MAR 2021 06:17:55
Patient Cloud Open Date & Time	21 MAR 2021 00:01
Patient Cloud Close Date & Time	25 MAR 2021 23:59

US3552412

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:53:07

**TIMEPOINT**

DAY 201

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

30 MAR 2021 12:00:25

Patient Cloud Open Date & Time

28 MAR 2021 00:01

Patient Cloud Close Date & Time

01 APR 2021 23:59

US3552412

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:53:07

**TIMEPOINT**

DAY 208

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

05 APR 2021 08:16:58

Patient Cloud Open Date & Time

04 APR 2021 00:01

Patient Cloud Close Date & Time

08 APR 2021 23:59

US3552412

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:53:07

**TIMEPOINT**

DAY 215

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

12 APR 2021 08:10:28

Patient Cloud Open Date & Time

11 APR 2021 00:01

Patient Cloud Close Date & Time

15 APR 2021 23:59

US3552412

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:53:07

**TIMEPOINT**

DAY 222

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

22 APR 2021 14:11:10

Patient Cloud Open Date & Time

18 APR 2021 00:01

Patient Cloud Close Date & Time

22 APR 2021 23:59

US3552412

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:53:07

<b>TIMEPOINT</b>	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 checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	25 APR 2021 20:59:10
Patient Cloud Open Date & Time	25 APR 2021 00:01
Patient Cloud Close Date & Time	29 APR 2021 23:59

US3552412

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:53:07

<b>TIMEPOINT</b>	DAY 236
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	02 MAY 2021 20:42:52
Patient Cloud Open Date & Time	02 MAY 2021 00:01
Patient Cloud Close Date & Time	06 MAY 2021 23:59

US3552412

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:53:07

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="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"/>

**US3552412**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:53:07**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

09 MAY 2021 00:01

[Patient Cloud Close Date & Time](#)

13 MAY 2021 23:59

US3552412

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:53:07

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

**US3552412**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:53:07**

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

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[Patient Cloud Open Date & Time](#)

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16 MAY 2021 00:01

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[Patient Cloud Close Date & Time](#)

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20 MAY 2021 23:59

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US3552412

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:53:07

TIMEPOINT	DAY 257
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="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"/>

**US3552412**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:53:07**

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

[Patient Cloud Close Date & Time](#)

27 MAY 2021 23:59

US3552412

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:53:07

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

**US3552412**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:53:07**

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

[Patient Cloud Close Date & Time](#)

03 JUN 2021 23:59

US3552412

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:53:07

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

**US3552412**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:53:07**

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

[Patient Cloud Close Date & Time](#)

10 JUN 2021 23:59

US3552412

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:53:07

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="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"/>

**US3552412**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:53:07**

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

[Patient Cloud Close Date & Time](#)

17 JUN 2021 23:59

US3552412

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:53:07

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

**US3552412**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:53:07**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

20 JUN 2021 00:01

[Patient Cloud Close Date & Time](#)

24 JUN 2021 23:59

US3552412

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:53:07

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

**US3552412**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:53:07**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

27 JUN 2021 00:01

[Patient Cloud Close Date & Time](#)

01 JUL 2021 23:59

US3552412

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:53:07

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"/>

**US3552412**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:53:07**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

04 JUL 2021 00:01

[Patient Cloud Close Date & Time](#)

08 JUL 2021 23:59

US3552412

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:53:07

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

**US3552412**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:53:07**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

11 JUL 2021 00:01

[Patient Cloud Close Date & Time](#)

15 JUL 2021 23:59

US3552412

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:53:07

TIMEPOINT	DAY 313
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$ )	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>

US3552412

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:53:07**

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

[Patient Cloud Close Date & Time](#)

22 JUL 2021 23:59

US3552412

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:53:07

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

US3552412

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:53:07**

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

[Patient Cloud Close Date & Time](#)

29 JUL 2021 23:59

US3552412

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:53:07

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

**US3552412**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:53:07**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

01 AUG 2021 00:01

[Patient Cloud Close Date & Time](#)

05 AUG 2021 23:59

US3552412

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:53:07

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

**US3552412**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:53:07**

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

[Patient Cloud Close Date & Time](#)

12 AUG 2021 23:59

US3552412

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:53:07

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

**US3552412**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:53:07**

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

[Patient Cloud Close Date & Time](#)

19 AUG 2021 23:59

US3552412

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:53:07

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="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"/>

US3552412

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:53:07**

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

[Patient Cloud Close Date & Time](#)

26 AUG 2021 23:59

US3552412

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:53:07

TIMEPOINT	DAY 355
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="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"/>

US3552412

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:53:07**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

29 AUG 2021 00:01

[Patient Cloud Close Date & Time](#)

02 SEP 2021 23:59

US3552412

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:53:07

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="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"/>

**US3552412**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:53:07**

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

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09 SEP 2021 23:59

US3552412

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:53:07

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 <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"/>

**US3552412**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:53:07**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

12 SEP 2021 00:01

[Patient Cloud Close Date & Time](#)

16 SEP 2021 23:59

US3552412

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:53:07

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

**US3552412**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:53:07**

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

[Patient Cloud Close Date & Time](#)

23 SEP 2021 23:59

US3552412

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:53:07

TIMEPOINT	DAY 383
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$ )	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

**US3552412**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:53:07**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

26 SEP 2021 00:01

[Patient Cloud Close Date & Time](#)

30 SEP 2021 23:59

US3552412

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:53:07

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"/>

**US3552412**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:53:07**

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

[Patient Cloud Close Date & Time](#)

07 OCT 2021 23:59

US3552412

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:53:07

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 <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"/>

**US3552412**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:53:07**

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

[Patient Cloud Close Date & Time](#)

14 OCT 2021 23:59

US3552412

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:53:07

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="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"/>

**US3552412**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:53:07**

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

[Patient Cloud Close Date & Time](#)

21 OCT 2021 23:59

US3552412

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:53:07

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

**US3552412**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:53:07**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

24 OCT 2021 00:01

[Patient Cloud Close Date & Time](#)

28 OCT 2021 23:59

US3552412

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:53:07

TIMEPOINT	DAY 418
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="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"/>

**US3552412**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:53:07**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

31 OCT 2021 00:01

[Patient Cloud Close Date & Time](#)

04 NOV 2021 23:59

US3552412

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:53:07

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 <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"/>

US3552412

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:53:07**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

07 NOV 2021 00:01

[Patient Cloud Close Date & Time](#)

11 NOV 2021 23:59

US3552412

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:53:07

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="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"/>

**US3552412**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:53:07**

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

[Patient Cloud Close Date & Time](#)

18 NOV 2021 23:59

US3552412

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:53:07

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"/>

**US3552412**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:53:07**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

21 NOV 2021 00:01

[Patient Cloud Close Date & Time](#)

25 NOV 2021 23:59

US3552412

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:53:07

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

**US3552412**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:53:07**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

28 NOV 2021 00:01

[Patient Cloud Close Date & Time](#)

02 DEC 2021 23:59

US3552412

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:53:07

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="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"/>

**US3552412**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:53:07**

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

[Patient Cloud Close Date & Time](#)

09 DEC 2021 23:59

US3552412

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:53:07

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"/>

**US3552412**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:53:07**

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

[Patient Cloud Close Date & Time](#)

16 DEC 2021 23:59

US3552412

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:53:07

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

**US3552412**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:53:07**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

19 DEC 2021 00:01

[Patient Cloud Close Date & Time](#)

23 DEC 2021 23:59

US3552412

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:53:07

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

**US3552412**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:53:07**

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

[Patient Cloud Close Date & Time](#)

30 DEC 2021 23:59

US3552412

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:53:07

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

**US3552412**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:53:07**

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

[Patient Cloud Close Date & Time](#)

06 JAN 2022 23:59

US3552412

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:53:07

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

**US3552412**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:53:07**

Please contact your study clinic immediately. Click below to confirm that you have read this 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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09 JAN 2022 00:01

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13 JAN 2022 23:59

US3552412

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:53:07

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

**US3552412**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:53:07**

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

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20 JAN 2022 23:59

US3552412

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:53:07

TIMEPOINT	DAY 502
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$ )	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

**US3552412**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:53:07**

Please contact your study clinic immediately. Click below to confirm that you have read this 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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23 JAN 2022 00:01

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27 JAN 2022 23:59

US3552412

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:53:07

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="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"/>

**US3552412**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:53:07**

Please contact your study clinic immediately. Click below to confirm that you have read this 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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30 JAN 2022 00:01

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03 FEB 2022 23:59

US3552412

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:53:07

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

US3552412

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:53:07**

Please contact your study clinic immediately. Click below to confirm that you have read this 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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10 FEB 2022 23:59

US3552412

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:53:07

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 <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"/>

**US3552412**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:53:07**

Please contact your study clinic immediately. Click below to confirm that you have read this 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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13 FEB 2022 00:01

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17 FEB 2022 23:59

US3552412

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:53:07

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

**US3552412**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:53:07**

Please contact your study clinic immediately. Click below to confirm that you have read this 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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20 FEB 2022 00:01

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24 FEB 2022 23:59

US3552412

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:53:07

**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 ☐

**US3552412**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:53:07**

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

[Patient Cloud Close Date & Time](#)

03 MAR 2022 23:59

US3552412

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:53:07

TIMEPOINT	DAY 544
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$ )	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

**US3552412**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:53:07**

Please contact your study clinic immediately. Click below to confirm that you have read this 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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10 MAR 2022 23:59

US3552412

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:53:07

TIMEPOINT	DAY 551
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$ )	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

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**Generated On: 11 Aug 2021 22:53:07**

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

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

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17 MAR 2022 23:59

US3552412

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:53:07

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 <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"/>

**US3552412**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:53:07**

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

[Patient Cloud Close Date & Time](#)

24 MAR 2022 23:59

US3552412

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:53:07

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 <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"/>

**US3552412**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:53:07**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

27 MAR 2022 00:01

[Patient Cloud Close Date & Time](#)

31 MAR 2022 23:59

US3552412

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:53:07

**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 ☐

**US3552412**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:53:07**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

03 APR 2022 00:01

[Patient Cloud Close Date & Time](#)

07 APR 2022 23:59

US3552412

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:53:07

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 <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"/>

**US3552412**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:53:07**

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

[Patient Cloud Close Date & Time](#)

14 APR 2022 23:59

US3552412

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:53:07

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

**US3552412**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:53:07**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

17 APR 2022 00:01

[Patient Cloud Close Date & Time](#)

21 APR 2022 23:59

US3552412

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:53:07

TIMEPOINT	DAY 593
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="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"/>

**US3552412**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:53:07**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

24 APR 2022 00:01

[Patient Cloud Close Date & Time](#)

28 APR 2022 23:59

US3552412

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:53:07

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

**US3552412**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:53:07**

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

[Patient Cloud Close Date & Time](#)

05 MAY 2022 23:59

US3552412

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:53:07

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

**US3552412**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:53:07**

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

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[Patient Cloud Open Date & Time](#)

08 MAY 2022 00:01

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[Patient Cloud Close Date & Time](#)

12 MAY 2022 23:59

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US3552412

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:53:07

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

**US3552412**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:53:07**

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

[Patient Cloud Close Date & Time](#)

19 MAY 2022 23:59

US3552412

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:53:07

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

**US3552412**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:53:07**

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

[Patient Cloud Close Date & Time](#)

26 MAY 2022 23:59

US3552412

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:53:07

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

**US3552412**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:53:07**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

29 MAY 2022 00:01

[Patient Cloud Close Date & Time](#)

02 JUN 2022 23:59

US3552412

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:53:07

TIMEPOINT	DAY 635
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$ )	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

**US3552412**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:53:07**

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

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

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09 JUN 2022 23:59

US3552412

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:53:07

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

**US3552412**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:53:07**

Please contact your study clinic immediately. Click below to confirm that you have read this 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 JUN 2022 23:59

US3552412

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:53:07

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

US3552412

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:53:07**

Please contact your study clinic immediately. Click below to confirm that you have read this 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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23 JUN 2022 23:59

US3552412

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:53:07

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

US3552412

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:53:07**

Please contact your study clinic immediately. Click below to confirm that you have read this 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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30 JUN 2022 23:59

US3552412

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:53:07

**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 ☐

**US3552412**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:53:07**

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

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

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07 JUL 2022 23:59

US3552412

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:53:07

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

**US3552412**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:53:07**

Please contact your study clinic immediately. Click below to confirm that you have read this 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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14 JUL 2022 23:59

US3552412

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:53:07

TIMEPOINT	DAY 677
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$ )	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

**US3552412**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:53:07**

Please contact your study clinic immediately. Click below to confirm that you have read this 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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21 JUL 2022 23:59

US3552412

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:53:07

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

US3552412

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:53:07**

Please contact your study clinic immediately. Click below to confirm that you have read this 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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28 JUL 2022 23:59

US3552412

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:53:07

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

**US3552412**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:53:07**

Please contact your study clinic immediately. Click below to confirm that you have read this 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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US3552412

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:53:07

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

**US3552412**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:53:07**

Please contact your study clinic immediately. Click below to confirm that you have read this 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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11 AUG 2022 23:59

US3552412

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:53:07

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="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"/>

**US3552412**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:53:07**

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

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

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18 AUG 2022 23:59

US3552412

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:53:07

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

**US3552412**

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

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

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

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25 AUG 2022 23:59

US3552412

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:53:07

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

**US3552412**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:53:07**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

28 AUG 2022 00:01

[Patient Cloud Close Date & Time](#)

01 SEP 2022 23:59

US3552412

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:53:07

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"/>

**US3552412**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:53:07**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

04 SEP 2022 00:01

[Patient Cloud Close Date & Time](#)

08 SEP 2022 23:59

US3552412

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:53:07

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"/>

**US3552412**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:53:07**

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

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15 SEP 2022 23:59

US3552412

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:53:07

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

**US3552412**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:53:07**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

18 SEP 2022 00:01

[Patient Cloud Close Date & Time](#)

22 SEP 2022 23:59

US3552412

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:53:07

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"/>

US3552412

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:53:07**

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

[Patient Cloud Close Date & Time](#)

29 SEP 2022 23:59

US3552412

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:53:07

TIMEPOINT	DAY 754
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="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"/>

**US3552412**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:53:07**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

02 OCT 2022 00:01

[Patient Cloud Close Date & Time](#)

06 OCT 2022 23:59

US3552412

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:53:07

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

**US3552412**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:53:07**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

09 OCT 2022 00:01

[Patient Cloud Close Date & Time](#)

13 OCT 2022 23:59

US3552412

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:53:07

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

**US3552412**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:53:07**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

16 OCT 2022 00:01

[Patient Cloud Close Date & Time](#)

20 OCT 2022 23:59

US3552412

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:53:07

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 <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"/>

**US3552412**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:53:07**

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

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[Patient Cloud Open Date & Time](#)

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23 OCT 2022 00:01

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[Patient Cloud Close Date & Time](#)

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27 OCT 2022 23:59

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US3552412

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:53:07

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="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"/>

**US3552412**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:53:07**

Please contact your study clinic immediately. Click below to confirm that you have read this 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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30 OCT 2022 00:01

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03 NOV 2022 23:59

US3552412

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:53:07

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

**US3552412**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:53:07**

Please contact your study clinic immediately. Click below to confirm that you have read this 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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06 NOV 2022 00:01

[Patient Cloud Close Date & Time](#)

10 NOV 2022 23:59

US3552412

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:53:07

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

**US3552412**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:53:07**

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

[Patient Cloud Close Date & Time](#)

17 NOV 2022 23:59

US3552412

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection\_ Dermal Filler eDiary

Generated On: 11 Aug 2021 22:53:07

Have you ever received facial cosmetic injections, such as Juvederm, Voluma, Radiesse, Restylane, Botox or other?	Have you ever received a dermal filler, such as Juvederm, Voluma, Radiesse, Restylane, or Botox or other for a medical indication such as a migraine headache?	Date & Time of Submission
No		01 MAR 2021 06:19:16

US3552412

Folder: Safety Call Day 85 (1)

Form: Safety Call

Data signed: (b) (4) 21 Feb 2021 19:11:19

Generated On: 11 Aug 2021 22:53:07

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

US3552412

Folder: Safety Call Day 85 (1)

Form: Continuing

Data signed: (b) (4) 21 Feb 2021 19:11:19

Generated On: 11 Aug 2021 22:53:07

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3552412

Folder: Safety Call Day 119 (1)

Form: Safety Call

Data signed: (b) (4) 21 Feb 2021 19:11:19

Generated On: 11 Aug 2021 22:53:07

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

07 JAN 2021

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

*If Contact Not Made, please provide Comments*

US3552412

Folder: Safety Call Day 119 (1)

Form: Continuing

Data signed: (b) (4) 21 Feb 2021 19:11:19

Generated On: 11 Aug 2021 22:53:07

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3552412

Folder: Safety Call Day 149 (1)

Form: Safety Call

Data signed: (b) (4) 21 Feb 2021 19:11:19

Generated On: 11 Aug 2021 22:53:07

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

05 FEB 2021

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

*If Contact Not Made, please provide Comments*

US3552412

Folder: Safety Call Day 149 (1)

Form: Continuing

Data signed: (b) (4) 21 Feb 2021 19:11:19

Generated On: 11 Aug 2021 22:53:07

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3552412

Folder: Safety Call Day 179 (1)

Form: Safety Call

Data signed: (b) (4) 09 Mar 2021 17:03:11

Generated On: 11 Aug 2021 22:53:07

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

8 MAR 2021

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

*If Contact Not Made, please provide Comments*

US3552412

Folder: Safety Call Day 179 (1)

Form: Continuing

Data signed: (b) (4) 09 Mar 2021 17:03:11

Generated On: 11 Aug 2021 22:53:07

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3552412

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Data signed: (b) (4) 06 Apr 2021 15:14:13

Generated On: 11 Aug 2021 22:53:07

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

Visit date (dd MMM yyyy)	30 MAR 2021
--------------------------	-------------

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

Folder OID	VISIT4
------------	--------

US3552412

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Data signed: (b) (4) 06 Apr 2021 15:14:13

Generated On: 11 Aug 2021 22:53:07

Were vital signs assessed? Yes ☐  
No ☒

Date of assessment (dd MMM yyyy) \_\_\_\_\_

Time of assessment (00:00-23:59) \_\_\_\_\_

Vital Signs Date and Time (derived) \_\_\_\_\_

Temperature (xxx.x) \_\_\_\_\_

Route of measurement Oral ☐  
Axillary ☐  
Other ☐

If Other, specify \_\_\_\_\_

Pulse (xxx) \_\_\_\_\_

Pulse units \_\_\_\_\_

Respiratory Rate (xxx) \_\_\_\_\_

Respiratory Rate units \_\_\_\_\_

Systolic Blood Pressure (xxx) \_\_\_\_\_

Systolic Blood Pressure units \_\_\_\_\_

Diastolic Blood Pressure (xxx) \_\_\_\_\_

Diastolic Blood Pressure units \_\_\_\_\_

Height (derived) \_\_\_\_\_

Weight (derived) \_\_\_\_\_

US3552412

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Data signed: (b) (4) 06 Apr 2021 15:14:13

Generated On: 11 Aug 2021 22:53:07

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.*

US3552412

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 06 Apr 2021 15:14:13

Generated On: 11 Aug 2021 22:53:07

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (dd MMM yyyy)	30 MAR 2021
Collection time (00:00-23:59)	15:45 (24 HR)
Collection date and time (derived)	30 MAR 2021 15:45

US3552412

Folder: Visit 4 Day 209 (1)

Form: Continuing

Data signed: (b) (4) 06 Apr 2021 15:14:13

Generated On: 11 Aug 2021 22:53:07

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3552412

Folder: Safety Call Day 239 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:53:07

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*

**US3552412**

**Folder: Safety Call Day 239 (1)**

**Form: Continuing**

**Generated On: 11 Aug 2021 22:53:07**

Is the participant continuing to the next visit?

Yes ☐

No ☐

Continuing Flag

US3552412

Folder: Covid-19 Assessment 15 Jan 2021

Form: COVID-19 Contact

Data signed: (b) (4) 21 Feb 2021 19:11:18

Generated On: 11 Aug 2021 22:53:07

Date of Contact	15 JAN 2021
Time of Contact	07:10
Date and Time of Contact (derived)	15 JAN 2021 07:10
Type of Contact	<div>Clinic Visit - Scheduled<input type="checkbox"/></div> <div>Clinical Visit - Unscheduled<input type="checkbox"/></div> <div>Safety Call<input checked="" type="checkbox"/></div> <div>Convalescent Tele-visit<input type="checkbox"/></div>
Has the subject reported symptoms of SARS-COV-2?	<div>Yes<input checked="" type="checkbox"/></div> <div>No<input type="checkbox"/></div>

US3552412

Folder: Covid-19 Assessment 15 Jan 2021

Form: Symptom Log (1)

Data signed: (b) (4) 21 Feb 2021 19:11:18

Generated On: 11 Aug 2021 22:53:07

Symptom Day

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

US3552412

Folder: Covid-19 Assessment 15 Jan 2021

Form: Symptom Log (1)

Data signed: (b) (4) 21 Feb 2021 19:11:18

Generated On: 11 Aug 2021 22:53:07

	Day 33	<input type="checkbox"/>
	Day 34	<input type="checkbox"/>
	Day 35	<input type="checkbox"/>
	Day 36	<input type="checkbox"/>
	Day 37	<input type="checkbox"/>
	Day 38	<input type="checkbox"/>
	Day 39	<input type="checkbox"/>
	Day 40	<input type="checkbox"/>

Date	12 JAN 2021
------	-------------

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

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

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

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

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

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

Shortness of Breath	None <input checked="" type="radio"/>
	Mild <input type="radio"/>
	Moderate <input type="radio"/>
	Severe <input type="radio"/>
	Not Done <input type="radio"/>

Difficulty Breathing	None <input checked="" type="radio"/>
	Mild <input type="radio"/>
	Moderate <input type="radio"/>
	Severe <input type="radio"/>

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Folder: Covid-19 Assessment 15 Jan 2021

Form: Symptom Log (1)

Data signed: (b) (4) 21 Feb 2021 19:11:18

Generated On: 11 Aug 2021 22:53:07

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

US3552412

Folder: Covid-19 Assessment 15 Jan 2021

Form: Symptom Log (1)

Data signed: (b) (4) 21 Feb 2021 19:11:18

Generated On: 11 Aug 2021 22:53:07

Nasal Congestion

None ☒  
Mild ☐  
Moderate ☐  
Severe ☐  
Not Done ☐

Runny Nose (Rhinorrhea)

None ☒  
Mild ☐  
Moderate ☐  
Severe ☐  
Not Done ☐

Nausea

None ☒  
Mild ☐  
Moderate ☐  
Severe ☐  
Not Done ☐

Vomiting

None ☒  
Mild ☐  
Moderate ☐  
Severe ☐  
Not Done ☐

Diarrhea

None ☒  
Mild ☐  
Moderate ☐  
Severe ☐  
Not Done ☐

Sore Throat

None ☐  
Mild ☒  
Moderate ☐  
Severe ☐  
Not Done ☐

US3552412

Folder: Covid-19 Assessment 15 Jan 2021

Form: Symptom Log (2)

Data signed: (b) (4) 21 Feb 2021 19:11:18

Generated On: 11 Aug 2021 22:53:07

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"/>

US3552412

Folder: Covid-19 Assessment 15 Jan 2021

Form: Symptom Log (2)

Data signed: (b) (4) 21 Feb 2021 19:11:18

Generated On: 11 Aug 2021 22:53:07

	Day 33	<input type="checkbox"/>
	Day 34	<input type="checkbox"/>
	Day 35	<input type="checkbox"/>
	Day 36	<input type="checkbox"/>
	Day 37	<input type="checkbox"/>
	Day 38	<input type="checkbox"/>
	Day 39	<input type="checkbox"/>
	Day 40	<input type="checkbox"/>

Date	13 JAN 2021
------	-------------

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

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

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

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

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

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

Shortness of Breath	None <input checked="" type="radio"/>
	Mild <input type="radio"/>
	Moderate <input type="radio"/>
	Severe <input type="radio"/>
	Not Done <input type="radio"/>

Difficulty Breathing	None <input checked="" type="radio"/>
	Mild <input type="radio"/>
	Moderate <input type="radio"/>
	Severe <input type="radio"/>

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Folder: Covid-19 Assessment 15 Jan 2021

Form: Symptom Log (2)

Data signed: (b) (4) 21 Feb 2021 19:11:18

Generated On: 11 Aug 2021 22:53:07

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

US3552412

Folder: Covid-19 Assessment 15 Jan 2021

Form: Symptom Log (2)

Data signed: (b) (4) 21 Feb 2021 19:11:18

Generated On: 11 Aug 2021 22:53:07

Nasal Congestion

None ☒  
Mild ☐  
Moderate ☐  
Severe ☐  
Not Done ☐

Runny Nose (Rhinorrhea)

None ☒  
Mild ☐  
Moderate ☐  
Severe ☐  
Not Done ☐

Nausea

None ☒  
Mild ☐  
Moderate ☐  
Severe ☐  
Not Done ☐

Vomiting

None ☒  
Mild ☐  
Moderate ☐  
Severe ☐  
Not Done ☐

Diarrhea

None ☒  
Mild ☐  
Moderate ☐  
Severe ☐  
Not Done ☐

Sore Throat

None ☐  
Mild ☒  
Moderate ☐  
Severe ☐  
Not Done ☐

US3552412

Folder: Covid-19 Assessment 15 Jan 2021

Form: Symptom Log (3)

Data signed: (b) (4) 21 Feb 2021 19:11:18

Generated On: 11 Aug 2021 22:53:07

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"/>

US3552412

Folder: Covid-19 Assessment 15 Jan 2021

Form: Symptom Log (3)

Data signed: (b) (4) 21 Feb 2021 19:11:18

Generated On: 11 Aug 2021 22:53:07

	Day 33	<input type="checkbox"/>
	Day 34	<input type="checkbox"/>
	Day 35	<input type="checkbox"/>
	Day 36	<input type="checkbox"/>
	Day 37	<input type="checkbox"/>
	Day 38	<input type="checkbox"/>
	Day 39	<input type="checkbox"/>
	Day 40	<input type="checkbox"/>

Date	14 JAN 2021
------	-------------

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

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

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

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

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

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

Shortness of Breath	None <input checked="" type="radio"/>
	Mild <input type="radio"/>
	Moderate <input type="radio"/>
	Severe <input type="radio"/>
	Not Done <input type="radio"/>

Difficulty Breathing	None <input checked="" type="radio"/>
	Mild <input type="radio"/>
	Moderate <input type="radio"/>
	Severe <input type="radio"/>

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Folder: Covid-19 Assessment 15 Jan 2021

Form: Symptom Log (3)

Data signed: (b) (4) 21 Feb 2021 19:11:18

Generated On: 11 Aug 2021 22:53:07

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

US3552412

Folder: Covid-19 Assessment 15 Jan 2021

Form: Symptom Log (3)

Data signed: (b) (4) 21 Feb 2021 19:11:18

Generated On: 11 Aug 2021 22:53:07

Nasal Congestion

None ☐  
Mild ☒  
Moderate ☐  
Severe ☐  
Not Done ☐

Runny Nose (Rhinorrhea)

None ☒  
Mild ☐  
Moderate ☐  
Severe ☐  
Not Done ☐

Nausea

None ☒  
Mild ☐  
Moderate ☐  
Severe ☐  
Not Done ☐

Vomiting

None ☒  
Mild ☐  
Moderate ☐  
Severe ☐  
Not Done ☐

Diarrhea

None ☒  
Mild ☐  
Moderate ☐  
Severe ☐  
Not Done ☐

Sore Throat

None ☐  
Mild ☒  
Moderate ☐  
Severe ☐  
Not Done ☐

US3552412

Folder: Covid-19 Assessment 15 Jan 2021

Form: Symptom Log (4)

Data signed: (b) (4) 21 Feb 2021 19:11:18

Generated On: 11 Aug 2021 22:53:07

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"/>

US3552412

Folder: Covid-19 Assessment 15 Jan 2021

Form: Symptom Log (4)

Data signed: (b) (4) 21 Feb 2021 19:11:18

Generated On: 11 Aug 2021 22:53:07

	Day 33	<input type="checkbox"/>
	Day 34	<input type="checkbox"/>
	Day 35	<input type="checkbox"/>
	Day 36	<input type="checkbox"/>
	Day 37	<input type="checkbox"/>
	Day 38	<input type="checkbox"/>
	Day 39	<input type="checkbox"/>
	Day 40	<input type="checkbox"/>

Date	15 JAN 2021
------	-------------

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

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

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

Temperature	96.5 F
-------------	--------

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

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

Shortness of Breath	None <input checked="" type="radio"/>
	Mild <input type="radio"/>
	Moderate <input type="radio"/>
	Severe <input type="radio"/>
	Not Done <input type="radio"/>

Difficulty Breathing	None <input checked="" type="radio"/>
	Mild <input type="radio"/>
	Moderate <input type="radio"/>
	Severe <input type="radio"/>

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Folder: Covid-19 Assessment 15 Jan 2021

Form: Symptom Log (4)

Data signed: (b) (4) 21 Feb 2021 19:11:18

Generated On: 11 Aug 2021 22:53:07

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

US3552412

Folder: Covid-19 Assessment 15 Jan 2021

Form: Symptom Log (4)

Data signed: (b) (4) 21 Feb 2021 19:11:18

Generated On: 11 Aug 2021 22:53:07

Nasal Congestion

None ☐  
Mild ☒  
Moderate ☐  
Severe ☐  
Not Done ☐

Runny Nose (Rhinorrhea)

None ☐  
Mild ☒  
Moderate ☐  
Severe ☐  
Not Done ☐

Nausea

None ☒  
Mild ☐  
Moderate ☐  
Severe ☐  
Not Done ☐

Vomiting

None ☒  
Mild ☐  
Moderate ☐  
Severe ☐  
Not Done ☐

Diarrhea

None ☒  
Mild ☐  
Moderate ☐  
Severe ☐  
Not Done ☐

Sore Throat

None ☐  
Mild ☒  
Moderate ☐  
Severe ☐  
Not Done ☐

US3552412

Folder: Covid-19 Assessment 15 Jan 2021

Form: Symptom Log (5)

Data signed: (b) (4) 21 Feb 2021 19:11:18

Generated On: 11 Aug 2021 22:53:07

Symptom Day

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

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Folder: Covid-19 Assessment 15 Jan 2021

Form: Symptom Log (5)

Data signed: (b) (4) 21 Feb 2021 19:11:18

Generated On: 11 Aug 2021 22:53:07

	Day 33	<input type="checkbox"/>
	Day 34	<input type="checkbox"/>
	Day 35	<input type="checkbox"/>
	Day 36	<input type="checkbox"/>
	Day 37	<input type="checkbox"/>
	Day 38	<input type="checkbox"/>
	Day 39	<input type="checkbox"/>
	Day 40	<input type="checkbox"/>

Date	16 JAN 2021
------	-------------

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

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

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

Temperature	96.4 F
-------------	--------

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

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

Shortness of Breath	None <input checked="" type="radio"/>
	Mild <input type="radio"/>
	Moderate <input type="radio"/>
	Severe <input type="radio"/>
	Not Done <input type="radio"/>

Difficulty Breathing	None <input checked="" type="radio"/>
	Mild <input type="radio"/>
	Moderate <input type="radio"/>
	Severe <input type="radio"/>

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Folder: Covid-19 Assessment 15 Jan 2021

Form: Symptom Log (5)

Data signed: (b) (4) 21 Feb 2021 19:11:18

Generated On: 11 Aug 2021 22:53:07

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

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Folder: Covid-19 Assessment 15 Jan 2021

Form: Symptom Log (5)

Data signed: (b) (4) 21 Feb 2021 19:11:18

Generated On: 11 Aug 2021 22:53:07

Nasal Congestion

None ☒  
Mild ☐  
Moderate ☐  
Severe ☐  
Not Done ☐

Runny Nose (Rhinorrhea)

None ☐  
Mild ☒  
Moderate ☐  
Severe ☐  
Not Done ☐

Nausea

None ☒  
Mild ☐  
Moderate ☐  
Severe ☐  
Not Done ☐

Vomiting

None ☒  
Mild ☐  
Moderate ☐  
Severe ☐  
Not Done ☐

Diarrhea

None ☒  
Mild ☐  
Moderate ☐  
Severe ☐  
Not Done ☐

Sore Throat

None ☒  
Mild ☐  
Moderate ☐  
Severe ☐  
Not Done ☐

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Folder: Covid-19 Assessment 15 Jan 2021

Form: COVID Diagnostic Test

Data signed: (b) (4) 21 Feb 2021 19:11:18

Generated On: 11 Aug 2021 22:53:07

Date of Visit	15 JAN 2021
Was the Subject Tested For SARS-CoV-2 by RT-PCR?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Did Subject Test Positive For SARS-CoV-2 by RT-PCR?	Yes <input type="radio"/> No <input checked="" type="radio"/>
Date of Test	15 JAN 2021
Type of Test Performed	Nasopharyngeal Swab <input checked="" type="radio"/> Nasal Swab <input type="radio"/> Saliva Test <input type="radio"/> Other <input type="radio"/>
Other, specify	
Was this diagnostic test performed at a lab other than the Study Central Lab?	Yes <input type="radio"/> No <input checked="" type="radio"/>
If yes, provide lab information below	
Lab/ Institution Test Performed	
CLIA Certified?	Yes <input type="radio"/> No <input type="radio"/>
COVID-19 Positive (CSA Programming Field Only)	0

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Folder: Covid-19 Assessment 15 Jan 2021

Form: COVID-19 Contact

Data signed: (b) (4) 21 Feb 2021 19:11:18

Generated On: 11 Aug 2021 22:53:07

Date of Contact	15 JAN 2021
Time of Contact	07:10
Date and Time of Contact (derived)	15 JAN 2021 07:10
Type of Contact	<div>Clinic Visit - Scheduled<input type="checkbox"/></div> <div>Clinical Visit - Unscheduled<input type="checkbox"/></div> <div>Safety Call<input checked="" type="checkbox"/></div> <div>Convalescent Tele-visit<input type="checkbox"/></div>
Has the subject reported symptoms of SARS-COV-2?	<div>Yes<input checked="" type="checkbox"/></div> <div>No<input type="checkbox"/></div>

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Folder: Covid-19 Assessment 15 Jan 2021

Form: COVID Diagnostic Test

Data signed: (b) (4) 21 Feb 2021 19:11:18

Generated On: 11 Aug 2021 22:53:07

Date of Visit 15 JAN 2021

Was the Subject Tested For SARS-CoV-2 by RT-PCR? Yes ☒ No ☐

Did Subject Test Positive For SARS-CoV-2 by RT-PCR? Yes ☐ No ☒

Date of Test 15 JAN 2021

Type of Test Performed Nasopharyngeal Swab ☒ Nasal Swab ☐ Saliva Test ☐ Other ☐

Other, specify \_\_\_\_\_

Was this diagnostic test performed at a lab other than the Study Central Lab? Yes ☒ No ☐

If yes, provide lab information below

Lab/ Institution Test Performed SAINT LOUIS UNIVERSITY'S VACCINE DEVELOPMENT CENTER

CLIA Certified? Yes ☒ No ☐

COVID-19 Positive (CSA Programming Field Only) 0

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Folder: Covid-19 Assessment 30 Nov 2020

Form: COVID-19 Contact

Data signed: (b) (4) 21 Feb 2021 19:11:18

Generated On: 11 Aug 2021 22:53:07

Date of Contact	30 NOV 2020
Time of Contact	07:56
Date and Time of Contact (derived)	30 NOV 2020 07:56
Type of Contact	<div>Clinic Visit - Scheduled<input type="checkbox"/></div> <div>Clinical Visit - Unscheduled<input type="checkbox"/></div> <div>Safety Call<input checked="" type="checkbox"/></div> <div>Convalescent Tele-visit<input type="checkbox"/></div>
Has the subject reported symptoms of SARS-COV-2?	<div>Yes<input checked="" type="checkbox"/></div> <div>No<input type="checkbox"/></div>

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Folder: Covid-19 Assessment 30 Nov 2020

Form: Symptom Log (1)

Data signed: (b) (4) 21 Feb 2021 19:11:18

Generated On: 11 Aug 2021 22:53:07

Symptom Day

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

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Folder: Covid-19 Assessment 30 Nov 2020

Form: Symptom Log (1)

Data signed: (b) (4) 21 Feb 2021 19:11:18

Generated On: 11 Aug 2021 22:53:07

	Day 33	<input type="checkbox"/>
	Day 34	<input type="checkbox"/>
	Day 35	<input type="checkbox"/>
	Day 36	<input type="checkbox"/>
	Day 37	<input type="checkbox"/>
	Day 38	<input type="checkbox"/>
	Day 39	<input type="checkbox"/>
	Day 40	<input type="checkbox"/>

Date	27 NOV 2020
------	-------------

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

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

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

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

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

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

Shortness of Breath	None <input checked="" type="radio"/>
	Mild <input type="radio"/>
	Moderate <input type="radio"/>
	Severe <input type="radio"/>
	Not Done <input type="radio"/>

Difficulty Breathing	None <input checked="" type="radio"/>
	Mild <input type="radio"/>
	Moderate <input type="radio"/>
	Severe <input type="radio"/>

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Folder: Covid-19 Assessment 30 Nov 2020

Form: Symptom Log (1)

Data signed: (b) (4) 21 Feb 2021 19:11:18

Generated On: 11 Aug 2021 22:53:07

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

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Folder: Covid-19 Assessment 30 Nov 2020

Form: Symptom Log (1)

Data signed: (b) (4) 21 Feb 2021 19:11:18

Generated On: 11 Aug 2021 22:53:07

Nasal Congestion

None ☐  
Mild ☐  
Moderate ☒  
Severe ☐  
Not Done ☐

Runny Nose (Rhinorrhea)

None ☐  
Mild ☒  
Moderate ☐  
Severe ☐  
Not Done ☐

Nausea

None ☒  
Mild ☐  
Moderate ☐  
Severe ☐  
Not Done ☐

Vomiting

None ☒  
Mild ☐  
Moderate ☐  
Severe ☐  
Not Done ☐

Diarrhea

None ☒  
Mild ☐  
Moderate ☐  
Severe ☐  
Not Done ☐

Sore Throat

None ☐  
Mild ☒  
Moderate ☐  
Severe ☐  
Not Done ☐

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Folder: Covid-19 Assessment 30 Nov 2020

Form: Symptom Log (2)

Data signed: (b) (4) 21 Feb 2021 19:11:18

Generated On: 11 Aug 2021 22:53:07

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"/>

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Folder: Covid-19 Assessment 30 Nov 2020

Form: Symptom Log (2)

Data signed: (b) (4) 21 Feb 2021 19:11:18

Generated On: 11 Aug 2021 22:53:07

	Day 33	<input type="checkbox"/>
	Day 34	<input type="checkbox"/>
	Day 35	<input type="checkbox"/>
	Day 36	<input type="checkbox"/>
	Day 37	<input type="checkbox"/>
	Day 38	<input type="checkbox"/>
	Day 39	<input type="checkbox"/>
	Day 40	<input type="checkbox"/>

Date	28 NOV 2020
------	-------------

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

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

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

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

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

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

Shortness of Breath	None <input checked="" type="radio"/>
	Mild <input type="radio"/>
	Moderate <input type="radio"/>
	Severe <input type="radio"/>
	Not Done <input type="radio"/>

Difficulty Breathing	None <input checked="" type="radio"/>
	Mild <input type="radio"/>
	Moderate <input type="radio"/>
	Severe <input type="radio"/>

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Folder: Covid-19 Assessment 30 Nov 2020

Form: Symptom Log (2)

Data signed: (b) (4) 21 Feb 2021 19:11:18

Generated On: 11 Aug 2021 22:53:07

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

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Folder: Covid-19 Assessment 30 Nov 2020

Form: Symptom Log (2)

Data signed: (b) (4) 21 Feb 2021 19:11:18

Generated On: 11 Aug 2021 22:53:07

Nasal Congestion

None ☐  
Mild ☐  
Moderate ☒  
Severe ☐  
Not Done ☐

Runny Nose (Rhinorrhea)

None ☐  
Mild ☒  
Moderate ☐  
Severe ☐  
Not Done ☐

Nausea

None ☒  
Mild ☐  
Moderate ☐  
Severe ☐  
Not Done ☐

Vomiting

None ☒  
Mild ☐  
Moderate ☐  
Severe ☐  
Not Done ☐

Diarrhea

None ☒  
Mild ☐  
Moderate ☐  
Severe ☐  
Not Done ☐

Sore Throat

None ☐  
Mild ☒  
Moderate ☐  
Severe ☐  
Not Done ☐

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Folder: Covid-19 Assessment 30 Nov 2020

Form: Symptom Log (3)

Data signed: (b) (4) 21 Feb 2021 19:11:18

Generated On: 11 Aug 2021 22:53:07

Symptom Day

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

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Folder: Covid-19 Assessment 30 Nov 2020

Form: Symptom Log (3)

Data signed: (b) (4) 21 Feb 2021 19:11:18

Generated On: 11 Aug 2021 22:53:07

	Day 33	<input type="checkbox"/>
	Day 34	<input type="checkbox"/>
	Day 35	<input type="checkbox"/>
	Day 36	<input type="checkbox"/>
	Day 37	<input type="checkbox"/>
	Day 38	<input type="checkbox"/>
	Day 39	<input type="checkbox"/>
	Day 40	<input type="checkbox"/>

Date	29 NOV 2020
------	-------------

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

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

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

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

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

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

Shortness of Breath	None <input checked="" type="radio"/>
	Mild <input type="radio"/>
	Moderate <input type="radio"/>
	Severe <input type="radio"/>
	Not Done <input type="radio"/>

Difficulty Breathing	None <input checked="" type="radio"/>
	Mild <input type="radio"/>
	Moderate <input type="radio"/>
	Severe <input type="radio"/>

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EAB) (1725)

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Folder: Covid-19 Assessment 30 Nov 2020

Form: Symptom Log (3)

Data signed: (b) (4) 21 Feb 2021 19:11:18

Generated On: 11 Aug 2021 22:53:07

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

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Folder: Covid-19 Assessment 30 Nov 2020

Form: Symptom Log (3)

Data signed: (b) (4) 21 Feb 2021 19:11:18

Generated On: 11 Aug 2021 22:53:07

Nasal Congestion

None ☐  
Mild ☐  
Moderate ☒  
Severe ☐  
Not Done ☐

Runny Nose (Rhinorrhea)

None ☐  
Mild ☒  
Moderate ☐  
Severe ☐  
Not Done ☐

Nausea

None ☒  
Mild ☐  
Moderate ☐  
Severe ☐  
Not Done ☐

Vomiting

None ☒  
Mild ☐  
Moderate ☐  
Severe ☐  
Not Done ☐

Diarrhea

None ☒  
Mild ☐  
Moderate ☐  
Severe ☐  
Not Done ☐

Sore Throat

None ☐  
Mild ☒  
Moderate ☐  
Severe ☐  
Not Done ☐

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Folder: Covid-19 Assessment 30 Nov 2020

Form: Symptom Log (4)

Data signed: (b) (4) 21 Feb 2021 19:11:18

Generated On: 11 Aug 2021 22:53:07

Symptom Day

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

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Folder: Covid-19 Assessment 30 Nov 2020

Form: Symptom Log (4)

Data signed: (b) (4) 21 Feb 2021 19:11:18

Generated On: 11 Aug 2021 22:53:07

	Day 33	<input type="checkbox"/>
	Day 34	<input type="checkbox"/>
	Day 35	<input type="checkbox"/>
	Day 36	<input type="checkbox"/>
	Day 37	<input type="checkbox"/>
	Day 38	<input type="checkbox"/>
	Day 39	<input type="checkbox"/>
	Day 40	<input type="checkbox"/>

Date	30 NOV 2020
------	-------------

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

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

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

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

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

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

Shortness of Breath	None <input checked="" type="radio"/>
	Mild <input type="radio"/>
	Moderate <input type="radio"/>
	Severe <input type="radio"/>
	Not Done <input type="radio"/>

Difficulty Breathing	None <input checked="" type="radio"/>
	Mild <input type="radio"/>
	Moderate <input type="radio"/>
	Severe <input type="radio"/>

PRODUCTION RELEASE (v12.003  
EAB) (1725)

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Folder: Covid-19 Assessment 30 Nov 2020

Form: Symptom Log (4)

Data signed: (b) (4) 21 Feb 2021 19:11:18

Generated On: 11 Aug 2021 22:53:07

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

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Folder: Covid-19 Assessment 30 Nov 2020

Form: Symptom Log (4)

Data signed: (b) (4) 21 Feb 2021 19:11:18

Generated On: 11 Aug 2021 22:53:07

Nasal Congestion

None ☐  
Mild ☒  
Moderate ☐  
Severe ☐  
Not Done ☐

Runny Nose (Rhinorrhea)

None ☐  
Mild ☒  
Moderate ☐  
Severe ☐  
Not Done ☐

Nausea

None ☒  
Mild ☐  
Moderate ☐  
Severe ☐  
Not Done ☐

Vomiting

None ☒  
Mild ☐  
Moderate ☐  
Severe ☐  
Not Done ☐

Diarrhea

None ☒  
Mild ☐  
Moderate ☐  
Severe ☐  
Not Done ☐

Sore Throat

None ☐  
Mild ☒  
Moderate ☐  
Severe ☐  
Not Done ☐

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Folder: Covid-19 Assessment 30 Nov 2020

Form: Symptom Log (5)

Data signed: (b) (4) 21 Feb 2021 19:11:18

Generated On: 11 Aug 2021 22:53:07

Symptom Day

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

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Folder: Covid-19 Assessment 30 Nov 2020

Form: Symptom Log (5)

Data signed: (b) (4) 21 Feb 2021 19:11:18

Generated On: 11 Aug 2021 22:53:07

	Day 33	<input type="checkbox"/>
	Day 34	<input type="checkbox"/>
	Day 35	<input type="checkbox"/>
	Day 36	<input type="checkbox"/>
	Day 37	<input type="checkbox"/>
	Day 38	<input type="checkbox"/>
	Day 39	<input type="checkbox"/>
	Day 40	<input type="checkbox"/>

Date	01 DEC 2020
------	-------------

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

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

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

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

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

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

Shortness of Breath	None <input checked="" type="radio"/>
	Mild <input type="radio"/>
	Moderate <input type="radio"/>
	Severe <input type="radio"/>
	Not Done <input type="radio"/>

Difficulty Breathing	None <input checked="" type="radio"/>
	Mild <input type="radio"/>
	Moderate <input type="radio"/>
	Severe <input type="radio"/>

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EAB) (1725)

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Folder: Covid-19 Assessment 30 Nov 2020

Form: Symptom Log (5)

Data signed: (b) (4) 21 Feb 2021 19:11:18

Generated On: 11 Aug 2021 22:53:07

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

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Folder: Covid-19 Assessment 30 Nov 2020

Form: Symptom Log (5)

Data signed: (b) (4) 21 Feb 2021 19:11:18

Generated On: 11 Aug 2021 22:53:07

Nasal Congestion

None ☐  
Mild ☒  
Moderate ☐  
Severe ☐  
Not Done ☐

Runny Nose (Rhinorrhea)

None ☐  
Mild ☒  
Moderate ☐  
Severe ☐  
Not Done ☐

Nausea

None ☒  
Mild ☐  
Moderate ☐  
Severe ☐  
Not Done ☐

Vomiting

None ☒  
Mild ☐  
Moderate ☐  
Severe ☐  
Not Done ☐

Diarrhea

None ☒  
Mild ☐  
Moderate ☐  
Severe ☐  
Not Done ☐

Sore Throat

None ☐  
Mild ☒  
Moderate ☐  
Severe ☐  
Not Done ☐

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Folder: Covid-19 Assessment 30 Nov 2020

Form: Symptom Log (6)

Data signed: (b) (4) 21 Feb 2021 19:11:18

Generated On: 11 Aug 2021 22:53:07

Symptom Day

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

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Folder: Covid-19 Assessment 30 Nov 2020

Form: Symptom Log (6)

Data signed: (b) (4) 21 Feb 2021 19:11:18

Generated On: 11 Aug 2021 22:53:07

	Day 33	<input type="checkbox"/>
	Day 34	<input type="checkbox"/>
	Day 35	<input type="checkbox"/>
	Day 36	<input type="checkbox"/>
	Day 37	<input type="checkbox"/>
	Day 38	<input type="checkbox"/>
	Day 39	<input type="checkbox"/>
	Day 40	<input type="checkbox"/>

Date	02 DEC 2020
------	-------------

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

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

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

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

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

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

Shortness of Breath	None <input checked="" type="radio"/>
	Mild <input type="radio"/>
	Moderate <input type="radio"/>
	Severe <input type="radio"/>
	Not Done <input type="radio"/>

Difficulty Breathing	None <input checked="" type="radio"/>
	Mild <input type="radio"/>
	Moderate <input type="radio"/>
	Severe <input type="radio"/>

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EAB) (1725)

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Folder: Covid-19 Assessment 30 Nov 2020

Form: Symptom Log (6)

Data signed: (b) (4) 21 Feb 2021 19:11:18

Generated On: 11 Aug 2021 22:53:07

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

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Folder: Covid-19 Assessment 30 Nov 2020

Form: Symptom Log (6)

Data signed: (b) (4) 21 Feb 2021 19:11:18

Generated On: 11 Aug 2021 22:53:07

Nasal Congestion

None ☐  
Mild ☒  
Moderate ☐  
Severe ☐  
Not Done ☐

Runny Nose (Rhinorrhea)

None ☐  
Mild ☒  
Moderate ☐  
Severe ☐  
Not Done ☐

Nausea

None ☒  
Mild ☐  
Moderate ☐  
Severe ☐  
Not Done ☐

Vomiting

None ☒  
Mild ☐  
Moderate ☐  
Severe ☐  
Not Done ☐

Diarrhea

None ☒  
Mild ☐  
Moderate ☐  
Severe ☐  
Not Done ☐

Sore Throat

None ☐  
Mild ☒  
Moderate ☐  
Severe ☐  
Not Done ☐

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Folder: Covid-19 Assessment 30 Nov 2020

Form: Symptom Log (7)

Data signed: (b) (4) 21 Feb 2021 19:11:18

Generated On: 11 Aug 2021 22:53:07

Symptom Day

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

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Folder: Covid-19 Assessment 30 Nov 2020

Form: Symptom Log (7)

Data signed: (b) (4) 21 Feb 2021 19:11:18

Generated On: 11 Aug 2021 22:53:07

	Day 33	<input type="checkbox"/>
	Day 34	<input type="checkbox"/>
	Day 35	<input type="checkbox"/>
	Day 36	<input type="checkbox"/>
	Day 37	<input type="checkbox"/>
	Day 38	<input type="checkbox"/>
	Day 39	<input type="checkbox"/>
	Day 40	<input type="checkbox"/>

Date	03 DEC 2020
------	-------------

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

O2 Saturation	99 %
---------------	------

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

Temperature	97.3 F
-------------	--------

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

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

Shortness of Breath	None <input checked="" type="radio"/>
	Mild <input type="radio"/>
	Moderate <input type="radio"/>
	Severe <input type="radio"/>
	Not Done <input type="radio"/>

Difficulty Breathing	None <input checked="" type="radio"/>
	Mild <input type="radio"/>
	Moderate <input type="radio"/>
	Severe <input type="radio"/>

PRODUCTION RELEASE (v12.003  
EAB) (1725)

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Folder: Covid-19 Assessment 30 Nov 2020

Form: Symptom Log (7)

Data signed: (b) (4) 21 Feb 2021 19:11:18

Generated On: 11 Aug 2021 22:53:07

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

US3552412

Folder: Covid-19 Assessment 30 Nov 2020

Form: Symptom Log (7)

Data signed: (b) (4) 21 Feb 2021 19:11:18

Generated On: 11 Aug 2021 22:53:07

Nasal Congestion

None ☐  
Mild ☒  
Moderate ☐  
Severe ☐  
Not Done ☐

Runny Nose (Rhinorrhea)

None ☐  
Mild ☒  
Moderate ☐  
Severe ☐  
Not Done ☐

Nausea

None ☒  
Mild ☐  
Moderate ☐  
Severe ☐  
Not Done ☐

Vomiting

None ☒  
Mild ☐  
Moderate ☐  
Severe ☐  
Not Done ☐

Diarrhea

None ☒  
Mild ☐  
Moderate ☐  
Severe ☐  
Not Done ☐

Sore Throat

None ☒  
Mild ☐  
Moderate ☐  
Severe ☐  
Not Done ☐

US3552412

Folder: Covid-19 Assessment 30 Nov 2020

Form: Symptom Log (8)

Data signed: (b) (4) 21 Feb 2021 19:11:18

Generated On: 11 Aug 2021 22:53:07

Symptom Day

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

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Folder: Covid-19 Assessment 30 Nov 2020

Form: Symptom Log (8)

Data signed: (b) (4) 21 Feb 2021 19:11:18

Generated On: 11 Aug 2021 22:53:07

	Day 33	<input type="checkbox"/>
	Day 34	<input type="checkbox"/>
	Day 35	<input type="checkbox"/>
	Day 36	<input type="checkbox"/>
	Day 37	<input type="checkbox"/>
	Day 38	<input type="checkbox"/>
	Day 39	<input type="checkbox"/>
	Day 40	<input type="checkbox"/>
Date	04 DEC 2020	
Assessment Not Done	False	
O2 Saturation	99 %	
O2 Saturation Units	%	
Temperature	97.5 F	
Chills	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Cough	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Shortness of Breath	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Difficulty Breathing	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>

US3552412

Folder: Covid-19 Assessment 30 Nov 2020

Form: Symptom Log (8)

Data signed: (b) (4) 21 Feb 2021 19:11:18

Generated On: 11 Aug 2021 22:53:07

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

US3552412

Folder: Covid-19 Assessment 30 Nov 2020

Form: Symptom Log (8)

Data signed: (b) (4) 21 Feb 2021 19:11:18

Generated On: 11 Aug 2021 22:53:07

Nasal Congestion

None ☐  
Mild ☒  
Moderate ☐  
Severe ☐  
Not Done ☐

Runny Nose (Rhinorrhea)

None ☒  
Mild ☐  
Moderate ☐  
Severe ☐  
Not Done ☐

Nausea

None ☒  
Mild ☐  
Moderate ☐  
Severe ☐  
Not Done ☐

Vomiting

None ☒  
Mild ☐  
Moderate ☐  
Severe ☐  
Not Done ☐

Diarrhea

None ☒  
Mild ☐  
Moderate ☐  
Severe ☐  
Not Done ☐

Sore Throat

None ☒  
Mild ☐  
Moderate ☐  
Severe ☐  
Not Done ☐

US3552412

Folder: Covid-19 Assessment 30 Nov 2020

Form: Symptom Log (9)

Data signed: (b) (4) 21 Feb 2021 19:11:18

Generated On: 11 Aug 2021 22:53:07

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"/>

US3552412

Folder: Covid-19 Assessment 30 Nov 2020

Form: Symptom Log (9)

Data signed: (b) (4) 21 Feb 2021 19:11:18

Generated On: 11 Aug 2021 22:53:07

	Day 33	<input type="checkbox"/>
	Day 34	<input type="checkbox"/>
	Day 35	<input type="checkbox"/>
	Day 36	<input type="checkbox"/>
	Day 37	<input type="checkbox"/>
	Day 38	<input type="checkbox"/>
	Day 39	<input type="checkbox"/>
	Day 40	<input type="checkbox"/>

Date	05 DEC 2020
------	-------------

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

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

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

Temperature	98.3 F
-------------	--------

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

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

Shortness of Breath	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>

Difficulty Breathing	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>

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Folder: Covid-19 Assessment 30 Nov 2020

Form: Symptom Log (9)

Data signed: (b) (4) 21 Feb 2021 19:11:18

Generated On: 11 Aug 2021 22:53:07

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

US3552412

Folder: Covid-19 Assessment 30 Nov 2020

Form: Symptom Log (9)

Data signed: (b) (4) 21 Feb 2021 19:11:18

Generated On: 11 Aug 2021 22:53:07

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

US3552412

Folder: Covid-19 Assessment 30 Nov 2020

Form: Symptom Log (10)

Data signed: (b) (4) 21 Feb 2021 19:11:18

Generated On: 11 Aug 2021 22:53:07

Symptom Day

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

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Folder: Covid-19 Assessment 30 Nov 2020

Form: Symptom Log (10)

Data signed: (b) (4) 21 Feb 2021 19:11:18

Generated On: 11 Aug 2021 22:53:07

	Day 33	<input type="checkbox"/>
	Day 34	<input type="checkbox"/>
	Day 35	<input type="checkbox"/>
	Day 36	<input type="checkbox"/>
	Day 37	<input type="checkbox"/>
	Day 38	<input type="checkbox"/>
	Day 39	<input type="checkbox"/>
	Day 40	<input type="checkbox"/>

Date	06 DEC 2020
------	-------------

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

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

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

Temperature	98.5 F
-------------	--------

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

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

Shortness of Breath	None <input checked="" type="radio"/>
	Mild <input type="radio"/>
	Moderate <input type="radio"/>
	Severe <input type="radio"/>
	Not Done <input type="radio"/>

Difficulty Breathing	None <input checked="" type="radio"/>
	Mild <input type="radio"/>
	Moderate <input type="radio"/>
	Severe <input type="radio"/>

PRODUCTION RELEASE (v12.003  
EAB) (1725)

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Folder: Covid-19 Assessment 30 Nov 2020

Form: Symptom Log (10)

Data signed: (b) (4) 21 Feb 2021 19:11:18

Generated On: 11 Aug 2021 22:53:07

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

US3552412

Folder: Covid-19 Assessment 30 Nov 2020

Form: Symptom Log (10)

Data signed: (b) (4) 21 Feb 2021 19:11:18

Generated On: 11 Aug 2021 22:53:07

Nasal Congestion

None ☐  
Mild ☒  
Moderate ☐  
Severe ☐  
Not Done ☐

Runny Nose (Rhinorrhea)

None ☒  
Mild ☐  
Moderate ☐  
Severe ☐  
Not Done ☐

Nausea

None ☒  
Mild ☐  
Moderate ☐  
Severe ☐  
Not Done ☐

Vomiting

None ☒  
Mild ☐  
Moderate ☐  
Severe ☐  
Not Done ☐

Diarrhea

None ☒  
Mild ☐  
Moderate ☐  
Severe ☐  
Not Done ☐

Sore Throat

None ☒  
Mild ☐  
Moderate ☐  
Severe ☐  
Not Done ☐

US3552412

Folder: Covid-19 Assessment 30 Nov 2020

Form: Symptom Log (11)

Data signed: (b) (4) 21 Feb 2021 19:11:18

Generated On: 11 Aug 2021 22:53:07

Symptom Day

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

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Folder: Covid-19 Assessment 30 Nov 2020

Form: Symptom Log (11)

Data signed: (b) (4) 21 Feb 2021 19:11:18

Generated On: 11 Aug 2021 22:53:07

	Day 33	<input type="checkbox"/>
	Day 34	<input type="checkbox"/>
	Day 35	<input type="checkbox"/>
	Day 36	<input type="checkbox"/>
	Day 37	<input type="checkbox"/>
	Day 38	<input type="checkbox"/>
	Day 39	<input type="checkbox"/>
	Day 40	<input type="checkbox"/>

Date	07 DEC 2020
------	-------------

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

O2 Saturation	98 %
---------------	------

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

Temperature	98.5 F
-------------	--------

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

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

Shortness of Breath	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>

Difficulty Breathing	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>

PRODUCTION RELEASE (v12.003  
EAB) (1725)

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Folder: Covid-19 Assessment 30 Nov 2020

Form: Symptom Log (11)

Data signed: (b) (4) 21 Feb 2021 19:11:18

Generated On: 11 Aug 2021 22:53:07

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

US3552412

Folder: Covid-19 Assessment 30 Nov 2020

Form: Symptom Log (11)

Data signed: (b) (4) 21 Feb 2021 19:11:18

Generated On: 11 Aug 2021 22:53:07

Nasal Congestion

None ☐  
Mild ☒  
Moderate ☐  
Severe ☐  
Not Done ☐

Runny Nose (Rhinorrhea)

None ☒  
Mild ☐  
Moderate ☐  
Severe ☐  
Not Done ☐

Nausea

None ☒  
Mild ☐  
Moderate ☐  
Severe ☐  
Not Done ☐

Vomiting

None ☒  
Mild ☐  
Moderate ☐  
Severe ☐  
Not Done ☐

Diarrhea

None ☒  
Mild ☐  
Moderate ☐  
Severe ☐  
Not Done ☐

Sore Throat

None ☒  
Mild ☐  
Moderate ☐  
Severe ☐  
Not Done ☐

US3552412

Folder: Covid-19 Assessment 30 Nov 2020

Form: COVID Diagnostic Test

Data signed: (b) (4) 21 Feb 2021 19:11:18

Generated On: 11 Aug 2021 22:53:07

Date of Visit 03 DEC 2020

Was the Subject Tested For SARS-CoV-2 by RT-PCR? Yes ☒ No ☐

Did Subject Test Positive For SARS-CoV-2 by RT-PCR? Yes ☐ No ☒

Date of Test 03 DEC 2020

Type of Test Performed Nasopharyngeal Swab ☒ Nasal Swab ☐ Saliva Test ☐ Other ☐

Other, specify \_\_\_\_\_

Was this diagnostic test performed at a lab other than the Study Central Lab? Yes ☐ No ☒

If yes, provide lab information below

Lab/ Institution Test Performed \_\_\_\_\_

CLIA Certified? Yes ☐ No ☐

COVID-19 Positive (CSA Programming Field Only) 0

US3552412

Folder: Covid-19 Assessment 30 Nov 2020

Form: Generate Next COVID-19 Assessment

Data signed: (b) (4) 21 Feb 2021 19:11:18

Generated On: 11 Aug 2021 22:53:07

---

[Generate Next COVID-19 Assessment](#)

Yes ☒

No ☐

---

US3552412

Folder: Illness Visit (1)

Form: Saliva Collection

Data signed: (b) (4) 21 Feb 2021 19:11:18

Generated On: 11 Aug 2021 22:53:07

Visit	Was Saliva Collected?	Date of Collection
Day 3	Yes	04 DEC 2020
Day 5	Yes	07 DEC 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 (2)

Form: Saliva Collection

Data signed: (b) (4) 21 Feb 2021 19:11:18

Generated On: 11 Aug 2021 22:53:07

Visit	Was Saliva Collected?	Date of Collection
Day 3	NA (COVID-19 Negative)	
Day 5	NA (COVID-19 Negative)	
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)	

US3552412

Folder: Illness Visit Day 1 (1)

Form: Visit Date

Data signed: (b) (4) 21 Feb 2021 19:11:18

Generated On: 11 Aug 2021 22:53:07

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	03 DEC 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

US3552412

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Data signed: (b) (4) 21 Feb 2021 19:11:18

Generated On: 11 Aug 2021 22:53:07

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (dd MMM yyyy)	03 DEC 2020
Time of assessment (00:00-23:59)	09:40 (24 HR)
Vital Signs Date and Time (derived)	03 DEC 2020 09:40
Height (xxx.x)	65 in
Weight (xxx.x)	101 lb
Temperature (xxx.x)	97.3 F
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	85 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	14 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	100 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	70 mmHg
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

US3552412

Folder: Illness Visit Day 1 (1)

Form: Physical Examination

Data signed: (b) (4) 21 Feb 2021 19:11:18

Generated On: 11 Aug 2021 22:53:07

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

03 DEC 2020

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

US3552412

Folder: Illness Visit Day 1 (1)

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

Data signed: (b) (4) 21 Feb 2021 19:11:18

Generated On: 11 Aug 2021 22:53:07

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

Yes ☒

No ☐

NA (COVID-19 Negative) ☐

Date of Collection

03 DEC 2020

US3552412

Folder: Illness Visit Day 1 (1)

Form: Visit Date

Data signed: (b) (4) 21 Feb 2021 19:11:18

Generated On: 11 Aug 2021 22:53:07

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	15 JAN 2021
Was visit performed at the participant's home or at the clinic?	Home <input checked="" type="radio"/>
	Clinic <input type="radio"/>
Folder OID	SICKD1

US3552412

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Data signed: (b) (4) 21 Feb 2021 19:11:19

Generated On: 11 Aug 2021 22:53:07

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (dd MMM yyyy)	15 JAN 2021
Time of assessment (00:00-23:59)	10:58 (24 HR)
Vital Signs Date and Time (derived)	15 JAN 2021 10:58
Height (xxx.x)	ND - Not Done
Weight (xxx.x)	ND - Not Done
Temperature (xxx.x)	96.5 F
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	67 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	18 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	80 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	42 mmHg
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

US3552412

Folder: Illness Visit Day 1 (1)

Form: Physical Examination

Data signed: (b) (4) 21 Feb 2021 19:11:18

Generated On: 11 Aug 2021 22:53:07

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.*

US3552412

Folder: Illness Visit Day 1 (1)

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

Data signed: (b) (4) 21 Feb 2021 19:11:18

Generated On: 11 Aug 2021 22:53:07

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

Yes ☒

No ☐

NA (COVID-19 Negative) ☐

Date of Collection

15 JAN 2021

**US3552412**

**Folder: Convalescence Visit Day 28 (1)**

**Form: Visit Date**

**Generated On: 11 Aug 2021 22:53:07**

Was this visit performed? Yes ☐  
No ☐

Visit date (dd MMM yyyy) \_\_\_\_\_

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

Folder OID \_\_\_\_\_

US3552412

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:53:07

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

US3552412

Folder: Convalescence Visit Day 28 (1)

Form: Physical Examination

Generated On: 11 Aug 2021 22:53:07

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.*

US3552412

Folder: Convalescence Visit Day 28 (1)

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

Generated On: 11 Aug 2021 22:53:07

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

Yes ☐

No ☐

NA (COVID-19 Negative) ☐

Date of Collection

**US3552412**

**Folder: Convalescence Visit Day 28 (1)**

**Form: Visit Date**

**Generated On: 11 Aug 2021 22:53:07**

Was this visit performed? Yes ☐  
No ☐

Visit date (dd MMM yyyy) \_\_\_\_\_

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

Folder OID \_\_\_\_\_

US3552412

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:53:07

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

US3552412

Folder: Convalescence Visit Day 28 (1)

Form: Physical Examination

Generated On: 11 Aug 2021 22:53:07

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.*

US3552412

Folder: Convalescence Visit Day 28 (1)

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

Generated On: 11 Aug 2021 22:53:07

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

Yes ☐

No ☐

NA (COVID-19 Negative) ☐

Date of Collection

US3552412

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

Form: Visit Date

Data signed: (b) (4) 21 Feb 2021 19:11:19

Generated On: 11 Aug 2021 22:53:07

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

Visit date (dd MMM yyyy)	12 JAN 2021
--------------------------	-------------

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

Folder OID	UNBLND_DECIDE
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US3552412

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

Form: Unblinding

Data signed: (b) (4) 23 Mar 2021 15:40:44

Generated On: 11 Aug 2021 22:53:07

Date of updated informed consent (dd MMM yyyy) 12 JAN 2021

N/A - Subject Unblinded under Amendment 5 and Discontinued from Study False

Was the participant unblinded? Yes ☒ No ☐

Under what version of the Protocol was the Participant unblinded? Amendment 5 ☐ Amendment 6 or later ☒

Date of unblinding (dd MMM yyyy) 12 JAN 2021

Participant randomization assignment mRNA-1273 ☒ Placebo ☐

Actual Dose 1 mRNA-1273 ☒ Placebo ☐ Not Administered ☐

Actual Dose 2 mRNA-1273 ☒ Placebo ☐ Not Administered ☐

Will participant receive mRNA-1273? Yes ☐ No ☒

Placebo Only Flag \_\_\_\_\_  
Continuing with mRNA-1273 \_\_\_\_\_

US3552412

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

Form: Immunogenicity Assessment

Data signed: (b) (4) 21 Feb 2021 19:11:19

Generated On: 11 Aug 2021 22:53:07

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (dd MMM yyyy)	12 JAN 2021
Collection time (00:00-23:59)	14:59 (24 HR)
Collection date and time (derived)	12 JAN 2021 14:59

US3552412

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Data signed: (b) (4) 21 Feb 2021 19:11:19

Generated On: 11 Aug 2021 22:53:07

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (dd MMM yyyy)	12 JAN 2021
Collection time (00:00 - 23:59)	15:03
Collection Date and Time (derived)	12 JAN 2021 15:03

US3552412

Folder: Adverse Events

Form: Adverse Events Summary

Data signed: (b) (4) 21 Feb 2021 19:11:17

Generated On: 11 Aug 2021 22:53:07

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Did the participant experience any adverse events?

Yes ☒

No ☐

---

If Yes, enter details on the Adverse Events form.

---

US3552412

Folder: Adverse Events

Form: Adverse Events (1)

Data signed: (b) (4) 21 Feb 2021 19:11:16

Generated On: 11 Aug 2021 22:53:07

AEID	
Adverse event	RHINO/ENTEROVIRUS
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)	27 NOV 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)	08 DEC 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	

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Folder: Adverse Events

Form: Adverse Events (1)

Data signed: (b) (4) 21 Feb 2021 19:11:16

Generated On: 11 Aug 2021 22:53:07

Persistent or significant disability or incapacity	False
Congenital anomaly or birth defect	False
Other medically important event	False
Relationship to investigational product	Not Related <input checked="" type="radio"/> Related <input type="radio"/> Not Applicable <input type="radio"/>
Relationship to Study Procedure	Not Related <input checked="" type="radio"/> Related <input type="radio"/> Not Applicable <input type="radio"/>
Action taken with investigational product	None <input type="radio"/> Dose Delayed <input type="radio"/> Investigational Product <input type="radio"/> Withdrawn <input type="radio"/> Not Applicable <input checked="" type="radio"/>
Other action taken (check all that apply)	
None	True
Concomitant Medication	False
Concomitant Procedure	False
Outcome	Fatal <input type="radio"/> Not Recovered/Not Resolved <input 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)	_____

US3552412

Folder: Adverse Events

Form: Adverse Events (2)

Data signed: (b) (4) 21 Feb 2021 19:11:16

Generated On: 11 Aug 2021 22:53:07

AEID

Adverse event

RHINO / ENTEROVIRUS

Was this a medically-attended AE?

Yes ☒

No ☐

Was this a Solicited Adverse Reaction?

Yes ☐

No ☒

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

Yes ☐

No ☒

Start date (dd MMM yyyy)

15 JAN 2021

Start time (00:00-23:59)

AE start date and time (derived)

Ongoing?

Yes ☐

No ☒

If not Ongoing, end date (dd MMM yyyy)

25 JAN 2021

End time (00:00-23:59)

AE End Date and Time (derived)

Severity

Grade 1/Mild ☒

Grade 2/Moderate ☐

Grade 3/Severe ☐

Grade 4 ☐

Is the adverse event serious?

Yes ☐

No ☒

AE is serious due To (check all that apply)

Death

False

Life threatening

False

Requires inpatient or prolongation of existing Hospitalization

False

Hospital Admission Date (dd MMM yyyy)

Hospital Discharge Date (dd MMM yyyy)

Admitted to ICU?

Yes ☐

No ☐

Unknown ☐

Number of Days in ICU

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Folder: Adverse Events

Form: Adverse Events (2)

Data signed: (b) (4) 21 Feb 2021 19:11:16

Generated On: 11 Aug 2021 22:53:07

Persistent or significant disability or incapacity	False
Congenital anomaly or birth defect	False
Other medically important event	False
Relationship to investigational product	Not Related <input checked="" type="radio"/> Related <input type="radio"/> Not Applicable <input type="radio"/>
Relationship to Study Procedure	Not Related <input checked="" type="radio"/> Related <input type="radio"/> Not Applicable <input type="radio"/>
Action taken with investigational product	None <input type="radio"/> Dose Delayed <input type="radio"/> Investigational Product <input type="radio"/> Withdrawn <input type="radio"/> Not Applicable <input checked="" type="radio"/>
Other action taken (check all that apply)	
None	True
Concomitant Medication	False
Concomitant Procedure	False
Outcome	Fatal <input type="radio"/> Not Recovered/Not Resolved <input 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)	_____

US3552412

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Data signed: (b) (4) 21 Feb 2021 19:11:18

Generated On: 11 Aug 2021 22:53:07

---

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

Yes ☒

No ☐

---

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

---

US3552412

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Data signed: (b) (4) 21 Feb 2021 19:11:17

Generated On: 11 Aug 2021 22:53:07

Name of Medication IBUPROFEN

Prophylaxis Yes ☐  
No ☒

Indication HEADACHE

Dose per administration 400

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Data signed: (b) (4) 21 Feb 2021 19:11:17

Generated On: 11 Aug 2021 22:53:07

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	UN UNK 2000	
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)	_____	
Interval Dosage Unit Number (derived)	_____	
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input type="radio"/>

US3552412

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Data signed: (b) (4) 21 Feb 2021 19:11:17

Generated On: 11 Aug 2021 22:53:07

Name of Medication MIRENA IUD

Prophylaxis Yes ☒  
No ☐

Indication CONTRACEPTION

Dose per administration 52

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Data signed: (b) (4) 21 Feb 2021 19:11:17

Generated On: 11 Aug 2021 22:53:07

	Intramuscular	<input type="radio"/>
	Respiratory (Inhalation)	<input type="radio"/>
	Intralesional	<input type="radio"/>
	Intraperitoneal	<input type="radio"/>
	Nasal	<input type="radio"/>
	Vaginal	<input type="radio"/>
	Rectal	<input type="radio"/>
	Intravenous	<input type="radio"/>
	Intravenous Bolus	<input type="radio"/>
	Intravenous Drip	<input type="radio"/>
	Other	<input checked="" type="radio"/>
If route of administration is Other, specify	INTRAUTERINE	
Start date (dd MMM yyyy)	07 OCT 2019	
Start date completely unknown	False	
Ongoing?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
If not Ongoing, End date (dd MMM yyyy)	06 JAN 2021	
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Data signed: (b) (4) 21 Feb 2021 19:11:17

Generated On: 11 Aug 2021 22:53:07

Name of Medication DIFFERIN .1%

Prophylaxis Yes ☐  
No ☒

Indication ACNE

Dose per administration 1

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

If dose unit is Other, specify APPLICATION

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Data signed: (b) (4) 21 Feb 2021 19:11:17

Generated On: 11 Aug 2021 22:53:07

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)		02 OCT 2020
Start date completely unknown		False
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)		1
Interval Dosage Unit Number (derived)		1
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Data signed: (b) (4) 21 Feb 2021 19:11:17

Generated On: 11 Aug 2021 22:53:07

Name of Medication TYLENOL

Prophylaxis Yes ☐  
No ☒

Indication BODY ACHES

Dose per administration 1000

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Data signed: (b) (4) 21 Feb 2021 19:11:17

Generated On: 11 Aug 2021 22:53:07

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)		09 OCT 2020
Start date completely unknown		False
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)		09 OCT 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"/>

US3552412

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Data signed: (b) (4) 21 Feb 2021 19:11:17

Generated On: 11 Aug 2021 22:53:07

Name of Medication IBUPROFEN

Prophylaxis Yes ☐  
No ☒

Indication BODY ACHES

Dose per administration 400

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Data signed: (b) (4) 21 Feb 2021 19:11:17

Generated On: 11 Aug 2021 22:53:07

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)		10 OCT 2020
Start date completely unknown		False
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)		10 OCT 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"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Data signed: (b) (4) 21 Feb 2021 19:11:17

Generated On: 11 Aug 2021 22:53:07

Name of Medication TYLENOL

Prophylaxis Yes ☐  
No ☒

Indication MIGRAINE

Dose per administration 650

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

PRODUCTION RELEASE (v12.003  
EAB) (1725)

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Data signed: (b) (4) 21 Feb 2021 19:11:17

Generated On: 11 Aug 2021 22:53:07

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

US3552412

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Data signed: (b) (4) 21 Feb 2021 19:11:17

Generated On: 11 Aug 2021 22:53:07

Name of Medication NAPROXEN

Prophylaxis Yes ☐  
No ☒

Indication MIGRAINE

Dose per administration 250

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

PRODUCTION RELEASE (v12.003  
EAB) (1725)

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Data signed: (b) (4) 21 Feb 2021 19:11:17

Generated On: 11 Aug 2021 22:53:07

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

US3552412

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Data signed: (b) (4) 21 Feb 2021 19:11:17

Generated On: 11 Aug 2021 22:53:07

Name of Medication INFLUENZA VACCINE

Prophylaxis Yes ☒  
No ☐

Indication INFLUENZA PROPHYLAXIS

Dose per administration 1

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

If dose unit is Other, specify INJECTION

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

If frequency is Other, specify

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

PRODUCTION RELEASE (v12.003  
EAB) (1725)

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Data signed: (b) (4) 21 Feb 2021 19:11:17

Generated On: 11 Aug 2021 22:53:07

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Data signed: (b) (4) 21 Feb 2021 19:11:17

Generated On: 11 Aug 2021 22:53:07

Name of Medication PRENATAL VITAMIN

Prophylaxis Yes ☒  
No ☐

Indication HEALTH PROMOTION

Dose per administration 1

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

PRODUCTION RELEASE (v12.003  
EAB) (1725)

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Data signed: (b) (4) 21 Feb 2021 19:11:17

Generated On: 11 Aug 2021 22:53:07

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)		07 JAN 2021
Start date completely unknown		False
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)		1
Interval Dosage Unit Number (derived)		1
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>

US3552412

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures Summary

Data signed: (b) (4) 09 Mar 2021 17:03:11

Generated On: 11 Aug 2021 22:53:07

---

Were any concomitant procedures performed?

Yes ☐

No ☒

---

If yes, please complete Concomitant Procedures form.

---

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Folder: End of Study (1)

Form: Dosing Discontinuation

Generated On: 11 Aug 2021 22:53:07

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

US3552412

Folder: End of Study (1)

Form: End of Study / Study Discontinuation

Generated On: 11 Aug 2021 22:53:07

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 ☐

Audit

US3552412 (Prod: Saint Louis University)

US3552412

Form: Participant Creation

Generated On: 11 Aug 2021 22:53:07

[Participant ID](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:11:21
User entered 'US3552412'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	11 Sep 2020 18:31:07

US3552412

Folder: Screening

Form: Visit Date

Generated On: 11 Aug 2021 22:53:07

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:19:00
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:11:21
User entered 'Yes (Y)'	(b) (4) Stanley Dublin (b) (4) (b) (4)	12 Sep 2020 19:01:50

US3552412

Folder: Screening

Form: Visit Date

Generated On: 11 Aug 2021 22:53:07

Visit date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:19:00
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:11:21
User entered '11 SEP 2020'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	11 Sep 2020 18:31:08

US3552412

Folder: Screening

Form: Visit Date

Generated On: 11 Aug 2021 22:53:07

[Was visit performed at the participant's home or at the clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:19:00
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:11:21
User entered 'Clinic (Clinic)'	(b) (4) Stanley Dublin (b) (4) (b) (4)	12 Sep 2020 19:01:50

US3552412

Folder: Screening

Form: Visit Date

Generated On: 11 Aug 2021 22:53:07

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:19:00
User entered 'SCRN'	System	12 Sep 2020 19:01:50

US3552412

Folder: Screening

Form: Demographics

Generated On: 11 Aug 2021 22:53:07

Date of Birth (MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:19:00
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:11:21
User entered (b) (6) 1991'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	11 Sep 2020 18:31:09

US3552412

Folder: Screening

Form: Demographics

Generated On: 11 Aug 2021 22:53:07

[Age](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:19:00
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:11:21
User entered '29'	(b) (4) Stanley Dublin (b) (4) (b) (4)	12 Sep 2020 19:02:28

US3552412

Folder: Screening

Form: Demographics

Generated On: 11 Aug 2021 22:53:07

[Age Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:19:00
User entered 'YEARS'	System	12 Sep 2020 19:02:28

US3552412

Folder: Screening

Form: Demographics

Generated On: 11 Aug 2021 22:53:07

[Age \(Derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:19:00
User entered '29'	System	11 Sep 2020 19:00:28

US3552412

Folder: Screening

Form: Demographics

Generated On: 11 Aug 2021 22:53:07

Sex

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:19:00
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:11:21
User entered 'Female (F)'	(b) (4) Stanley Dublin (b) (4) (b) (4)	12 Sep 2020 19:02:28

US3552412

Folder: Screening

Form: Demographics

Generated On: 11 Aug 2021 22:53:07

[Ethnicity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:19:00
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:11:21
User entered 'Not Hispanic or Latino (NOT HISPANIC OR LATINO)'	(b) (4) Stanley Doublin (b) (4)	12 Sep 2020 19:02:28

US3552412

Folder: Screening

Form: Demographics

Generated On: 11 Aug 2021 22:53:07

White

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:19:00
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:11:21
User entered 'l'	(b) (4) Stanley Dublin (b) (4) (b) (4)	12 Sep 2020 19:02:28

US3552412

Folder: Screening

Form: Demographics

Generated On: 11 Aug 2021 22:53:07

[Black](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:19:00
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:11:21
User entered '0'	(b) (4) Stanley Dublin (b) (4) (b) (4)	12 Sep 2020 19:02:28

US3552412

Folder: Screening

Form: Demographics

Generated On: 11 Aug 2021 22:53:07

[Asian](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:19:00
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:11:21
User entered '0'	(b) (4) Stanley Dublin (b) (4) (b) (4)	12 Sep 2020 19:02:28

US3552412

Folder: Screening

Form: Demographics

Generated On: 11 Aug 2021 22:53:07

[American Indian or Alaska Native](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:19:00
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:11:21
User entered '0'	(b) (4) Stanley Dublin (b) (4) (b) (4)	12 Sep 2020 19:02:28

US3552412

Folder: Screening

Form: Demographics

Generated On: 11 Aug 2021 22:53:07

[Native Hawaiian or other Pacific Islander](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:19:00
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:11:21
User entered '0'	(b) (4) Stanley Dublin (b) (4) (b) (4)	12 Sep 2020 19:02:28

US3552412

Folder: Screening

Form: Demographics

Generated On: 11 Aug 2021 22:53:07

[Other](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:19:00
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:11:21
User entered '0'	(b) (4) Stanley Dublin (b) (4) (b) (4)	12 Sep 2020 19:02:28

US3552412

Folder: Screening

Form: Demographics

Generated On: 11 Aug 2021 22:53:07

If race is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:19:00
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:11:21
User entered empty.	(b) (4) Stanley Dublin (b) (4)	12 Sep 2020 19:02:28

US3552412

Folder: Screening

Form: Demographics

Generated On: 11 Aug 2021 22:53:07

Unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:19:00
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:11:21
User entered '0'	(b) (4) Stanley Dublin (b) (4) (b) (4)	12 Sep 2020 19:02:28

US3552412

Folder: Screening

Form: Demographics

Generated On: 11 Aug 2021 22:53:07

[Not reported](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:19:00
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:11:21
User entered '0'	(b) (4) Stanley Dublin (b) (4) (b) (4)	12 Sep 2020 19:02:28

US3552412

Folder: Screening

Form: Enrollment

Generated On: 11 Aug 2021 22:53:07

Date of Informed Consent (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:19:00
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:11:21
User entered '11 Sep 2020'	(b) (4) (b) (4), (b) (6)	11 Sep 2020 19:00:28

US3552412

Folder: Screening

Form: Enrollment

Generated On: 11 Aug 2021 22:53:07

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:19:00
User entered 'Sep 2020'	System	11 Sep 2020 19:00:28

US3552412

Folder: Screening

Form: Enrollment

Generated On: 11 Aug 2021 22:53:07

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:19:00
User entered '2020'	System	11 Sep 2020 19:00:28

US3552412

Folder: Screening

Form: Enrollment

Generated On: 11 Aug 2021 22:53:07

[Protocol Version](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:19:00
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:11:21
User entered 'Amendment 3 (3)'	(b) (4) (b) (4), (b) (6)	11 Sep 2020 19:00:28

US3552412

Folder: Screening

Form: Enrollment

Generated On: 11 Aug 2021 22:53:07

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:19:00
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:11:21
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	11 Sep 2020 19:00:28

US3552412

Folder: Screening

Form: Enrollment

Generated On: 11 Aug 2021 22:53:07

If No, indicate reason for screen fail

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:19:00
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:11:21
User entered empty.	(b) (4)	(b) (4), (b) (6) 11 Sep 2020 19:00:28

US3552412

Folder: Screening

Form: Enrollment

Generated On: 11 Aug 2021 22:53:07

If reason for screen fail is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:19:00
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:11:21
User entered empty.	(b) (4), (b) (6)	11 Sep 2020 19:00:28

US3552412

Folder: Screening

Form: Enrollment

Generated On: 11 Aug 2021 22:53:07

[Was this participant screened previously?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:19:00
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:11:21
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	11 Sep 2020 19:00:28

US3552412

Folder: Screening

Form: Enrollment

Generated On: 11 Aug 2021 22:53:07

[If Yes, previous participant number](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:19:00
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:11:21
User entered empty.	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	11 Sep 2020 18:31:08

US3552412

Folder: Screening

Form: Enrollment

Generated On: 11 Aug 2021 22:53:07

[Enrollment Trigger](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:19:00
User entered 'l'	System	11 Sep 2020 19:00:34

US3552412

Folder: Screening

Form: Inclusion/Exclusion Criteria Summary

Generated On: 11 Aug 2021 22:53:07

[Did the participant meet all eligibility criteria?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:19:00
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:11:21
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	11 Sep 2020 19:00:34

US3552412

Folder: Screening

Form: Medical History Summary

Generated On: 11 Aug 2021 22:53:07

[Were any significant conditions reported?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:19:00
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:11:21
User entered 'Yes (Y)'	(b) (4) Stanley Dublin (b) (4) (b) (4)	12 Sep 2020 19:02:38

US3552412

Folder: Screening

Form: Medical History (1)

Generated On: 11 Aug 2021 22:53:07

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:19:00
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:11:21
User coded data point as SOC: Eye disorders, HLGT: Vision disorders, HLT: Refractive and accommodative disorders, PT: Myopia, LLT: Myopia - version MedDRA\\23.0.	Coder Import (b) (4)	12 Sep 2020 19:03:42
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	12 Sep 2020 19:03:42
Data point term sent to Coder	System	12 Sep 2020 19:03:20
User entered 'myopia'	Stanley Dublin (b) (4)	12 Sep 2020 19:03:04

US3552412

Folder: Screening

Form: Medical History (1)

Generated On: 11 Aug 2021 22:53:07

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:19:00
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:11:21
User entered 'un UNK 2000'	(b) (4) Stanley Dublin (b) (4) (b) (4)	12 Sep 2020 19:03:04

US3552412

Folder: Screening

Form: Medical History (1)

Generated On: 11 Aug 2021 22:53:07

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:19:00
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:11:21
User entered '0'	(b) (4) Stanley Dublin (b) (4) (b) (4)	12 Sep 2020 19:03:04

US3552412

Folder: Screening

Form: Medical History (1)

Generated On: 11 Aug 2021 22:53:07

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:19:00
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:11:21
User entered 'Yes (Y)'	(b) (4) Stanley Dublin (b) (4) (b) (4)	12 Sep 2020 19:03:04

US3552412

Folder: Screening

Form: Medical History (1)

Generated On: 11 Aug 2021 22:53:07

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:19:00
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:11:21
User entered empty.	(b) (4) Stanley Dublin (b) (4)	12 Sep 2020 19:03:04

US3552412

Folder: Screening

Form: Medical History (1)

Generated On: 11 Aug 2021 22:53:07

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:19:00
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:11:21
User entered '0'	(b) (4) Stanley Dublin (b) (4) (b) (4)	12 Sep 2020 19:03:04

US3552412

Folder: Screening

Form: Medical History (1)

Generated On: 11 Aug 2021 22:53:07

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:19:00
User entered 'Jan 2000'	System	12 Sep 2020 19:03:04

US3552412

Folder: Screening

Form: Medical History (1)

Generated On: 11 Aug 2021 22:53:07

Start Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:19:00
User entered '2000'	System	12 Sep 2020 19:03:04

US3552412

Folder: Screening

Form: Medical History (1)

Generated On: 11 Aug 2021 22:53:07

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:19:00
User entered empty.	System	12 Sep 2020 19:03:04

US3552412

Folder: Screening

Form: Medical History (1)

Generated On: 11 Aug 2021 22:53:07

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:19:00
User entered empty.	System	12 Sep 2020 19:03:04

US3552412

Folder: Screening

Form: Medical History (2)

Generated On: 11 Aug 2021 22:53:07

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:19:00
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 19:11:21
User coded data point as SOC: Eye disorders, HLGT: Ocular structural change, deposit and degeneration NEC, HLT: Retinal structural change, deposit and degeneration, PT: Retinal degeneration, LLT: Lattice degeneration of retina - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	12 Sep 2020 20:31:36
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	12 Sep 2020 20:31:36
Data point term sent to Coder	System	12 Sep 2020 19:04:20
User entered 'bilateral lattice degeneration'	Stanley Doublin (b) (4) (b) (4)	12 Sep 2020 19:03:24

US3552412

Folder: Screening

Form: Medical History (2)

Generated On: 11 Aug 2021 22:53:07

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:19:00
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:11:21
User entered 'un UNK 2018'	(b) (4) Stanley Dublin (b) (4) (b) (4)	12 Sep 2020 19:03:24

US3552412

Folder: Screening

Form: Medical History (2)

Generated On: 11 Aug 2021 22:53:07

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:19:00
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:11:21
User entered '0'	(b) (4) Stanley Dublin (b) (4) (b) (4)	12 Sep 2020 19:03:24

US3552412

Folder: Screening

Form: Medical History (2)

Generated On: 11 Aug 2021 22:53:07

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:19:00
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:11:21
User entered 'Yes (Y)'	(b) (4) Stanley Dublin (b) (4) (b) (4)	12 Sep 2020 19:03:24

US3552412

Folder: Screening

Form: Medical History (2)

Generated On: 11 Aug 2021 22:53:07

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:19:00
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:11:21
User entered empty.	(b) (4) Stanley Dublin (b) (4) (b) (4)	12 Sep 2020 19:03:24

US3552412

Folder: Screening

Form: Medical History (2)

Generated On: 11 Aug 2021 22:53:07

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:19:00
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:11:21
User entered '0'	(b) (4) Stanley Dublin (b) (4) (b) (4)	12 Sep 2020 19:03:24

US3552412

Folder: Screening

Form: Medical History (2)

Generated On: 11 Aug 2021 22:53:07

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:19:00
User entered 'Jan 2018'	System	12 Sep 2020 19:03:24

US3552412

Folder: Screening

Form: Medical History (2)

Generated On: 11 Aug 2021 22:53:07

Start Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:19:00
User entered '2018'	System	12 Sep 2020 19:03:24

US3552412

Folder: Screening

Form: Medical History (2)

Generated On: 11 Aug 2021 22:53:07

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:19:00
User entered empty.	System	12 Sep 2020 19:03:24

US3552412

Folder: Screening

Form: Medical History (2)

Generated On: 11 Aug 2021 22:53:07

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:19:00
User entered empty.	System	12 Sep 2020 19:03:24

US3552412

Folder: Screening

Form: Medical History (3)

Generated On: 11 Aug 2021 22:53:07

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:19:00
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:11:21
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)	12 Sep 2020 19:04:42
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	12 Sep 2020 19:04:42
Data point term sent to Coder	System	12 Sep 2020 19:04:20
User entered 'headaches'	Stanley Doublin (b) (4)	12 Sep 2020 19:03:36

US3552412

Folder: Screening

Form: Medical History (3)

Generated On: 11 Aug 2021 22:53:07

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:19:00
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 19:11:21
User entered 'un UNK 2000'	Stanley Dublin (b) (4) (b) (4)	12 Sep 2020 19:03:36

US3552412

Folder: Screening

Form: Medical History (3)

Generated On: 11 Aug 2021 22:53:07

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:19:00
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:11:21
User entered '0'	(b) (4) Stanley Dublin (b) (4) (b) (4)	12 Sep 2020 19:03:36

US3552412

Folder: Screening

Form: Medical History (3)

Generated On: 11 Aug 2021 22:53:07

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:19:00
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:11:21
User entered 'Yes (Y)'	(b) (4) Stanley Dublin (b) (4) (b) (4)	12 Sep 2020 19:03:36

US3552412

Folder: Screening

Form: Medical History (3)

Generated On: 11 Aug 2021 22:53:07

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:19:00
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:11:21
User entered empty.	(b) (4) Stanley Dublin (b) (4) (b) (4)	12 Sep 2020 19:03:36

US3552412

Folder: Screening

Form: Medical History (3)

Generated On: 11 Aug 2021 22:53:07

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:19:00
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:11:21
User entered '0'	(b) (4) Stanley Dublin (b) (4) (b) (4)	12 Sep 2020 19:03:36

US3552412

Folder: Screening

Form: Medical History (3)

Generated On: 11 Aug 2021 22:53:07

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:19:00
User entered 'Jan 2000'	System	12 Sep 2020 19:03:36

US3552412

Folder: Screening

Form: Medical History (3)

Generated On: 11 Aug 2021 22:53:07

Start Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:19:00
User entered '2000'	System	12 Sep 2020 19:03:36

US3552412

Folder: Screening

Form: Medical History (3)

Generated On: 11 Aug 2021 22:53:07

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:19:00
User entered empty.	System	12 Sep 2020 19:03:36

US3552412

Folder: Screening

Form: Medical History (3)

Generated On: 11 Aug 2021 22:53:07

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:19:00
User entered empty.	System	12 Sep 2020 19:03:36

US3552412

Folder: Screening

Form: Medical History (4)

Generated On: 11 Aug 2021 22:53:07

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:19:00
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:11:21
User coded data point as SOC: Nervous system disorders, HLGT: Headaches, HLT: Migraine headaches, PT: Migraine, LLT: Migraine - version MedDRA\\23.0.	(b) (4) Coder Import (b) (4)	12 Sep 2020 19:04:42
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	12 Sep 2020 19:04:42
Data point term sent to Coder	System	12 Sep 2020 19:04:21
User entered 'migraines'	Stanley Doublin (b) (4)	12 Sep 2020 19:03:50
	(b) (4)	

US3552412

Folder: Screening

Form: Medical History (4)

Generated On: 11 Aug 2021 22:53:07

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:19:00
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:11:21
User entered 'un UNK 2010'	(b) (4) Stanley Dublin (b) (4) (b) (4)	12 Sep 2020 19:03:50

US3552412

Folder: Screening

Form: Medical History (4)

Generated On: 11 Aug 2021 22:53:07

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:19:00
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:11:21
User entered '0'	(b) (4) Stanley Dublin (b) (4) (b) (4)	12 Sep 2020 19:03:50

US3552412

Folder: Screening

Form: Medical History (4)

Generated On: 11 Aug 2021 22:53:07

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:19:00
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:11:21
User entered 'Yes (Y)'	(b) (4) Stanley Dublin (b) (4) (b) (4)	12 Sep 2020 19:03:50

US3552412

Folder: Screening

Form: Medical History (4)

Generated On: 11 Aug 2021 22:53:07

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:19:00
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:11:21
User entered empty.	(b) (4) Stanley Dublin (b) (4) (b) (4)	12 Sep 2020 19:03:50

US3552412

Folder: Screening

Form: Medical History (4)

Generated On: 11 Aug 2021 22:53:07

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:19:00
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:11:21
User entered '0'	(b) (4) Stanley Dublin (b) (4) (b) (4)	12 Sep 2020 19:03:50

US3552412

Folder: Screening

Form: Medical History (4)

Generated On: 11 Aug 2021 22:53:07

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:19:00
User entered 'Jan 2010'	System	12 Sep 2020 19:03:50

US3552412

Folder: Screening

Form: Medical History (4)

Generated On: 11 Aug 2021 22:53:07

Start Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:19:00
User entered '2010'	System	12 Sep 2020 19:03:50

US3552412

Folder: Screening

Form: Medical History (4)

Generated On: 11 Aug 2021 22:53:07

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:19:00
User entered empty.	System	12 Sep 2020 19:03:50

US3552412

Folder: Screening

Form: Medical History (4)

Generated On: 11 Aug 2021 22:53:07

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:19:00
User entered empty.	System	12 Sep 2020 19:03:50

US3552412

Folder: Screening

Form: Medical History (5)

Generated On: 11 Aug 2021 22:53:07

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:19:00
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:11:21
User coded data point as SOC: Skin and subcutaneous tissue disorders, HLGT: Skin appendage conditions, HLT: Acnes, PT: Acne, LLT: Acne - version MedDRA\23.0.	(b) (4) Coder Import (b) (4)	09 Oct 2020 15:30:29
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4)	09 Oct 2020 15:30:29
Data point term sent to Coder	System	09 Oct 2020 15:28:50
User entered 'acne'	Stanley Dublin (b) (4)	09 Oct 2020 15:28:01

US3552412

Folder: Screening

Form: Medical History (5)

Generated On: 11 Aug 2021 22:53:07

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:19:00
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:11:21
User entered 'un Jul 2020'	(b) (4) Stanley Dublin (b) (4) (b) (4)	09 Oct 2020 15:28:01

US3552412

Folder: Screening

Form: Medical History (5)

Generated On: 11 Aug 2021 22:53:07

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:19:00
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:11:21
User entered '0'	(b) (4) Stanley Dublin (b) (4) (b) (4)	09 Oct 2020 15:28:01

US3552412

Folder: Screening

Form: Medical History (5)

Generated On: 11 Aug 2021 22:53:07

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:19:00
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:11:21
User entered 'Yes (Y)'	(b) (4) Stanley Dublin (b) (4) (b) (4)	09 Oct 2020 15:28:01

US3552412

Folder: Screening

Form: Medical History (5)

Generated On: 11 Aug 2021 22:53:07

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:19:00
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:11:21
User entered empty.	(b) (4) Stanley Dublin (b) (4) (b) (4)	09 Oct 2020 15:28:01

US3552412

Folder: Screening

Form: Medical History (5)

Generated On: 11 Aug 2021 22:53:07

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:19:00
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:11:21
User entered '0'	(b) (4) Stanley Dublin (b) (4) (b) (4)	09 Oct 2020 15:28:01

US3552412

Folder: Screening

Form: Medical History (5)

Generated On: 11 Aug 2021 22:53:07

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:19:00
User entered 'Jul 2020'	System	09 Oct 2020 15:28:01

US3552412

Folder: Screening

Form: Medical History (5)

Generated On: 11 Aug 2021 22:53:07

Start Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:19:00
User entered '2020'	System	09 Oct 2020 15:28:01

US3552412

Folder: Screening

Form: Medical History (5)

Generated On: 11 Aug 2021 22:53:07

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:19:00
User entered empty.	System	09 Oct 2020 15:28:01

US3552412

Folder: Screening

Form: Medical History (5)

Generated On: 11 Aug 2021 22:53:07

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:19:00
User entered empty.	System	09 Oct 2020 15:28:01

US3552412

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:53:07

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:19:00
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:11:21
User entered 'Yes (Y)'	(b) (4) Stanley Dublin (b) (4) (b) (4)	12 Sep 2020 19:06:11

US3552412

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:53:07

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:19:00
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:11:21
User entered '11 Sep 2020'	(b) (4) Stanley Dublin (b) (4) (b) (4)	12 Sep 2020 19:06:11

US3552412

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:53:07

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:19:00
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:11:21
User entered '12:55'	(b) (4) Stanley Dublin (b) (4) (b) (4)	12 Sep 2020 19:06:11

US3552412

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:53:07

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:19:00
User entered '11 Sep 2020 12:55'	System	12 Sep 2020 19:06:11

US3552412

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:53:07

[Height \(xxx.x\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:19:00
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:11:21
User entered '66' in	(b) (4) Stanley Dublin (b) (4)	12 Sep 2020 19:06:11
DataPoint set to visible.	(b) (4) System	11 Sep 2020 19:00:34

US3552412

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:53:07

[Weight \(xxx.x\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:19:00
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:11:21
User entered '103.2' lb	(b) (4) Stanley Dublin (b) (4)	12 Sep 2020 19:06:11
DataPoint set to visible.	(b) (4) System	11 Sep 2020 19:00:34

US3552412

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:53:07

BMI (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:19:00
User entered '16.69174'	System	12 Sep 2020 19:06:11
DataPoint set to visible.	System	11 Sep 2020 19:00:34

US3552412

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:53:07

[BMI units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:19:00
User entered 'kg/m2'	System	12 Sep 2020 19:06:11
DataPoint set to visible.	System	11 Sep 2020 19:00:34

US3552412

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:53:07

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:19:00
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:11:21
User entered missing code ND - Not Done.	(b) (4) Stanley Dublin (b) (4) (b) (4)	12 Sep 2020 19:06:11

US3552412

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:53:07

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:19:00
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:11:21
User entered empty.	(b) (4) Stanley Dublin (b) (4) (b) (4)	12 Sep 2020 19:06:11

US3552412

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:53:07

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:19:00
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:11:21
User entered empty.	(b) (4) Stanley Dublin (b) (4) (b) (4)	12 Sep 2020 19:06:11

US3552412

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:53:07

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:19:00
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:11:21
User entered missing code ND - Not Done.	(b) (4) Stanley Dublin (b) (4) (b) (4)	12 Sep 2020 19:06:11

US3552412

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:53:07

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:19:00
User entered 'bpm'	System	12 Sep 2020 19:06:11

US3552412

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:53:07

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:19:00
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:11:21
User entered missing code ND - Not Done.	(b) (4) Stanley Doublin (b) (4) (b) (4)	12 Sep 2020 19:06:11

US3552412

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:53:07

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:19:00
User entered 'breaths/min'	System	12 Sep 2020 19:06:11

US3552412

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:53:07

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:19:00
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:11:21
User entered missing code ND - Not Done.	(b) (4) Stanley Dublin (b) (4) (b) (4)	12 Sep 2020 19:06:11

US3552412

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:53:07

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:19:00
User entered 'mmHg'	System	12 Sep 2020 19:06:11

US3552412

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:53:07

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:19:00
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:11:21
User entered missing code ND - Not Done.	(b) (4) Stanley Dublin (b) (4) (b) (4)	12 Sep 2020 19:06:11

US3552412

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:53:07

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:19:00
User entered 'mmHg'	System	12 Sep 2020 19:06:11

US3552412

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:53:07

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:19:00

US3552412

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:53:07

Weight (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:19:00

US3552412

Folder: Screening

Form: Physical Examination

Generated On: 11 Aug 2021 22:53:07

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:19:00
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:11:21
User entered 'Yes (Y)'	(b) (4) Stanley Dublin (b) (4) (b) (4)	12 Sep 2020 19:06:21

US3552412

Folder: Screening

Form: Physical Examination

Generated On: 11 Aug 2021 22:53:07

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:19:00
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:11:21
User closed query 'The Physical Examination Date is prior to the Screening Visit Date. Please review and reconcile.' (Site from System).	(b) (4) System	12 Sep 2020 19:08:02
User opened query 'The Physical Examination Date is prior to the Screening Visit Date. Please review and reconcile.' (Site from System).	System	12 Sep 2020 19:07:57
User entered '11 Sep 2020'	Stanley Doublin (b) (4)	12 Sep 2020 19:06:21
	(b) (4)	

US3552412

Folder: Screening

Form: Childbearing Potential

Generated On: 11 Aug 2021 22:53:07

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:19:00
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:11:21
User entered '11 Sep 2020'	(b) (4) Stanley Dublin (b) (4) (b) (4)	12 Sep 2020 19:06:33

US3552412

Folder: Screening

Form: Childbearing Potential

Generated On: 11 Aug 2021 22:53:07

[Is the participant of childbearing potential?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:19:00
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:11:21
User entered 'Yes (Y)'	(b) (4) Stanley Dublin (b) (4) (b) (4)	12 Sep 2020 19:06:33

US3552412

Folder: Screening

Form: Childbearing Potential

Generated On: 11 Aug 2021 22:53:07

[If No, what is the reason?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:19:00
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:11:21
User entered empty.	(b) (4) Stanley Dublin (b) (4) (b) (4)	12 Sep 2020 19:06:33

US3552412

Folder: Screening

Form: Childbearing Potential

Generated On: 11 Aug 2021 22:53:07

If Partner medically sterile or Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:19:00
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:11:21
User entered empty.	(b) (4) Stanley Dublin (b) (4) (b) (4)	12 Sep 2020 19:06:33

US3552412

Folder: Screening

Form: Childbearing Potential

Generated On: 11 Aug 2021 22:53:07

If Surgically sterile, date of surgery (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:19:00
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:11:21
User entered empty.	(b) (4) Stanley Dublin (b) (4) (b) (4)	12 Sep 2020 19:06:33

US3552412

Folder: Screening

Form: Childbearing Potential

Generated On: 11 Aug 2021 22:53:07

Date of surgery unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:19:00
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:11:21
User entered '0'	(b) (4) Stanley Dublin (b) (4) (b) (4)	12 Sep 2020 19:06:33

US3552412

Folder: Screening

Form: Childbearing Potential

Generated On: 11 Aug 2021 22:53:07

If Post-menopausal, date of last menstruation (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:19:00
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:11:21
User entered empty.	(b) (4) Stanley Dublin (b) (4) (b) (4)	12 Sep 2020 19:06:33

US3552412

Folder: Screening

Form: Childbearing Potential

Generated On: 11 Aug 2021 22:53:07

[Date of last menstruation unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:19:00
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:11:21
User entered '0'	(b) (4) Stanley Dublin (b) (4) (b) (4)	12 Sep 2020 19:06:33

US3552412

Folder: Screening

Form: Pregnancy Test

Generated On: 11 Aug 2021 22:53:07

[Was the pregnancy test performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:19:00
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:11:21
User entered 'Yes (Y)'	(b) (4) Stanley Dublin (b) (4)	12 Sep 2020 19:06:50

US3552412

Folder: Screening

Form: Pregnancy Test

Generated On: 11 Aug 2021 22:53:07

Date of test (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:19:00
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:11:21
User entered '11 Sep 2020'	(b) (4) Stanley Dublin (b) (4) (b) (4)	12 Sep 2020 19:06:50

US3552412

Folder: Screening

Form: Pregnancy Test

Generated On: 11 Aug 2021 22:53:07

[Test performed](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:19:00
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:11:21
User entered 'Urine (URINE)'	(b) (4) Stanley Dublin (b) (4) (b) (4)	12 Sep 2020 19:06:50

US3552412

Folder: Screening

Form: Pregnancy Test

Generated On: 11 Aug 2021 22:53:07

[Result](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:19:00
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:11:21
User entered 'Negative (NEGATIVE)'	(b) (4) Stanley Dublin (b) (4) (b) (4)	12 Sep 2020 19:06:50

US3552412

Folder: Screening

Form: Pregnancy Test

Generated On: 11 Aug 2021 22:53:07

[Was FSH sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:19:00
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:11:21
User entered 'No (N)'	(b) (4) Stanley Dublin (b) (4) (b) (4)	12 Sep 2020 19:06:50

US3552412

Folder: Screening

Form: Pregnancy Test

Generated On: 11 Aug 2021 22:53:07

[Collection date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:19:00
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:11:21
User entered empty.	(b) (4) Stanley Dublin (b) (4) (b) (4)	12 Sep 2020 19:06:50

US3552412

Folder: Screening

Form: Pregnancy Test

Generated On: 11 Aug 2021 22:53:07

[Collection time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:19:00
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:11:21
User entered empty.	(b) (4) Stanley Dublin (b) (4) (b) (4)	12 Sep 2020 19:06:50

US3552412

Folder: Screening

Form: Pregnancy Test

Generated On: 11 Aug 2021 22:53:07

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:19:00
User entered empty.	System	12 Sep 2020 19:06:50

US3552412

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:53:07

**Healthcare workers** (e.g., doctors, nurses, dentists, hospital support staff, morgue/mortuary workers)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:19:00
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:11:21
User entered 'Yes (Y)'	(b) (4) Stanley Dublin (b) (4) (b) (4)	12 Sep 2020 19:07:45

US3552412

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:53:07

**Emergency Response** (e.g., Law enforcement officers, Firefighters, emergency medical service workers)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:19:00
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:11:21
User entered 'No (N)'	(b) (4) Stanley Dublin (b) (4) (b) (4)	12 Sep 2020 19:07:45

US3552412

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:53:07

**Retail or Restaurant Operations**, particularly those in critical and/high-customer volume (e.g., grocery, convenience, hardware, big-box stores)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:19:00
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 19:11:21
User entered 'No (N)'	Stanley Doublin (b) (4) (b) (4)	12 Sep 2020 19:07:45

US3552412

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:53:07

**Manufacturing & Production Operations** with inherent overcrowding (e.g., factory workers, meat/food processing plants)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:19:00
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 19:11:21
User entered 'No (N)'	Stanley Dublin (b) (4) (b) (4)	12 Sep 2020 19:07:45

US3552412

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:53:07

Warehouse shipping and fulfillment centers and jobs (e.g., Amazon facilities)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:19:00
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:11:21
User entered 'No (N)'	(b) (4) Stanley Dublin (b) (4) (b) (4)	12 Sep 2020 19:07:45

US3552412

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:53:07

[Transportation and delivery services](#) (e.g., airlines, public transit, taxi/UBER, fed ex/UPS, postal workers)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:19:00
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 19:11:21
User entered 'No (N)'	Stanley Dublin (b) (4) (b) (4)	12 Sep 2020 19:07:45

US3552412

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:53:07

**Border Protection and Military Personnel** (e.g., TSA, custom and border protection agents, military personnel not social distancing)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:19:00
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 19:11:21
User entered 'No (N)'	Stanley Dublin (b) (4) (b) (4)	12 Sep 2020 19:07:45

US3552412

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:53:07

[Personal Care and in-home services](#) (e.g., barber/salon/spa, in-home repair services, electricians, plumbers, janitorial services)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:19:00
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 19:11:21
User entered 'No (N)'	Stanley Dublin (b) (4) (b) (4)	12 Sep 2020 19:07:45

US3552412

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:53:07

[Hospitality and Tourism Workers](#) (e.g., hotel, casino, amusement/theme park, entertainment, ski resorts)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:19:00
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:11:21
User entered 'No (N)'	(b) (4) Stanley Dublin (b) (4) (b) (4)	12 Sep 2020 19:07:45

US3552412

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:53:07

**Pastoral, Social or Public Health Workers** requiring frequent contact with community members (e.g., social workers, volunteers, religious clergy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:19:00
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 19:11:21
User entered 'No (N)'	Stanley Dublin (b) (4) (b) (4)	12 Sep 2020 19:07:45

US3552412

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:53:07

**Educators and Students** (e.g., teachers, administrators, support staff, and students interacting in face-to-face school setting)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:19:00
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 19:11:21
User entered 'No (N)'	Stanley Dublin (b) (4) (b) (4)	12 Sep 2020 19:07:45

US3552412

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:53:07

[Other](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:19:00
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:11:21
User entered 'Yes (Y)'	(b) (4) Stanley Dublin (b) (4) (b) (4)	12 Sep 2020 19:07:45

US3552412

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:53:07

[Specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:19:00
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 19:11:21
User entered 'physician assistant - (b) (6) (b) (6) , shopping, child in daycare'	Stanley Dublin (b) (4) (b) (4)	12 Sep 2020 19:07:45

US3552412

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:53:07

No Risk Identified

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:19:00
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:11:21
User entered '0'	(b) (4) Stanley Dublin (b) (4) (b) (4)	12 Sep 2020 19:07:45

US3552412

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:53:07

[Resides in Nursing Home or Assisted Living Facility](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:19:00
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:11:21
User entered '0'	(b) (4) Stanley Dublin (b) (4) (b) (4)	12 Sep 2020 19:07:45

US3552412

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:53:07

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:19:00
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 19:11:21
User entered '0'	Stanley Dublin (b) (4) (b) (4)	12 Sep 2020 19:07:45

US3552412

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:53:07

[Resides in high density housing](#) (e.g., high rise apartments with shared entrances or elevators)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:19:00
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:11:21
User entered '0'	(b) (4) Stanley Dublin (b) (4) (b) (4)	12 Sep 2020 19:07:45

US3552412

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:53:07

Resides in low density, multi-family setting without (e.g., apartments complex without shared entrances or elevators, duplexes)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:19:00
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:11:21
User entered '0'	(b) (4) Stanley Dublin (b) (4) (b) (4)	12 Sep 2020 19:07:45

US3552412

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:53:07

[Resides in a single family home](#) (i.e., detached housing)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:19:00
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:11:21
User entered 'l'	(b) (4) Stanley Dublin (b) (4) (b) (4)	12 Sep 2020 19:07:45

US3552412

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:53:07

[Other](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:19:00
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:11:21
User entered '0'	(b) (4) Stanley Dublin (b) (4) (b) (4)	12 Sep 2020 19:07:45

US3552412

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:53:07

[Specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:19:00
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:11:21
User entered empty.	(b) (4) Stanley Dublin (b) (4) (b) (4)	12 Sep 2020 19:07:45

US3552412

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 11 Aug 2021 22:53:07

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 11:14:37
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 19:11:21
User entered 'Yes (Y)'	Stanley Dublin (b) (4) (b) (4)	12 Sep 2020 19:07:57

US3552412

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 11 Aug 2021 22:53:07

Visit date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 11:14:37
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:11:21
User closed query 'Visit 1 Date is not equal to the Visit 1 Treatment Date. Please reconcile or confirm dates.' (Site from System).	(b) (4)	
	System	12 Sep 2020 19:08:02
Query 'Visit 1 Date is not equal to the Visit 1 Treatment Date. Please reconcile or confirm dates.' answered by data change (Site from System).	System	12 Sep 2020 19:08:02
User entered '11 Sep 2020' reason for change: Data Entry Error	Stanley Dublin (b) (4)	12 Sep 2020 19:08:02
	(b) (4)	
User opened query 'Visit 1 Date is not equal to the Visit 1 Treatment Date. Please reconcile or confirm dates.' (Site from System).	System	12 Sep 2020 19:07:57
User entered '12 Sep 2020'	Stanley Dublin (b) (4)	12 Sep 2020 19:07:57
	(b) (4)	

US3552412

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 11 Aug 2021 22:53:07

[Was visit performed at the participant's home or at the clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 11:14:37
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:11:21
User entered 'Clinic (Clinic)'	(b) (4) Stanley Dublin (b) (4) (b) (4)	12 Sep 2020 19:07:57

US3552412

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 11 Aug 2021 22:53:07

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 11:14:37
User entered 'VISIT1'	System	12 Sep 2020 19:07:57

US3552412

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 11 Aug 2021 22:53:07

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 11:14:37
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:11:21
User closed query 'The Randomization Date is not equal to Visit Date. Please review and reconcile.' (Site from System).	(b) (4)	12 Sep 2020 19:08:02
Query 'The Randomization Date is not equal to Visit Date. Please review and reconcile.' answered by data change (Site from System).	System	12 Sep 2020 19:08:02
User opened query 'The Randomization Date is not equal to Visit Date. Please review and reconcile.' (Site from System).	System	12 Sep 2020 19:07:57
User entered '11 SEP 2020'	RWS_ENDPOINT ENDPOINT (b) (4)	11 Sep 2020 18:31:16

US3552412

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 11 Aug 2021 22:53:07

[What was the participant's randomization number?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 11:14:37
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 19:11:21
User entered '113394'	RWS_ENDPOINT ENDPOINT (b) (4)	11 Sep 2020 18:31:16

US3552412

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 11 Aug 2021 22:53:07

[In what Cohort was the participant enrolled?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 11:14:37
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 19:11:21
User entered '>=18 and <65 years and not at risk (1)'	RWS_ENDPOINT ENDPOINT (b) (4)	11 Sep 2020 18:31:16

US3552412

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 11 Aug 2021 22:53:07

Chronic lung disease (eg, emphysema and chronic bronchitis, idiopathic pulmonary fibrosis and cystic fibrosis, or moderate to severe asthma)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 11:14:37
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 19:11:21
User entered 'No (N)'	Stanley Dublin (b) (4) (b) (4)	12 Sep 2020 19:08:12

US3552412

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 11 Aug 2021 22:53:07

Significant cardiac disease (eg, heart failure, coronary artery disease, congenital heart disease, cardiomyopathies, and pulmonary hypertension)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 11:14:37
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 19:11:21
User entered 'No (N)'	Stanley Dublin (b) (4) (b) (4)	12 Sep 2020 19:08:12

US3552412

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 11 Aug 2021 22:53:07

Severe obesity (body mass index > or = 40kg/m2

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 11:14:37
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 19:11:21
User entered 'No (N)'	Stanley Dublin (b) (4) (b) (4)	12 Sep 2020 19:08:12

US3552412

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 11 Aug 2021 22:53:07

Diabetes (Type I, Type 2, or gestational)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 11:14:37
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 19:11:21
User entered 'No (N)'	Stanley Dublin (b) (4) (b) (4)	12 Sep 2020 19:08:12

US3552412

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 11 Aug 2021 22:53:07

[Liver Disease](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 11:14:37
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 19:11:21
User entered 'No (N)'	Stanley Dublin (b) (4) (b) (4)	12 Sep 2020 19:08:12

US3552412

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 11 Aug 2021 22:53:07

[Human Immunodeficiency Virus \(HIV\) infection](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 11:14:37
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:11:21
User entered 'No (N)'	(b) (4)	
	Stanley Doublin (b) (4)	21 Sep 2020 18:10:53
	(b) (4)	
Amendment Manager: DataPoint set to visible.	System	19 Sep 2020 06:14:19
Amendment Manager inserted this DataPoint.	System	19 Sep 2020 06:14:17

US3552412

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 11 Aug 2021 22:53:07

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 11:14:37
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 19:11:21
User entered missing code ND - Not Done.	Stanley Dublin (b) (4) (b) (4)	12 Sep 2020 19:09:04

US3552412

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 11 Aug 2021 22:53:07

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 11:14:37
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 19:11:21
User entered missing code ND - Not Done.	Stanley Dublin (b) (4) (b) (4)	12 Sep 2020 19:09:04

US3552412

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 11 Aug 2021 22:53:07

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 11:14:37
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 19:11:21
User entered missing code ND - Not Done.	Stanley Dublin (b) (4) (b) (4)	12 Sep 2020 19:09:04

US3552412

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 11 Aug 2021 22:53:07

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 11:14:37
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 19:11:21
User entered missing code ND - Not Done.	Stanley Dublin (b) (4) (b) (4)	12 Sep 2020 19:09:04

US3552412

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:53:07

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 11:14:37
User accepted default value 'Pre-Dose (PREDOSE)'	Stanley Doublin (b) (4) (b) (4)	12 Sep 2020 19:09:04

US3552412

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:53:07

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 11:14:37
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 19:11:21
User entered 'Yes (Y)'	Stanley Dublin (b) (4) (b) (4)	12 Sep 2020 19:09:04

US3552412

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:53:07

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 11:14:37
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:11:21
User entered '11 Sep 2020'	(b) (4) Stanley Dublin (b) (4) (b) (4)	12 Sep 2020 19:09:04

US3552412

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:53:07

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 11:14:37
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 19:11:21
User entered '12:55'	Stanley Dublin (b) (4) (b) (4)	12 Sep 2020 19:09:04

US3552412

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:53:07

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 11:14:37
User entered '11 Sep 2020 12:55'	System	12 Sep 2020 19:09:04

US3552412

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:53:07

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 11:14:37
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 19:11:21
User entered '97.6' F	Stanley Dublin (b) (4) (b) (4)	12 Sep 2020 19:09:04

US3552412

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:53:07

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 11:14:37
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 19:11:21
User entered 'Oral (Oral)'	Stanley Dublin (b) (4) (b) (4)	12 Sep 2020 19:09:04

US3552412

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:53:07

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 11:14:37
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 19:11:21
User entered empty.	Stanley Dublin (b) (4) (b) (4)	12 Sep 2020 19:09:04

US3552412

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:53:07

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 11:14:37
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 19:11:21
User entered '82'	Stanley Dublin (b) (4) (b) (4)	12 Sep 2020 19:09:04

US3552412

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:53:07

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 11:14:37
User entered 'bpm'	System	12 Sep 2020 19:09:04

US3552412

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:53:07

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 11:14:37
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 19:11:21
User entered '14'	Stanley Dublin (b) (4) (b) (4)	12 Sep 2020 19:09:04

US3552412

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:53:07

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 11:14:37
User entered 'breaths/min'	System	12 Sep 2020 19:09:04

US3552412

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:53:07

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 11:14:37
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 19:11:21
User entered '100'	Stanley Dublin (b) (4) (b) (4)	12 Sep 2020 19:09:04

US3552412

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:53:07

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 11:14:37
User entered 'mmHg'	System	12 Sep 2020 19:09:04

US3552412

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:53:07

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 11:14:37
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 19:11:21
User closed query 'Diastolic Blood Pressure reported is out of range < 60 or > 110 per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' (Site from System).	(b) (4), (b) (6)	23 Sep 2020 04:16:58
Query 'Diastolic Blood Pressure reported is out of range < 60 or > 110 per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' answered with 'NCS' (Site from System).	Heather Douds (b) (4) (b) (4)	22 Sep 2020 14:21:49
Amendment Manager: User opened query 'Diastolic Blood Pressure reported is out of range < 60 or > 110 per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' (Site from System).	System	17 Sep 2020 00:33:40
User entered '56'	Stanley Doublin (b) (4) (b) (4)	12 Sep 2020 19:09:04

US3552412

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:53:07

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 11:14:37
User entered 'mmHg'	System	12 Sep 2020 19:09:04

US3552412

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 11 Aug 2021 22:53:07

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 11:14:37
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 19:11:21
User entered missing code ND - Not Done.	Stanley Dublin (b) (4) (b) (4)	12 Sep 2020 19:09:04

US3552412

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 11 Aug 2021 22:53:07

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 11:14:37
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 19:11:21
User entered missing code ND - Not Done.	Stanley Dublin (b) (4) (b) (4)	12 Sep 2020 19:09:04

US3552412

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:53:07

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 11:14:37
User accepted default value 'Post-Dose (POSTDOSE)'	Stanley Doublin (b) (4) (b) (4)	12 Sep 2020 19:09:34

US3552412

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:53:07

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 11:14:37
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 19:11:21
User entered 'Yes (Y)'	Stanley Dublin (b) (4) (b) (4)	12 Sep 2020 19:09:34

US3552412

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:53:07

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 11:14:37
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:11:21
User entered '11 Sep 2020'	(b) (4) Stanley Dublin (b) (4) (b) (4)	12 Sep 2020 19:09:34

US3552412

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:53:07

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 11:14:37
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 19:11:21
User entered '14:26'	Stanley Dublin (b) (4) (b) (4)	12 Sep 2020 19:09:34

US3552412

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:53:07

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 11:14:37
User entered '11 Sep 2020 14:26'	System	12 Sep 2020 19:09:34

US3552412

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:53:07

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 11:14:37
User signature succeeded.	sharon trey (b) (4) (b) (4)	21 Feb 2021 19:11:21
User closed query 'Temperature reported is out of range < 36C (96.8 F) per protocol considered grade 3 Please indicate if CS/NCS and report as AE, if appropriate.' (Site from System).	(b) (4), (b) (6)	23 Sep 2020 04:17:08
Query 'Temperature reported is out of range < 36C (96.8 F) per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.'	Heather Douds (b) (4) (b) (4)	22 Sep 2020 14:22:18
answered with 'NCS' (Site from System).		
Amendment Manager: User opened query 'Temperature reported is out of range < 36C (96.8 F) per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' (Site from System).	System	17 Sep 2020 00:33:40
User entered '96.5' F	Stanley Dublin (b) (4) (b) (4)	12 Sep 2020 19:09:34

US3552412

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:53:07

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 11:14:37
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 19:11:21
User entered 'Oral (Oral)'	Stanley Dublin (b) (4) (b) (4)	12 Sep 2020 19:09:34

US3552412

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:53:07

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 11:14:37
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 19:11:21
User entered empty.	Stanley Dublin (b) (4) (b) (4)	12 Sep 2020 19:09:34

US3552412

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:53:07

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 11:14:37
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 19:11:21
User entered '69'	Stanley Dublin (b) (4) (b) (4)	12 Sep 2020 19:09:34

US3552412

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:53:07

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 11:14:37
User entered 'bpm'	System	12 Sep 2020 19:09:34

US3552412

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:53:07

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 11:14:37
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 19:11:21
User entered '16'	Stanley Dublin (b) (4) (b) (4)	12 Sep 2020 19:09:34

US3552412

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:53:07

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 11:14:37
User entered 'breaths/min'	System	12 Sep 2020 19:09:34

US3552412

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:53:07

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 11:14:37
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 19:11:21
User entered '97'	Stanley Dublin (b) (4) (b) (4)	12 Sep 2020 19:09:34

US3552412

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:53:07

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 11:14:37
User entered 'mmHg'	System	12 Sep 2020 19:09:34

US3552412

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:53:07

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 11:14:37
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 19:11:21
User entered '68'	Stanley Dublin (b) (4) (b) (4)	12 Sep 2020 19:09:34

US3552412

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:53:07

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 11:14:37
User entered 'mmHg'	System	12 Sep 2020 19:09:34

US3552412

Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 11 Aug 2021 22:53:07

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 11:14:37
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 19:11:21
User entered 'No (N)'	Stanley Dublin (b) (4) (b) (4)	12 Sep 2020 19:09:43

US3552412

Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 11 Aug 2021 22:53:07

Date of examination (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 11:14:37
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 19:11:21
User entered empty.	Stanley Dublin (b) (4) (b) (4)	12 Sep 2020 19:09:43

US3552412

Folder: Visit 1 Day 1

Form: Pregnancy Test

Generated On: 11 Aug 2021 22:53:07

[Was the pregnancy test performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 11:14:37
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 19:11:21
User entered 'No (N)'	Stanley Dublin (b) (4) (b) (4)	12 Sep 2020 19:09:50

US3552412

Folder: Visit 1 Day 1

Form: Pregnancy Test

Generated On: 11 Aug 2021 22:53:07

Date of test (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 11:14:37
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 19:11:21
User entered empty.	Stanley Dublin (b) (4) (b) (4)	12 Sep 2020 19:09:50

US3552412

Folder: Visit 1 Day 1

Form: Pregnancy Test

Generated On: 11 Aug 2021 22:53:07

[Test performed](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 11:14:37
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 19:11:21
User entered empty.	Stanley Dublin (b) (4) (b) (4)	12 Sep 2020 19:09:50

US3552412

Folder: Visit 1 Day 1

Form: Pregnancy Test

Generated On: 11 Aug 2021 22:53:07

[Result](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 11:14:37
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 19:11:21
User entered empty.	Stanley Dublin (b) (4) (b) (4)	12 Sep 2020 19:09:50

US3552412

Folder: Visit 1 Day 1

Form: Pregnancy Test

Generated On: 11 Aug 2021 22:53:07

[Was FSH sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 11:14:37
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 19:11:21
User entered 'No (N)'	Stanley Dublin (b) (4) (b) (4)	12 Sep 2020 19:09:50

US3552412

Folder: Visit 1 Day 1

Form: Pregnancy Test

Generated On: 11 Aug 2021 22:53:07

[Collection date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 11:14:37
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 19:11:21
User entered empty.	Stanley Dublin (b) (4) (b) (4)	12 Sep 2020 19:09:50

US3552412

Folder: Visit 1 Day 1

Form: Pregnancy Test

Generated On: 11 Aug 2021 22:53:07

[Collection time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 11:14:37
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 19:11:21
User entered empty.	Stanley Dublin (b) (4) (b) (4)	12 Sep 2020 19:09:50

US3552412

Folder: Visit 1 Day 1

Form: Pregnancy Test

Generated On: 11 Aug 2021 22:53:07

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 11:14:37
User entered empty.	System	12 Sep 2020 19:09:50

US3552412

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 11 Aug 2021 22:53:07

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 11:14:37
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:11:21
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	11 Sep 2020 19:01:06

US3552412

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 11 Aug 2021 22:53:07

[If No, reason not given](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 11:14:37
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 19:11:21
User entered empty.	(b) (4), (b) (6)	11 Sep 2020 19:01:06

US3552412

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 11 Aug 2021 22:53:07

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 11:14:37
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:11:21
User entered empty.	(b) (4), (b) (6)	11 Sep 2020 19:01:06

US3552412

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 11 Aug 2021 22:53:07

[What was the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 11:14:37
User entered 'MRNA-1273 OR PLACEBO'	System	11 Sep 2020 19:01:06

US3552412

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 11 Aug 2021 22:53:07

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 11:14:37
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:11:21
User closed query 'The Treatment Date is not equal to the Visit Date. Please review and reconcile.' (Site from System).	(b) (4)	12 Sep 2020 19:08:02
Query 'The Treatment Date is not equal to the Visit Date. Please review and reconcile.' answered by data change (Site from System).	System	12 Sep 2020 19:08:02
User opened query 'The Treatment Date is not equal to the Visit Date. Please review and reconcile.' (Site from System).	System	12 Sep 2020 19:07:57
User entered '11 Sep 2020'	(b) (4), (b) (6)	11 Sep 2020 19:01:06

US3552412

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 11 Aug 2021 22:53:07

[What was the treatment time? \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 11:14:37
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 19:11:21
User entered '13:56'	(b) (4), (b) (6)	11 Sep 2020 19:01:06

US3552412

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 11 Aug 2021 22:53:07

[Treatment Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 11:14:37
User entered '11 Sep 2020 13:56'	System	11 Sep 2020 19:01:06

US3552412

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 11 Aug 2021 22:53:07

[Which arm was used to give treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 11:14:37
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:11:21
User entered 'Left Arm (LEFT ARM)'	(b) (4) (b) (4), (b) (6)	11 Sep 2020 19:01:06

US3552412

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 11 Aug 2021 22:53:07

[What was the frequency of the study treatment dosing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 11:14:37
User entered 'ONCE'	System	11 Sep 2020 19:01:06

US3552412

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 11 Aug 2021 22:53:07

What was the route of administration for the study treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 11:14:37
User entered 'INTRAMUSCULAR'	System	11 Sep 2020 19:01:06

US3552412

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:53:07

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 11:14:37
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 19:11:21
User entered 'Yes (Y)'	Stanley Dublin (b) (4) (b) (4)	12 Sep 2020 19:10:02

US3552412

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:53:07

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 11:14:37
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:11:21
User entered '11 Sep 2020'	(b) (4) Stanley Dublin (b) (4) (b) (4)	12 Sep 2020 19:10:02

US3552412

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:53:07

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 11:14:37
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 19:11:21
User entered '13:21'	Stanley Dublin (b) (4) (b) (4)	12 Sep 2020 19:10:02

US3552412

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:53:07

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 11:14:37
User entered '11 Sep 2020 13:21'	System	12 Sep 2020 19:10:02

US3552412

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 11 Aug 2021 22:53:07

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 11:14:37
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:11:21
User entered '11 Sep 2020'	(b) (4) Stanley Dublin (b) (4) (b) (4)	12 Sep 2020 19:10:17

US3552412

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 11 Aug 2021 22:53:07

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 11:14:37
User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)'	Stanley Doublin (b) (4) (b) (4)	12 Sep 2020 19:10:17

US3552412

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 11 Aug 2021 22:53:07

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 11:14:37
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 19:11:21
User entered 'Yes (Y)'	Stanley Dublin (b) (4) (b) (4)	12 Sep 2020 19:10:17

US3552412

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 11 Aug 2021 22:53:07

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 11:14:37
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 19:11:21
User entered '13:25'	Stanley Dublin (b) (4) (b) (4)	12 Sep 2020 19:10:17

US3552412

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 11 Aug 2021 22:53:07

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 11:14:37
User entered '11 Sep 2020 13:25'	System	12 Sep 2020 19:10:17

US3552412

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 11 Aug 2021 22:53:07

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 11:14:37
User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)'	Stanley Dublin (b) (4) (b) (4)	12 Sep 2020 19:10:17

US3552412

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 11 Aug 2021 22:53:07

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 11:14:37
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 19:11:21
User entered 'No (N)'	Stanley Dublin (b) (4) (b) (4)	12 Sep 2020 19:10:17

US3552412

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 11 Aug 2021 22:53:07

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 11:14:37
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 19:11:21
User entered empty.	Stanley Dublin (b) (4) (b) (4)	12 Sep 2020 19:10:17

US3552412

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 11 Aug 2021 22:53:07

Collection date and time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 11:14:37
User entered empty.	System	12 Sep 2020 19:10:17

US3552412

Folder: Visit 1 Day 1

Form: Continuing

Generated On: 11 Aug 2021 22:53:07

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 11:14:37
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 19:11:21
User entered 'Yes (Y)'	Mikayla Frye (b) (4) (b) (4)	18 Sep 2020 17:03:42

US3552412

Folder: Visit 1 Day 1

Form: Continuing

Generated On: 11 Aug 2021 22:53:07

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 11:14:37
User entered 'l'	System	18 Sep 2020 17:03:42

US3552412

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/1)

Generated On: 11 Aug 2021 22:53:07

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:25:24
Data entry locked.	System	11 Sep 2020 19:01:06
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	11 Sep 2020 19:01:06

US3552412

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/1)

Generated On: 11 Aug 2021 22:53:07

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:25:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7f466cdad72abdb)', Time: '2020-09-11T14:29:17', User OID: 'PatientReportedOutcome (US3552412)', ODM File OID: 'a9d6e817-3461-44e0-ad73-ade83ab695dc'	System	11 Sep 2020 19:29:37
User entered 'Yes (Y)'	System	11 Sep 2020 19:29:37

US3552412

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/1)

Generated On: 11 Aug 2021 22:53:07

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:25:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7f466cdad72abdb)', Time: '2020-09-11T14:29:25', User OID: 'PatientReportedOutcome (US3552412)', ODM File OID: 'a9d6e817-3461-44e0-ad73-ade83ab695dc'	System	11 Sep 2020 19:29:37
User entered '96.5'	System	11 Sep 2020 19:29:37

US3552412

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/1)

Generated On: 11 Aug 2021 22:53:07

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:25:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7f466cdad72abdb)', Time: '2020-09-11T14:29:28', User OID: 'PatientReportedOutcome (US3552412)', ODM File OID: 'a9d6e817-3461-44e0-ad73-ade83ab695dc'	System	11 Sep 2020 19:29:37
User entered 'No (N)'	System	11 Sep 2020 19:29:37

US3552412

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/1)

Generated On: 11 Aug 2021 22:53:07

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:25:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7f466cdad72abdb)', Time: '2020-09-11T14:29:31', User OID: 'PatientReportedOutcome (US3552412)', ODM File OID: 'a9d6e817-3461-44e0-ad73-ade83ab695dc'	System	11 Sep 2020 19:29:37
User entered '11 Sep 2020 14:29'	System	11 Sep 2020 19:29:37

US3552412

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/1)

Generated On: 11 Aug 2021 22:53:07

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:25:24
User entered '11 Sep 2020 14:16'	System	11 Sep 2020 19:01:06

US3552412

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/1)

Generated On: 11 Aug 2021 22:53:07

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:25:24
User entered '11 Sep 2020 16:46'	System	11 Sep 2020 19:01:06

US3552412

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/2)

Generated On: 11 Aug 2021 22:53:07

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:25:24
Data entry locked.	System	11 Sep 2020 19:01:06
User entered 'Day 1, after vaccination (at home)'	System	11 Sep 2020 19:01:06

US3552412

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/2)

Generated On: 11 Aug 2021 22:53:07

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:25:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7f466cdad72abdb)', Time: '2020-09-11T21:39:51', User OID: 'PatientReportedOutcome (US3552412)', ODM File OID: '18eb6ab8-914c-4896-b000-1374114616d3'	System	12 Sep 2020 02:40:09
User entered 'Yes (Y)'	System	12 Sep 2020 02:40:09

US3552412

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/2)

Generated On: 11 Aug 2021 22:53:07

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:25:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7f466cdad72abdb)', Time: '2020-09-11T21:39:56', User OID: 'PatientReportedOutcome (US3552412)', ODM File OID: '18eb6ab8-914c-4896-b000-1374114616d3'	System	12 Sep 2020 02:40:09
User entered '97.2'	System	12 Sep 2020 02:40:09

US3552412

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/2)

Generated On: 11 Aug 2021 22:53:07

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:25:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7f466cdad72abdb)', Time: '2020-09-11T21:39:58', User OID: 'PatientReportedOutcome (US3552412)', ODM File OID: '18eb6ab8-914c-4896-b000-1374114616d3'	System	12 Sep 2020 02:40:09
User entered 'No (N)'	System	12 Sep 2020 02:40:09

US3552412

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/2)

Generated On: 11 Aug 2021 22:53:07

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:25:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7f466cdad72abdb)', Time: '2020-09-11T21:40:01', User OID: 'PatientReportedOutcome (US3552412)', ODM File OID: '18eb6ab8-914c-4896-b000-1374114616d3'	System	12 Sep 2020 02:40:09
User entered '11 Sep 2020 21:40'	System	12 Sep 2020 02:40:09

US3552412

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/2)

Generated On: 11 Aug 2021 22:53:07

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:25:24
User entered '11 Sep 2020 17:41'	System	11 Sep 2020 19:01:06

US3552412

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/2)

Generated On: 11 Aug 2021 22:53:07

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:25:24
User entered '12 Sep 2020 11:59'	System	11 Sep 2020 19:01:06

US3552412

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(2)

Generated On: 11 Aug 2021 22:53:07

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:25:24
Data entry locked.	System	11 Sep 2020 19:01:06
User entered 'Day 2'	System	11 Sep 2020 19:01:06

US3552412

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(2)

Generated On: 11 Aug 2021 22:53:07

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:25:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7f466cdad72abdb)', Time: '2020-09-12T21:18:44', User OID: 'PatientReportedOutcome (US3552412)', ODM File OID: 'db10309b-8c6d-4816-9616-4ecb3d278fda'	System	13 Sep 2020 02:19:00
User entered 'Yes (Y)'	System	13 Sep 2020 02:19:00

US3552412

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(2)

Generated On: 11 Aug 2021 22:53:07

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:25:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7f466cdad72abdb)', Time: '2020-09-12T21:18:51', User OID: 'PatientReportedOutcome (US3552412)', ODM File OID: 'db10309b-8c6d-4816-9616-4ecb3d278fda'	System	13 Sep 2020 02:19:00
User entered '97.2'	System	13 Sep 2020 02:19:00

US3552412

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(2)

Generated On: 11 Aug 2021 22:53:07

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:25:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7f466cdad72abdb)', Time: '2020-09-12T21:18:54', User OID: 'PatientReportedOutcome (US3552412)', ODM File OID: 'db10309b-8c6d-4816-9616-4ecb3d278fda'	System	13 Sep 2020 02:19:00
User entered 'No (N)'	System	13 Sep 2020 02:19:00

US3552412

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(2)

Generated On: 11 Aug 2021 22:53:07

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:25:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7f466cdad72abdb)', Time: '2020-09-12T21:18:56', User OID: 'PatientReportedOutcome (US3552412)', ODM File OID: 'db10309b-8c6d-4816-9616-4ecb3d278fda'	System	13 Sep 2020 02:19:00
User entered '12 Sep 2020 21:18'	System	13 Sep 2020 02:19:00

US3552412

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(2)

Generated On: 11 Aug 2021 22:53:07

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:25:24
User entered '12 Sep 2020 12:00'	System	11 Sep 2020 19:01:06

US3552412

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(2)

Generated On: 11 Aug 2021 22:53:07

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:25:24
User entered '13 Sep 2020 11:59'	System	11 Sep 2020 19:01:06

US3552412

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(3)

Generated On: 11 Aug 2021 22:53:07

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:25:24
Data entry locked.	System	11 Sep 2020 19:01:06
User entered 'Day 3'	System	11 Sep 2020 19:01:06

US3552412

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(3)

Generated On: 11 Aug 2021 22:53:07

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:25:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7f466cdad72abdb)', Time: '2020-09-13T21:45:27', User OID: 'PatientReportedOutcome (US3552412)', ODM File OID: '205353cd-7f32-4b4d-860d-7a698b7f4830'	System	14 Sep 2020 02:45:53
User entered 'Yes (Y)'	System	14 Sep 2020 02:45:53

US3552412

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(3)

Generated On: 11 Aug 2021 22:53:07

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:25:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7f466cdad72abdb)', Time: '2020-09-13T21:45:43', User OID: 'PatientReportedOutcome (US3552412)', ODM File OID: '205353cd-7f32-4b4d-860d-7a698b7f4830'	System	14 Sep 2020 02:45:53
User entered '97.4'	System	14 Sep 2020 02:45:53

US3552412

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(3)

Generated On: 11 Aug 2021 22:53:07

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:25:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7f466cdad72abdb)', Time: '2020-09-13T21:45:47', User OID: 'PatientReportedOutcome (US3552412)', ODM File OID: '205353cd-7f32-4b4d-860d-7a698b7f4830'	System	14 Sep 2020 02:45:53
User entered 'No (N)'	System	14 Sep 2020 02:45:53

US3552412

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(3)

Generated On: 11 Aug 2021 22:53:07

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:25:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7f466cdad72abdb)', Time: '2020-09-13T21:45:49', User OID: 'PatientReportedOutcome (US3552412)', ODM File OID: '205353cd-7f32-4b4d-860d-7a698b7f4830'	System	14 Sep 2020 02:45:53
User entered '13 Sep 2020 21:45'	System	14 Sep 2020 02:45:53

US3552412

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(3)

Generated On: 11 Aug 2021 22:53:07

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:25:24
User entered '13 Sep 2020 12:00'	System	11 Sep 2020 19:01:06

US3552412

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(3)

Generated On: 11 Aug 2021 22:53:07

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:25:24
User entered '14 Sep 2020 11:59'	System	11 Sep 2020 19:01:06

US3552412

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(4)

Generated On: 11 Aug 2021 22:53:07

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:25:24
Data entry locked.	System	11 Sep 2020 19:01:06
User entered 'Day 4'	System	11 Sep 2020 19:01:06

US3552412

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(4)

Generated On: 11 Aug 2021 22:53:07

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:25:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7f466cdad72abdb)', Time: '2020-09-14T21:37:45', User OID: 'PatientReportedOutcome (US3552412)', ODM File OID: '324b755e-abc5-40aa-b7ad-a9eeba42a28c'	System	15 Sep 2020 02:38:00
User entered 'Yes (Y)'	System	15 Sep 2020 02:38:00

US3552412

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(4)

Generated On: 11 Aug 2021 22:53:07

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:25:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7f466cdad72abdb)', Time: '2020-09-14T21:37:50', User OID: 'PatientReportedOutcome (US3552412)', ODM File OID: '324b755e-abc5-40aa-b7ad-a9eeba42a28c'	System	15 Sep 2020 02:38:00
User entered '96.8'	System	15 Sep 2020 02:38:00

US3552412

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(4)

Generated On: 11 Aug 2021 22:53:07

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:25:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7f466cdad72abdb)', Time: '2020-09-14T21:37:52', User OID: 'PatientReportedOutcome (US3552412)', ODM File OID: '324b755e-abc5-40aa-b7ad-a9eeba42a28c'	System	15 Sep 2020 02:38:00
User entered 'No (N)'	System	15 Sep 2020 02:38:00

US3552412

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(4)

Generated On: 11 Aug 2021 22:53:07

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:25:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7f466cdad72abdb)', Time: '2020-09-14T21:37:54', User OID: 'PatientReportedOutcome (US3552412)', ODM File OID: '324b755e-abc5-40aa-b7ad-a9eeba42a28c'	System	15 Sep 2020 02:38:00
User entered '14 Sep 2020 21:37'	System	15 Sep 2020 02:38:00

US3552412

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(4)

Generated On: 11 Aug 2021 22:53:07

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:25:24
User entered '14 Sep 2020 12:00'	System	11 Sep 2020 19:01:06

US3552412

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(4)

Generated On: 11 Aug 2021 22:53:07

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:25:24
User entered '15 Sep 2020 11:59'	System	11 Sep 2020 19:01:06

US3552412

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(5)

Generated On: 11 Aug 2021 22:53:07

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:25:24
Data entry locked.	System	11 Sep 2020 19:01:06
User entered 'Day 5'	System	11 Sep 2020 19:01:06

US3552412

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(5)

Generated On: 11 Aug 2021 22:53:07

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:25:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7f466cdad72abdb)', Time: '2020-09-15T21:18:46', User OID: 'PatientReportedOutcome (US3552412)', ODM File OID: 'dd16af43-29ec-471b-9332-165fb0f6e79f'	System	16 Sep 2020 02:18:57
User entered 'Yes (Y)'	System	16 Sep 2020 02:18:57

US3552412

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(5)

Generated On: 11 Aug 2021 22:53:07

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:25:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7f466cdad72abdb)', Time: '2020-09-15T21:18:50', User OID: 'PatientReportedOutcome (US3552412)', ODM File OID: 'dd16af43-29ec-471b-9332-165fb0f6e79f'	System	16 Sep 2020 02:18:57
User entered '97.8'	System	16 Sep 2020 02:18:57

US3552412

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(5)

Generated On: 11 Aug 2021 22:53:07

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:25:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7f466cdad72abdb)', Time: '2020-09-15T21:18:52', User OID: 'PatientReportedOutcome (US3552412)', ODM File OID: 'dd16af43-29ec-471b-9332-165fb0f6e79f'	System	16 Sep 2020 02:18:57
User entered 'No (N)'	System	16 Sep 2020 02:18:57

US3552412

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(5)

Generated On: 11 Aug 2021 22:53:07

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:25:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7f466cdad72abdb)', Time: '2020-09-15T21:18:54', User OID: 'PatientReportedOutcome (US3552412)', ODM File OID: 'dd16af43-29ec-471b-9332-165fb0f6e79f'	System	16 Sep 2020 02:18:57
User entered '15 Sep 2020 21:18'	System	16 Sep 2020 02:18:57

US3552412

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(5)

Generated On: 11 Aug 2021 22:53:07

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:25:24
User entered '15 Sep 2020 12:00'	System	11 Sep 2020 19:01:06

US3552412

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(5)

Generated On: 11 Aug 2021 22:53:07

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:25:24
User entered '16 Sep 2020 11:59'	System	11 Sep 2020 19:01:06

US3552412

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(6)

Generated On: 11 Aug 2021 22:53:07

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:25:24
Data entry locked.	System	11 Sep 2020 19:01:06
User entered 'Day 6'	System	11 Sep 2020 19:01:06

US3552412

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(6)

Generated On: 11 Aug 2021 22:53:07

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:25:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7f466cdad72abdb)', Time: '2020-09-16T21:59:39', User OID: 'PatientReportedOutcome (US3552412)', ODM File OID: '99ca5b92-3c2a-4a00-b343-17b7940f854e'	System	17 Sep 2020 02:59:49
User entered 'Yes (Y)'	System	17 Sep 2020 02:59:49

US3552412

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(6)

Generated On: 11 Aug 2021 22:53:07

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:25:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7f466cdad72abdb)', Time: '2020-09-16T21:59:43', User OID: 'PatientReportedOutcome (US3552412)', ODM File OID: '99ca5b92-3c2a-4a00-b343-17b7940f854e' User entered '97.1'	System	17 Sep 2020 02:59:49
	System	17 Sep 2020 02:59:49

US3552412

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(6)

Generated On: 11 Aug 2021 22:53:07

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:25:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7f466cdad72abdb)', Time: '2020-09-16T21:59:45', User OID: 'PatientReportedOutcome (US3552412)', ODM File OID: '99ca5b92-3c2a-4a00-b343-17b7940f854e'	System	17 Sep 2020 02:59:49
User entered 'No (N)'	System	17 Sep 2020 02:59:49

US3552412

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(6)

Generated On: 11 Aug 2021 22:53:07

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:25:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7f466cdad72abdb)', Time: '2020-09-16T21:59:46', User OID: 'PatientReportedOutcome (US3552412)', ODM File OID: '99ca5b92-3c2a-4a00-b343-17b7940f854e'	System	17 Sep 2020 02:59:49
User entered '16 Sep 2020 21:59'	System	17 Sep 2020 02:59:49

US3552412

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(6)

Generated On: 11 Aug 2021 22:53:07

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:25:24
User entered '16 Sep 2020 12:00'	System	11 Sep 2020 19:01:06

US3552412

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(6)

Generated On: 11 Aug 2021 22:53:07

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:25:24
User entered '17 Sep 2020 11:59'	System	11 Sep 2020 19:01:06

US3552412

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(7)

Generated On: 11 Aug 2021 22:53:07

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:25:24
Data entry locked.	System	11 Sep 2020 19:01:06
User entered 'Day 7'	System	11 Sep 2020 19:01:06

US3552412

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(7)

Generated On: 11 Aug 2021 22:53:07

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:25:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7f466cdad72abdb)', Time: '2020-09-17T22:02:09', User OID: 'PatientReportedOutcome (US3552412)', ODM File OID: 'c53e5feb-ba23-4a98-8d0b-a9c9134d055d'	System	18 Sep 2020 03:02:45
User entered 'Yes (Y)'	System	18 Sep 2020 03:02:45

US3552412

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(7)

Generated On: 11 Aug 2021 22:53:07

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:25:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7f466cdad72abdb)', Time: '2020-09-17T22:02:35', User OID: 'PatientReportedOutcome (US3552412)', ODM File OID: 'c53e5feb-ba23-4a98-8d0b-a9c9134d055d' User entered '97.1'	System	18 Sep 2020 03:02:45
	System	18 Sep 2020 03:02:45

US3552412

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(7)

Generated On: 11 Aug 2021 22:53:07

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:25:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7f466cdad72abdb)', Time: '2020-09-17T22:02:37', User OID: 'PatientReportedOutcome (US3552412)', ODM File OID: 'c53e5feb-ba23-4a98-8d0b-a9c9134d055d'	System	18 Sep 2020 03:02:45
User entered 'No (N)'	System	18 Sep 2020 03:02:45

US3552412

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(7)

Generated On: 11 Aug 2021 22:53:07

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:25:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7f466cdad72abdb)', Time: '2020-09-17T22:02:40', User OID: 'PatientReportedOutcome (US3552412)', ODM File OID: 'c53e5feb-ba23-4a98-8d0b-a9c9134d055d'	System	18 Sep 2020 03:02:45
User entered '17 Sep 2020 22:02'	System	18 Sep 2020 03:02:45

US3552412

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(7)

Generated On: 11 Aug 2021 22:53:07

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:25:24
User entered '17 Sep 2020 12:00'	System	11 Sep 2020 19:01:06

US3552412

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(7)

Generated On: 11 Aug 2021 22:53:07

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:25:24
User entered '18 Sep 2020 11:59'	System	11 Sep 2020 19:01:06

US3552412

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 11 Aug 2021 22:53:07

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:25:24
Data entry locked.	System	11 Sep 2020 19:01:06
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	11 Sep 2020 19:01:06

US3552412

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 11 Aug 2021 22:53:07

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:25:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7f466cdad72abdb)', Time: '2020-09-11T14:29:41', User OID: 'PatientReportedOutcome (US3552412)', ODM File OID: 'cc289991-026c-40e6-bfce-8cc0ab329e8a'	System	11 Sep 2020 19:30:10
User entered 'None (1)'	System	11 Sep 2020 19:30:10

US3552412

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 11 Aug 2021 22:53:07

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:25:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7f466cdad72abdb)', Time: '2020-09-11T14:29:46', User OID: 'PatientReportedOutcome (US3552412)', ODM File OID: 'cc289991-026c-40e6-bfce-8cc0ab329e8a'	System	11 Sep 2020 19:30:10
User entered 'No (N)'	System	11 Sep 2020 19:30:10

US3552412

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 11 Aug 2021 22:53:07

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:25:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7f466cdad72abdb)', Time: '2020-09-11T14:29:52', User OID: 'PatientReportedOutcome (US3552412)', ODM File OID: 'cc289991-026c-40e6-bfce-8cc0ab329e8a'	System	11 Sep 2020 19:30:10
User entered 'No (N)'	System	11 Sep 2020 19:30:10

US3552412

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 11 Aug 2021 22:53:07

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:25:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7f466cdad72abdb)', Time: '2020-09-11T14:29:59', User OID: 'PatientReportedOutcome (US3552412)', ODM File OID: 'cc289991-026c-40e6-bfce-8cc0ab329e8a'	System	11 Sep 2020 19:30:10
User entered 'None (1)'	System	11 Sep 2020 19:30:10

US3552412

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 11 Aug 2021 22:53:07

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:25:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7f466cdad72abddb)', Time: '2020-09-11T14:30:02', User OID: 'PatientReportedOutcome (US3552412)', ODM File OID: 'cc289991-026c-40e6-bfce-8cc0ab329e8a'	System	11 Sep 2020 19:30:10
User entered '11 Sep 2020 14:30'	System	11 Sep 2020 19:30:10

US3552412

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 11 Aug 2021 22:53:07

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:25:24
User entered '11 Sep 2020 14:16'	System	11 Sep 2020 19:01:06

US3552412

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 11 Aug 2021 22:53:07

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:25:24
User entered '11 Sep 2020 16:46'	System	11 Sep 2020 19:01:06

US3552412

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 11 Aug 2021 22:53:07

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:25:24
Data entry locked.	System	11 Sep 2020 19:01:06
User entered 'Day 1, after vaccination (at home)'	System	11 Sep 2020 19:01:06

US3552412

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 11 Aug 2021 22:53:07

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:25:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7f466cdad72abddb)', Time: '2020-09-11T21:40:33', User OID: 'PatientReportedOutcome (US3552412)', ODM File OID: 'd5491799-94b9-4c03-a664-7acac5d83aaf'	System	12 Sep 2020 02:41:11
User entered 'Does not interfere with activity (2)'	System	12 Sep 2020 02:41:11

US3552412

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 11 Aug 2021 22:53:07

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:25:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7f466cdad72abdb)', Time: '2020-09-11T21:40:35', User OID: 'PatientReportedOutcome (US3552412)', ODM File OID: 'd5491799-94b9-4c03-a664-7acac5d83aaf'	System	12 Sep 2020 02:41:11
User entered 'No (N)'	System	12 Sep 2020 02:41:11

US3552412

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 11 Aug 2021 22:53:07

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:25:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7f466cdad72abdb)', Time: '2020-09-11T21:40:48', User OID: 'PatientReportedOutcome (US3552412)', ODM File OID: 'd5491799-94b9-4c03-a664-7acac5d83aaf'	System	12 Sep 2020 02:41:11
User entered 'No (N)'	System	12 Sep 2020 02:41:11

US3552412

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 11 Aug 2021 22:53:07

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:25:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7f466cdad72abdb)', Time: '2020-09-11T21:41:02', User OID: 'PatientReportedOutcome (US3552412)', ODM File OID: 'd5491799-94b9-4c03-a664-7acac5d83aaf'	System	12 Sep 2020 02:41:11
User entered 'None (1)'	System	12 Sep 2020 02:41:11

US3552412

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 11 Aug 2021 22:53:07

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:25:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7f466cdad72abdb)', Time: '2020-09-11T21:41:05', User OID: 'PatientReportedOutcome (US3552412)', ODM File OID: 'd5491799-94b9-4c03-a664-7aac5d83aaf'	System	12 Sep 2020 02:41:11
User entered '11 Sep 2020 21:41'	System	12 Sep 2020 02:41:11

US3552412

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 11 Aug 2021 22:53:07

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:25:24
User entered '11 Sep 2020 17:41'	System	11 Sep 2020 19:01:06

US3552412

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 11 Aug 2021 22:53:07

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:25:24
User entered '12 Sep 2020 11:59'	System	11 Sep 2020 19:01:06

US3552412

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 11 Aug 2021 22:53:07

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:25:24
Data entry locked.	System	11 Sep 2020 19:01:06
User entered 'Day 2'	System	11 Sep 2020 19:01:06

US3552412

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 11 Aug 2021 22:53:07

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:25:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7f466cdad72abddb)', Time: '2020-09-12T21:16:17', User OID: 'PatientReportedOutcome (US3552412)', ODM File OID: 'b2834702-50c0-4dac-9624-627e9749d19a'	System	13 Sep 2020 02:17:01
User entered 'Does not interfere with activity (2)'	System	13 Sep 2020 02:17:01

US3552412

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 11 Aug 2021 22:53:07

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:25:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7f466cdad72abdb)', Time: '2020-09-12T21:16:35', User OID: 'PatientReportedOutcome (US3552412)', ODM File OID: 'b2834702-50c0-4dac-9624-627e9749d19a'	System	13 Sep 2020 02:17:01
User entered 'No (N)'	System	13 Sep 2020 02:17:01

US3552412

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 11 Aug 2021 22:53:07

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:25:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7f466cdad72abdb)', Time: '2020-09-12T21:16:41', User OID: 'PatientReportedOutcome (US3552412)', ODM File OID: 'b2834702-50c0-4dac-9624-627e9749d19a'	System	13 Sep 2020 02:17:01
User entered 'No (N)'	System	13 Sep 2020 02:17:01

US3552412

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 11 Aug 2021 22:53:07

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:25:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7f466cdad72abdb)', Time: '2020-09-12T21:16:53', User OID: 'PatientReportedOutcome (US3552412)', ODM File OID: 'b2834702-50c0-4dac-9624-627e9749d19a'	System	13 Sep 2020 02:17:01
User entered 'None (1)'	System	13 Sep 2020 02:17:01

US3552412

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 11 Aug 2021 22:53:07

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:25:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7f466cdad72abddb)', Time: '2020-09-12T21:16:56', User OID: 'PatientReportedOutcome (US3552412)', ODM File OID: 'b2834702-50c0-4dac-9624-627e9749d19a'	System	13 Sep 2020 02:17:01
User entered '12 Sep 2020 21:16'	System	13 Sep 2020 02:17:01

US3552412

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 11 Aug 2021 22:53:07

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:25:24
User entered '12 Sep 2020 12:00'	System	11 Sep 2020 19:01:06

US3552412

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 11 Aug 2021 22:53:07

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:25:24
User entered '13 Sep 2020 11:59'	System	11 Sep 2020 19:01:06

US3552412

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 11 Aug 2021 22:53:07

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:25:24
Data entry locked.	System	11 Sep 2020 19:01:06
User entered 'Day 3'	System	11 Sep 2020 19:01:06

US3552412

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 11 Aug 2021 22:53:07

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:25:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7f466cdad72abdb)', Time: '2020-09-13T21:44:09', User OID: 'PatientReportedOutcome (US3552412)', ODM File OID: '33b38386-0230-4477-8bd3-9dcebdf1596'	System	14 Sep 2020 02:44:20
User entered 'Does not interfere with activity (2)'	System	14 Sep 2020 02:44:20

US3552412

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 11 Aug 2021 22:53:07

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:25:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7f466cdad72abdb)', Time: '2020-09-13T21:44:12', User OID: 'PatientReportedOutcome (US3552412)', ODM File OID: '33b38386-0230-4477-8bd3-9dcebdf1596'	System	14 Sep 2020 02:44:20
User entered 'No (N)'	System	14 Sep 2020 02:44:20

US3552412

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 11 Aug 2021 22:53:07

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:25:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7f466cdad72abddb)', Time: '2020-09-13T21:44:14', User OID: 'PatientReportedOutcome (US3552412)', ODM File OID: '33b38386-0230-4477-8bd3-9dcebdf1596'	System	14 Sep 2020 02:44:20
User entered 'No (N)'	System	14 Sep 2020 02:44:20

US3552412

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 11 Aug 2021 22:53:07

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:25:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7f466cdad72abdb)', Time: '2020-09-13T21:44:16', User OID: 'PatientReportedOutcome (US3552412)', ODM File OID: '33b38386-0230-4477-8bd3-9dcebdf1596'	System	14 Sep 2020 02:44:20
User entered 'None (1)'	System	14 Sep 2020 02:44:20

US3552412

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 11 Aug 2021 22:53:07

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:25:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7f466cdad72abdb)', Time: '2020-09-13T21:44:18', User OID: 'PatientReportedOutcome (US3552412)', ODM File OID: '33b38386-0230-4477-8bd3-9dcebdf1596'	System	14 Sep 2020 02:44:20
User entered '13 Sep 2020 21:44'	System	14 Sep 2020 02:44:20

US3552412

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 11 Aug 2021 22:53:07

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:25:24
User entered '13 Sep 2020 12:00'	System	11 Sep 2020 19:01:06

US3552412

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 11 Aug 2021 22:53:07

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:25:24
User entered '14 Sep 2020 11:59'	System	11 Sep 2020 19:01:06

US3552412

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 11 Aug 2021 22:53:07

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:25:24
Data entry locked.	System	11 Sep 2020 19:01:06
User entered 'Day 4'	System	11 Sep 2020 19:01:06

US3552412

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 11 Aug 2021 22:53:07

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:25:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7f466cdad72abdb)', Time: '2020-09-14T21:37:59', User OID: 'PatientReportedOutcome (US3552412)', ODM File OID: '7c849391-b454-4989-8af0-0516db90b59f'	System	15 Sep 2020 02:38:10
User entered 'None (1)'	System	15 Sep 2020 02:38:10

US3552412

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 11 Aug 2021 22:53:07

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:25:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7f466cdad72abdb)', Time: '2020-09-14T21:38:01', User OID: 'PatientReportedOutcome (US3552412)', ODM File OID: '7c849391-b454-4989-8af0-0516db90b59f'	System	15 Sep 2020 02:38:10
User entered 'No (N)'	System	15 Sep 2020 02:38:10

US3552412

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 11 Aug 2021 22:53:07

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:25:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7f466cdad72abdb)', Time: '2020-09-14T21:38:03', User OID: 'PatientReportedOutcome (US3552412)', ODM File OID: '7c849391-b454-4989-8af0-0516db90b59f'	System	15 Sep 2020 02:38:10
User entered 'No (N)'	System	15 Sep 2020 02:38:10

US3552412

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 11 Aug 2021 22:53:07

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:25:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7f466cdad72abdb)', Time: '2020-09-14T21:38:05', User OID: 'PatientReportedOutcome (US3552412)', ODM File OID: '7c849391-b454-4989-8af0-0516db90b59f'	System	15 Sep 2020 02:38:10
User entered 'None (1)'	System	15 Sep 2020 02:38:10

US3552412

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 11 Aug 2021 22:53:07

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:25:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7f466cdad72abddb)', Time: '2020-09-14T21:38:07', User OID: 'PatientReportedOutcome (US3552412)', ODM File OID: '7c849391-b454-4989-8af0-0516db90b59f'	System	15 Sep 2020 02:38:10
User entered '14 Sep 2020 21:38'	System	15 Sep 2020 02:38:10

US3552412

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 11 Aug 2021 22:53:07

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:25:24
User entered '14 Sep 2020 12:00'	System	11 Sep 2020 19:01:06

US3552412

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 11 Aug 2021 22:53:07

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:25:24
User entered '15 Sep 2020 11:59'	System	11 Sep 2020 19:01:06

US3552412

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 11 Aug 2021 22:53:07

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:25:24
Data entry locked.	System	11 Sep 2020 19:01:06
User entered 'Day 5'	System	11 Sep 2020 19:01:06

US3552412

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 11 Aug 2021 22:53:07

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:25:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7f466cdad72abddb)', Time: '2020-09-15T21:17:43', User OID: 'PatientReportedOutcome (US3552412)', ODM File OID: '828abc74-4a82-4c58-a188-6bff0023024a'	System	16 Sep 2020 02:18:07
User entered 'None (1)'	System	16 Sep 2020 02:18:07

US3552412

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 11 Aug 2021 22:53:07

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:25:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7f466cdad72abdb)', Time: '2020-09-15T21:17:46', User OID: 'PatientReportedOutcome (US3552412)', ODM File OID: '828abc74-4a82-4c58-a188-6bff0023024a'	System	16 Sep 2020 02:18:07
User entered 'No (N)'	System	16 Sep 2020 02:18:07

US3552412

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 11 Aug 2021 22:53:07

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:25:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7f466cdad72abdb)', Time: '2020-09-15T21:17:49', User OID: 'PatientReportedOutcome (US3552412)', ODM File OID: '828abc74-4a82-4c58-a188-6bff0023024a'	System	16 Sep 2020 02:18:07
User entered 'No (N)'	System	16 Sep 2020 02:18:07

US3552412

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 11 Aug 2021 22:53:07

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:25:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7f466cdad72abdb)', Time: '2020-09-15T21:18:00', User OID: 'PatientReportedOutcome (US3552412)', ODM File OID: '828abc74-4a82-4c58-a188-6bff0023024a'	System	16 Sep 2020 02:18:07
User entered 'None (1)'	System	16 Sep 2020 02:18:07

US3552412

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 11 Aug 2021 22:53:07

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:25:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7f466cdad72abdb)', Time: '2020-09-15T21:18:02', User OID: 'PatientReportedOutcome (US3552412)', ODM File OID: '828abc74-4a82-4c58-a188-6bff0023024a'	System	16 Sep 2020 02:18:07
User entered '15 Sep 2020 21:18'	System	16 Sep 2020 02:18:07

US3552412

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 11 Aug 2021 22:53:07

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:25:24
User entered '15 Sep 2020 12:00'	System	11 Sep 2020 19:01:06

US3552412

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 11 Aug 2021 22:53:07

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:25:24
User entered '16 Sep 2020 11:59'	System	11 Sep 2020 19:01:06

US3552412

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(6)

Generated On: 11 Aug 2021 22:53:07

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:25:24
Data entry locked.	System	11 Sep 2020 19:01:06
User entered 'Day 6'	System	11 Sep 2020 19:01:06

US3552412

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(6)

Generated On: 11 Aug 2021 22:53:07

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:25:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7f466cdad72abdb)', Time: '2020-09-16T21:59:06', User OID: 'PatientReportedOutcome (US3552412)', ODM File OID: 'fb749816-21e4-4562-814b-08142af2ee51'	System	17 Sep 2020 02:59:20
User entered 'None (1)'	System	17 Sep 2020 02:59:20

US3552412

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(6)

Generated On: 11 Aug 2021 22:53:07

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:25:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7f466cdad72abdb)', Time: '2020-09-16T21:59:09', User OID: 'PatientReportedOutcome (US3552412)', ODM File OID: 'fb749816-21e4-4562-814b-08142af2ee51'	System	17 Sep 2020 02:59:20
User entered 'No (N)'	System	17 Sep 2020 02:59:20

US3552412

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(6)

Generated On: 11 Aug 2021 22:53:07

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:25:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7f466cdad72abdb)', Time: '2020-09-16T21:59:10', User OID: 'PatientReportedOutcome (US3552412)', ODM File OID: 'fb749816-21e4-4562-814b-08142af2ee51'	System	17 Sep 2020 02:59:20
User entered 'No (N)'	System	17 Sep 2020 02:59:20

US3552412

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(6)

Generated On: 11 Aug 2021 22:53:07

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:25:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7f466cdad72abdb)', Time: '2020-09-16T21:59:12', User OID: 'PatientReportedOutcome (US3552412)', ODM File OID: 'fb749816-21e4-4562-814b-08142af2ee51'	System	17 Sep 2020 02:59:20
User entered 'None (1)'	System	17 Sep 2020 02:59:20

US3552412

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(6)

Generated On: 11 Aug 2021 22:53:07

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:25:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7f466cdad72abdb)', Time: '2020-09-16T21:59:14', User OID: 'PatientReportedOutcome (US3552412)', ODM File OID: 'fb749816-21e4-4562-814b-08142af2ee51'	System	17 Sep 2020 02:59:20
User entered '16 Sep 2020 21:59'	System	17 Sep 2020 02:59:20

US3552412

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(6)

Generated On: 11 Aug 2021 22:53:07

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:25:24
User entered '16 Sep 2020 12:00'	System	11 Sep 2020 19:01:06

US3552412

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(6)

Generated On: 11 Aug 2021 22:53:07

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:25:24
User entered '17 Sep 2020 11:59'	System	11 Sep 2020 19:01:06

US3552412

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 11 Aug 2021 22:53:07

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:25:24
Data entry locked.	System	11 Sep 2020 19:01:06
User entered 'Day 7'	System	11 Sep 2020 19:01:06

US3552412

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 11 Aug 2021 22:53:07

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:25:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7f466cdad72abddb)', Time: '2020-09-17T22:01:41', User OID: 'PatientReportedOutcome (US3552412)', ODM File OID: 'ef7c60e1-508c-4740-bc17-8850bbe1b2b'	System	18 Sep 2020 03:01:50
User entered 'None (1)'	System	18 Sep 2020 03:01:50

US3552412

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 11 Aug 2021 22:53:07

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:25:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7f466cdad72abdb)', Time: '2020-09-17T22:01:39', User OID: 'PatientReportedOutcome (US3552412)', ODM File OID: 'ef7c60e1-508c-4740-bc17-8850bbe1b2b'	System	18 Sep 2020 03:01:50
User entered 'No (N)'	System	18 Sep 2020 03:01:50

US3552412

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 11 Aug 2021 22:53:07

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:25:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7f466cdad72abdb)', Time: '2020-09-17T22:01:43', User OID: 'PatientReportedOutcome (US3552412)', ODM File OID: 'ef7c60e1-508c-4740-bc17-8850bbe1b2b'	System	18 Sep 2020 03:01:50
User entered 'No (N)'	System	18 Sep 2020 03:01:50

US3552412

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 11 Aug 2021 22:53:07

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:25:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7f466cdad72abdb)', Time: '2020-09-17T22:01:45', User OID: 'PatientReportedOutcome (US3552412)', ODM File OID: 'ef7c60e1-508c-4740-bc17-8850bbe1b2b'	System	18 Sep 2020 03:01:50
User entered 'None (1)'	System	18 Sep 2020 03:01:50

US3552412

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 11 Aug 2021 22:53:07

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:25:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7f466cdad72abddb)', Time: '2020-09-17T22:01:48', User OID: 'PatientReportedOutcome (US3552412)', ODM File OID: 'ef7c60e1-508c-4740-bc17-8850bbee1b2b'	System	18 Sep 2020 03:01:50
User entered '17 Sep 2020 22:01'	System	18 Sep 2020 03:01:50

US3552412

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 11 Aug 2021 22:53:07

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:25:24
User entered '17 Sep 2020 12:00'	System	11 Sep 2020 19:01:06

US3552412

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 11 Aug 2021 22:53:07

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:25:24
User entered '18 Sep 2020 11:59'	System	11 Sep 2020 19:01:06

US3552412

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 11 Aug 2021 22:53:07

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:25:24
Data entry locked.	System	11 Sep 2020 19:01:06
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	11 Sep 2020 19:01:06

US3552412

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 11 Aug 2021 22:53:07

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:25:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7f466cdad72abdb)', Time: '2020-09-11T14:30:06', User OID: 'PatientReportedOutcome (US3552412)', ODM File OID: 'a89e599a-cb96-4dab-a3a0-9941bf9a7a04'	System	11 Sep 2020 19:30:24
User entered 'None (0)'	System	11 Sep 2020 19:30:24

US3552412

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 11 Aug 2021 22:53:07

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:25:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7f466cdad72abdb)', Time: '2020-09-11T14:30:07', User OID: 'PatientReportedOutcome (US3552412)', ODM File OID: 'a89e599a-cb96-4dab-a3a0-9941bf9a7a04'	System	11 Sep 2020 19:30:24
User entered 'None (0)'	System	11 Sep 2020 19:30:24

US3552412

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 11 Aug 2021 22:53:07

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:25:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7f466cdad72abdb)', Time: '2020-09-11T14:30:09', User OID: 'PatientReportedOutcome (US3552412)', ODM File OID: 'a89e599a-cb96-4dab-a3a0-9941bf9a7a04'	System	11 Sep 2020 19:30:24
User entered 'None (0)'	System	11 Sep 2020 19:30:24

US3552412

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 11 Aug 2021 22:53:07

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:25:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7f466cdad72abddb)', Time: '2020-09-11T14:30:11', User OID: 'PatientReportedOutcome (US3552412)', ODM File OID: 'a89e599a-cb96-4dab-a3a0-9941bf9a7a04'	System	11 Sep 2020 19:30:24
User entered 'None (0)'	System	11 Sep 2020 19:30:24

US3552412

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 11 Aug 2021 22:53:07

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:25:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7f466cdad72abdb)', Time: '2020-09-11T14:30:12', User OID: 'PatientReportedOutcome (US3552412)', ODM File OID: 'a89e599a-cb96-4dab-a3a0-9941bf9a7a04'	System	11 Sep 2020 19:30:24
User entered 'None (0)'	System	11 Sep 2020 19:30:24

US3552412

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 11 Aug 2021 22:53:07

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:25:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7f466cdad72abdb)', Time: '2020-09-11T14:30:13', User OID: 'PatientReportedOutcome (US3552412)', ODM File OID: 'a89e599a-cb96-4dab-a3a0-9941bf9a7a04'	System	11 Sep 2020 19:30:24
User entered 'None (0)'	System	11 Sep 2020 19:30:24

US3552412

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 11 Aug 2021 22:53:07

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:25:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7f466cdad72abdb)', Time: '2020-09-11T14:30:16', User OID: 'PatientReportedOutcome (US3552412)', ODM File OID: 'a89e599a-cb96-4dab-a3a0-9941bf9a7a04'	System	11 Sep 2020 19:30:24
User entered 'No (N)'	System	11 Sep 2020 19:30:24

US3552412

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 11 Aug 2021 22:53:07

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:25:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7f466cdad72abdb)', Time: '2020-09-11T14:30:18', User OID: 'PatientReportedOutcome (US3552412)', ODM File OID: 'a89e599a-cb96-4dab-a3a0-9941bf9a7a04'	System	11 Sep 2020 19:30:24
User entered '11 Sep 2020 14:30'	System	11 Sep 2020 19:30:24

US3552412

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 11 Aug 2021 22:53:07

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:25:24
User entered '11 Sep 2020 14:16'	System	11 Sep 2020 19:01:06

US3552412

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 11 Aug 2021 22:53:07

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:25:24
User entered '11 Sep 2020 16:46'	System	11 Sep 2020 19:01:06

US3552412

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 11 Aug 2021 22:53:07

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:25:24
Data entry locked.	System	11 Sep 2020 19:01:06
User entered 'Day 1, after vaccination (at home)'	System	11 Sep 2020 19:01:06

US3552412

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 11 Aug 2021 22:53:07

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:25:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7f466cdad72abdb)', Time: '2020-09-11T21:38:33', User OID: 'PatientReportedOutcome (US3552412)', ODM File OID: '296f9ca8-8b26-4f26-bb96-b9ca2e910182'	System	12 Sep 2020 02:39:05
User entered 'None (0)'	System	12 Sep 2020 02:39:05

US3552412

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 11 Aug 2021 22:53:07

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:25:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7f466cdad72abdb)', Time: '2020-09-11T21:38:36', User OID: 'PatientReportedOutcome (US3552412)', ODM File OID: '296f9ca8-8b26-4f26-bb96-b9ca2e910182'	System	12 Sep 2020 02:39:05
User entered 'No interference with activity (1)'	System	12 Sep 2020 02:39:05

US3552412

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 11 Aug 2021 22:53:07

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:25:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7f466cdad72abdb)', Time: '2020-09-11T21:38:39', User OID: 'PatientReportedOutcome (US3552412)', ODM File OID: '296f9ca8-8b26-4f26-bb96-b9ca2e910182'	System	12 Sep 2020 02:39:05
User entered 'None (0)'	System	12 Sep 2020 02:39:05

US3552412

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 11 Aug 2021 22:53:07

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:25:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7f466cdad72abdb)', Time: '2020-09-11T21:38:41', User OID: 'PatientReportedOutcome (US3552412)', ODM File OID: '296f9ca8-8b26-4f26-bb96-b9ca2e910182'	System	12 Sep 2020 02:39:05
User entered 'None (0)'	System	12 Sep 2020 02:39:05

US3552412

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 11 Aug 2021 22:53:07

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:25:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7f466cdad72abdb)', Time: '2020-09-11T21:38:43', User OID: 'PatientReportedOutcome (US3552412)', ODM File OID: '296f9ca8-8b26-4f26-bb96-b9ca2e910182'	System	12 Sep 2020 02:39:05
User entered 'None (0)'	System	12 Sep 2020 02:39:05

US3552412

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 11 Aug 2021 22:53:07

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:25:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7f466cdad72abdb)', Time: '2020-09-11T21:38:45', User OID: 'PatientReportedOutcome (US3552412)', ODM File OID: '296f9ca8-8b26-4f26-bb96-b9ca2e910182'	System	12 Sep 2020 02:39:05
User entered 'None (0)'	System	12 Sep 2020 02:39:05

US3552412

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 11 Aug 2021 22:53:07

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:25:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7f466cdad72abdb)', Time: '2020-09-11T21:38:49', User OID: 'PatientReportedOutcome (US3552412)', ODM File OID: '296f9ca8-8b26-4f26-bb96-b9ca2e910182'	System	12 Sep 2020 02:39:05
User entered 'No (N)'	System	12 Sep 2020 02:39:05

US3552412

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 11 Aug 2021 22:53:07

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:25:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7f466cdad72abdb)', Time: '2020-09-11T21:39:01', User OID: 'PatientReportedOutcome (US3552412)', ODM File OID: '296f9ca8-8b26-4f26-bb96-b9ca2e910182'	System	12 Sep 2020 02:39:05
User entered '11 Sep 2020 21:39'	System	12 Sep 2020 02:39:05

US3552412

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 11 Aug 2021 22:53:07

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:25:24
User entered '11 Sep 2020 17:41'	System	11 Sep 2020 19:01:06

US3552412

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 11 Aug 2021 22:53:07

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:25:24
User entered '12 Sep 2020 11:59'	System	11 Sep 2020 19:01:06

US3552412

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 11 Aug 2021 22:53:07

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:25:24
Data entry locked.	System	11 Sep 2020 19:01:06
User entered 'Day 2'	System	11 Sep 2020 19:01:06

US3552412

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 11 Aug 2021 22:53:07

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:25:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7f466cdad72abdb)', Time: '2020-09-12T21:17:03', User OID: 'PatientReportedOutcome (US3552412)', ODM File OID: 'dd0d36e5-b775-4975-b51a-ac80e1645af0'	System	13 Sep 2020 02:17:24
User entered 'None (0)'	System	13 Sep 2020 02:17:24

US3552412

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 11 Aug 2021 22:53:07

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:25:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7f466cdad72abdb)', Time: '2020-09-12T21:17:07', User OID: 'PatientReportedOutcome (US3552412)', ODM File OID: 'dd0d36e5-b775-4975-b51a-ac80e1645af0'	System	13 Sep 2020 02:17:24
User entered 'None (0)'	System	13 Sep 2020 02:17:24

US3552412

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 11 Aug 2021 22:53:07

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:25:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7f466cdad72abdb)', Time: '2020-09-12T21:17:10', User OID: 'PatientReportedOutcome (US3552412)', ODM File OID: 'dd0d36e5-b775-4975-b51a-ac80e1645af0'	System	13 Sep 2020 02:17:24
User entered 'None (0)'	System	13 Sep 2020 02:17:24

US3552412

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 11 Aug 2021 22:53:07

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:25:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7f466cdad72abdb)', Time: '2020-09-12T21:17:12', User OID: 'PatientReportedOutcome (US3552412)', ODM File OID: 'dd0d36e5-b775-4975-b51a-ac80e1645af0'	System	13 Sep 2020 02:17:24
User entered 'None (0)'	System	13 Sep 2020 02:17:24

US3552412

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 11 Aug 2021 22:53:07

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:25:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7f466cdad72abdb)', Time: '2020-09-12T21:17:14', User OID: 'PatientReportedOutcome (US3552412)', ODM File OID: 'dd0d36e5-b775-4975-b51a-ac80e1645af0'	System	13 Sep 2020 02:17:24
User entered 'None (0)'	System	13 Sep 2020 02:17:24

US3552412

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 11 Aug 2021 22:53:07

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:25:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7f466cdad72abdb)', Time: '2020-09-12T21:17:16', User OID: 'PatientReportedOutcome (US3552412)', ODM File OID: 'dd0d36e5-b775-4975-b51a-ac80e1645af0'	System	13 Sep 2020 02:17:24
User entered 'None (0)'	System	13 Sep 2020 02:17:24

US3552412

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 11 Aug 2021 22:53:07

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:25:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7f466cdad72abdb)', Time: '2020-09-12T21:17:18', User OID: 'PatientReportedOutcome (US3552412)', ODM File OID: 'dd0d36e5-b775-4975-b51a-ac80e1645af0'	System	13 Sep 2020 02:17:24
User entered 'No (N)'	System	13 Sep 2020 02:17:24

US3552412

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 11 Aug 2021 22:53:07

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:25:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7f466cdad72abdb)', Time: '2020-09-12T21:17:21', User OID: 'PatientReportedOutcome (US3552412)', ODM File OID: 'dd0d36e5-b775-4975-b51a-ac80e1645af0'	System	13 Sep 2020 02:17:24
User entered '12 Sep 2020 21:17'	System	13 Sep 2020 02:17:24

US3552412

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 11 Aug 2021 22:53:07

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:25:24
User entered '12 Sep 2020 12:00'	System	11 Sep 2020 19:01:06

US3552412

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 11 Aug 2021 22:53:07

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:25:24
User entered '13 Sep 2020 11:59'	System	11 Sep 2020 19:01:06

US3552412

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 11 Aug 2021 22:53:07

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:25:24
Data entry locked.	System	11 Sep 2020 19:01:06
User entered 'Day 3'	System	11 Sep 2020 19:01:06

US3552412

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 11 Aug 2021 22:53:07

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:25:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7f466cdad72abdb)', Time: '2020-09-13T21:44:21', User OID: 'PatientReportedOutcome (US3552412)', ODM File OID: 'deab9f1b-36b8-4ccb-b3ad-fa8c5d151638'	System	14 Sep 2020 02:44:38
User entered 'None (0)'	System	14 Sep 2020 02:44:38

US3552412

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 11 Aug 2021 22:53:07

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:25:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7f466cdad72abdb)', Time: '2020-09-13T21:44:23', User OID: 'PatientReportedOutcome (US3552412)', ODM File OID: 'deab9f1b-36b8-4ccb-b3ad-fa8c5d151638'	System	14 Sep 2020 02:44:38
User entered 'None (0)'	System	14 Sep 2020 02:44:38

US3552412

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 11 Aug 2021 22:53:07

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:25:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7f466cdad72abdb)', Time: '2020-09-13T21:44:25', User OID: 'PatientReportedOutcome (US3552412)', ODM File OID: 'deab9f1b-36b8-4ccb-b3ad-fa8c5d151638'	System	14 Sep 2020 02:44:38
User entered 'None (0)'	System	14 Sep 2020 02:44:38

US3552412

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 11 Aug 2021 22:53:07

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:25:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7f466cdad72abdb)', Time: '2020-09-13T21:44:26', User OID: 'PatientReportedOutcome (US3552412)', ODM File OID: 'deab9f1b-36b8-4ccb-b3ad-fa8c5d151638'	System	14 Sep 2020 02:44:38
User entered 'None (0)'	System	14 Sep 2020 02:44:38

US3552412

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 11 Aug 2021 22:53:07

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:25:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7f466cdad72abdb)', Time: '2020-09-13T21:44:28', User OID: 'PatientReportedOutcome (US3552412)', ODM File OID: 'deab9f1b-36b8-4ccb-b3ad-fa8c5d151638'	System	14 Sep 2020 02:44:38
User entered 'None (0)'	System	14 Sep 2020 02:44:38

US3552412

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 11 Aug 2021 22:53:07

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:25:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7f466cdad72abdb)', Time: '2020-09-13T21:44:29', User OID: 'PatientReportedOutcome (US3552412)', ODM File OID: 'deab9f1b-36b8-4ccb-b3ad-fa8c5d151638'	System	14 Sep 2020 02:44:38
User entered 'None (0)'	System	14 Sep 2020 02:44:38

US3552412

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 11 Aug 2021 22:53:07

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:25:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7f466cdad72abdb)', Time: '2020-09-13T21:44:32', User OID: 'PatientReportedOutcome (US3552412)', ODM File OID: 'deab9f1b-36b8-4ccb-b3ad-fa8c5d151638'	System	14 Sep 2020 02:44:38
User entered 'No (N)'	System	14 Sep 2020 02:44:38

US3552412

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 11 Aug 2021 22:53:07

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:25:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7f466cdad72abdb)', Time: '2020-09-13T21:44:34', User OID: 'PatientReportedOutcome (US3552412)', ODM File OID: 'deab9f1b-36b8-4ccb-b3ad-fa8c5d151638'	System	14 Sep 2020 02:44:38
User entered '13 Sep 2020 21:44'	System	14 Sep 2020 02:44:38

US3552412

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 11 Aug 2021 22:53:07

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:25:24
User entered '13 Sep 2020 12:00'	System	11 Sep 2020 19:01:06

US3552412

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 11 Aug 2021 22:53:07

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:25:24
User entered '14 Sep 2020 11:59'	System	11 Sep 2020 19:01:06

US3552412

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 11 Aug 2021 22:53:07

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:25:24
Data entry locked.	System	11 Sep 2020 19:01:06
User entered 'Day 4'	System	11 Sep 2020 19:01:06

US3552412

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 11 Aug 2021 22:53:07

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:25:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7f466cdad72abdb)', Time: '2020-09-14T21:38:11', User OID: 'PatientReportedOutcome (US3552412)', ODM File OID: '22dcbe8f-2d41-4985-b1ba-0b563cdecde6'	System	15 Sep 2020 02:38:26
User entered 'None (0)'	System	15 Sep 2020 02:38:26

US3552412

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 11 Aug 2021 22:53:07

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:25:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7f466cdad72abdb)', Time: '2020-09-14T21:38:12', User OID: 'PatientReportedOutcome (US3552412)', ODM File OID: '22dcbe8f-2d41-4985-b1ba-0b563cdecde6'	System	15 Sep 2020 02:38:26
User entered 'None (0)'	System	15 Sep 2020 02:38:26

US3552412

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 11 Aug 2021 22:53:07

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:25:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7f466cdad72abdb)', Time: '2020-09-14T21:38:14', User OID: 'PatientReportedOutcome (US3552412)', ODM File OID: '22dcbe8f-2d41-4985-b1ba-0b563cdecde6'	System	15 Sep 2020 02:38:26
User entered 'None (0)'	System	15 Sep 2020 02:38:26

US3552412

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 11 Aug 2021 22:53:07

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:25:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7f466cdad72abdb)', Time: '2020-09-14T21:38:15', User OID: 'PatientReportedOutcome (US3552412)', ODM File OID: '22dcbe8f-2d41-4985-b1ba-0b563cdecde6'	System	15 Sep 2020 02:38:26
User entered 'None (0)'	System	15 Sep 2020 02:38:26

US3552412

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 11 Aug 2021 22:53:07

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:25:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7f466cdad72abdb)', Time: '2020-09-14T21:38:17', User OID: 'PatientReportedOutcome (US3552412)', ODM File OID: '22dcbe8f-2d41-4985-b1ba-0b563cdecde6'	System	15 Sep 2020 02:38:26
User entered 'None (0)'	System	15 Sep 2020 02:38:26

US3552412

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 11 Aug 2021 22:53:07

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:25:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7f466cdad72abdb)', Time: '2020-09-14T21:38:19', User OID: 'PatientReportedOutcome (US3552412)', ODM File OID: '22dcbe8f-2d41-4985-b1ba-0b563cdecde6'	System	15 Sep 2020 02:38:26
User entered 'None (0)'	System	15 Sep 2020 02:38:26

US3552412

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 11 Aug 2021 22:53:07

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:25:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7f466cdad72abdb)', Time: '2020-09-14T21:38:21', User OID: 'PatientReportedOutcome (US3552412)', ODM File OID: '22dcbe8f-2d41-4985-b1ba-0b563cdecde6'	System	15 Sep 2020 02:38:26
User entered 'No (N)'	System	15 Sep 2020 02:38:26

US3552412

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 11 Aug 2021 22:53:07

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:25:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7f466cdad72abdb)', Time: '2020-09-14T21:38:23', User OID: 'PatientReportedOutcome (US3552412)', ODM File OID: '22dcbe8f-2d41-4985-b1ba-0b563cdecde6'	System	15 Sep 2020 02:38:26
User entered '14 Sep 2020 21:38'	System	15 Sep 2020 02:38:26

US3552412

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 11 Aug 2021 22:53:07

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:25:24
User entered '14 Sep 2020 12:00'	System	11 Sep 2020 19:01:06

US3552412

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 11 Aug 2021 22:53:07

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:25:24
User entered '15 Sep 2020 11:59'	System	11 Sep 2020 19:01:06

US3552412

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 11 Aug 2021 22:53:07

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:25:24
Data entry locked.	System	11 Sep 2020 19:01:06
User entered 'Day 5'	System	11 Sep 2020 19:01:06

US3552412

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 11 Aug 2021 22:53:07

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:25:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7f466cdad72abdb)', Time: '2020-09-15T21:18:09', User OID: 'PatientReportedOutcome (US3552412)', ODM File OID: '3d526c2e-a6c1-4249-b7a7-eb2f9d81b4fe'	System	16 Sep 2020 02:18:44
User entered 'None (0)'	System	16 Sep 2020 02:18:44

US3552412

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 11 Aug 2021 22:53:07

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:25:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7f466cdad72abdb)', Time: '2020-09-15T21:18:27', User OID: 'PatientReportedOutcome (US3552412)', ODM File OID: '3d526c2e-a6c1-4249-b7a7-eb2f9d81b4fe'	System	16 Sep 2020 02:18:44
User entered 'None (0)'	System	16 Sep 2020 02:18:44

US3552412

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 11 Aug 2021 22:53:07

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:25:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7f466cdad72abdb)', Time: '2020-09-15T21:18:29', User OID: 'PatientReportedOutcome (US3552412)', ODM File OID: '3d526c2e-a6c1-4249-b7a7-eb2f9d81b4fe'	System	16 Sep 2020 02:18:44
User entered 'None (0)'	System	16 Sep 2020 02:18:44

US3552412

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 11 Aug 2021 22:53:07

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:25:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7f466cdad72abdb)', Time: '2020-09-15T21:18:32', User OID: 'PatientReportedOutcome (US3552412)', ODM File OID: '3d526c2e-a6c1-4249-b7a7-eb2f9d81b4fe'	System	16 Sep 2020 02:18:44
User entered 'None (0)'	System	16 Sep 2020 02:18:44

US3552412

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 11 Aug 2021 22:53:07

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:25:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7f466cdad72abdb)', Time: '2020-09-15T21:18:34', User OID: 'PatientReportedOutcome (US3552412)', ODM File OID: '3d526c2e-a6c1-4249-b7a7-eb2f9d81b4fe'	System	16 Sep 2020 02:18:44
User entered 'None (0)'	System	16 Sep 2020 02:18:44

US3552412

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 11 Aug 2021 22:53:07

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:25:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7f466cdad72abdb)', Time: '2020-09-15T21:18:35', User OID: 'PatientReportedOutcome (US3552412)', ODM File OID: '3d526c2e-a6c1-4249-b7a7-eb2f9d81b4fe'	System	16 Sep 2020 02:18:44
User entered 'None (0)'	System	16 Sep 2020 02:18:44

US3552412

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 11 Aug 2021 22:53:07

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:25:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7f466cdad72abdb)', Time: '2020-09-15T21:18:37', User OID: 'PatientReportedOutcome (US3552412)', ODM File OID: '3d526c2e-a6c1-4249-b7a7-eb2f9d81b4fe'	System	16 Sep 2020 02:18:44
User entered 'No (N)'	System	16 Sep 2020 02:18:44

US3552412

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 11 Aug 2021 22:53:07

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:25:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7f466cdad72abdb)', Time: '2020-09-15T21:18:40', User OID: 'PatientReportedOutcome (US3552412)', ODM File OID: '3d526c2e-a6c1-4249-b7a7-eb2f9d81b4fe'	System	16 Sep 2020 02:18:44
User entered '15 Sep 2020 21:18'	System	16 Sep 2020 02:18:44

US3552412

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 11 Aug 2021 22:53:07

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:25:24
User entered '15 Sep 2020 12:00'	System	11 Sep 2020 19:01:06

US3552412

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 11 Aug 2021 22:53:07

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:25:24
User entered '16 Sep 2020 11:59'	System	11 Sep 2020 19:01:06

US3552412

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 11 Aug 2021 22:53:07

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:25:24
Data entry locked.	System	11 Sep 2020 19:01:06
User entered 'Day 6'	System	11 Sep 2020 19:01:06

US3552412

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 11 Aug 2021 22:53:07

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:25:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7f466cdad72abdb)', Time: '2020-09-16T21:59:17', User OID: 'PatientReportedOutcome (US3552412)', ODM File OID: '08ff3a6b-36f9-485e-8ee7-b5e7780b807f'	System	17 Sep 2020 02:59:32
User entered 'None (0)'	System	17 Sep 2020 02:59:32

US3552412

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 11 Aug 2021 22:53:07

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:25:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7f466cdad72abdb)', Time: '2020-09-16T21:59:19', User OID: 'PatientReportedOutcome (US3552412)', ODM File OID: '08ff3a6b-36f9-485e-8ee7-b5e7780b807f' User entered 'None (0)'	System	17 Sep 2020 02:59:32
	System	17 Sep 2020 02:59:32

US3552412

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 11 Aug 2021 22:53:07

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:25:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7f466cdad72abdb)', Time: '2020-09-16T21:59:20', User OID: 'PatientReportedOutcome (US3552412)', ODM File OID: '08ff3a6b-36f9-485e-8ee7-b5e7780b807f' User entered 'None (0)'	System	17 Sep 2020 02:59:32
	System	17 Sep 2020 02:59:32

US3552412

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 11 Aug 2021 22:53:07

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:25:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7f466cdad72abdb)', Time: '2020-09-16T21:59:22', User OID: 'PatientReportedOutcome (US3552412)', ODM File OID: '08ff3a6b-36f9-485e-8ee7-b5e7780b807f' User entered 'None (0)'	System	17 Sep 2020 02:59:32
	System	17 Sep 2020 02:59:32

US3552412

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 11 Aug 2021 22:53:07

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:25:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7f466cdad72abdb)', Time: '2020-09-16T21:59:23', User OID: 'PatientReportedOutcome (US3552412)', ODM File OID: '08ff3a6b-36f9-485e-8ee7-b5e7780b807f'	System	17 Sep 2020 02:59:32
User entered 'None (0)'	System	17 Sep 2020 02:59:32

US3552412

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 11 Aug 2021 22:53:07

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:25:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7f466cdad72abdb)', Time: '2020-09-16T21:59:25', User OID: 'PatientReportedOutcome (US3552412)', ODM File OID: '08ff3a6b-36f9-485e-8ee7-b5e7780b807f'	System	17 Sep 2020 02:59:32
User entered 'None (0)'	System	17 Sep 2020 02:59:32

US3552412

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 11 Aug 2021 22:53:07

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:25:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7f466cdad72abdb)', Time: '2020-09-16T21:59:27', User OID: 'PatientReportedOutcome (US3552412)', ODM File OID: '08ff3a6b-36f9-485e-8ee7-b5e7780b807f'	System	17 Sep 2020 02:59:32
User entered 'No (N)'	System	17 Sep 2020 02:59:32

US3552412

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 11 Aug 2021 22:53:07

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:25:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7f466cdad72abdb)', Time: '2020-09-16T21:59:29', User OID: 'PatientReportedOutcome (US3552412)', ODM File OID: '08ff3a6b-36f9-485e-8ee7-b5e7780b807f' User entered '16 Sep 2020 21:59'	System	17 Sep 2020 02:59:32
	System	17 Sep 2020 02:59:32

US3552412

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 11 Aug 2021 22:53:07

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:25:24
User entered '16 Sep 2020 12:00'	System	11 Sep 2020 19:01:06

US3552412

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 11 Aug 2021 22:53:07

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:25:24
User entered '17 Sep 2020 11:59'	System	11 Sep 2020 19:01:06

US3552412

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 11 Aug 2021 22:53:07

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:25:24
Data entry locked.	System	11 Sep 2020 19:01:06
User entered 'Day 7'	System	11 Sep 2020 19:01:06

US3552412

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 11 Aug 2021 22:53:07

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:25:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7f466cdad72abdb)', Time: '2020-09-17T22:01:51', User OID: 'PatientReportedOutcome (US3552412)', ODM File OID: '92f58466-3666-45af-9cfd-978b9977cdff'	System	18 Sep 2020 03:02:10
User entered 'None (0)'	System	18 Sep 2020 03:02:10

US3552412

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 11 Aug 2021 22:53:07

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:25:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7f466cdad72abdb)', Time: '2020-09-17T22:01:53', User OID: 'PatientReportedOutcome (US3552412)', ODM File OID: '92f58466-3666-45af-9cfd-978b9977cdff'	System	18 Sep 2020 03:02:10
User entered 'None (0)'	System	18 Sep 2020 03:02:10

US3552412

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 11 Aug 2021 22:53:07

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:25:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7f466cdad72abdb)', Time: '2020-09-17T22:01:54', User OID: 'PatientReportedOutcome (US3552412)', ODM File OID: '92f58466-3666-45af-9cfd-978b9977cdff'	System	18 Sep 2020 03:02:10
User entered 'None (0)'	System	18 Sep 2020 03:02:10

US3552412

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 11 Aug 2021 22:53:07

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:25:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7f466cdad72abdb)', Time: '2020-09-17T22:01:56', User OID: 'PatientReportedOutcome (US3552412)', ODM File OID: '92f58466-3666-45af-9cfd-978b9977cdff'	System	18 Sep 2020 03:02:10
User entered 'None (0)'	System	18 Sep 2020 03:02:10

US3552412

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 11 Aug 2021 22:53:07

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:25:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7f466cdad72abddb)', Time: '2020-09-17T22:01:57', User OID: 'PatientReportedOutcome (US3552412)', ODM File OID: '92f58466-3666-45af-9cfd-978b9977cdff'	System	18 Sep 2020 03:02:10
User entered 'None (0)'	System	18 Sep 2020 03:02:10

US3552412

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 11 Aug 2021 22:53:07

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:25:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7f466cdad72abdb)', Time: '2020-09-17T22:01:59', User OID: 'PatientReportedOutcome (US3552412)', ODM File OID: '92f58466-3666-45af-9cfd-978b9977cdff'	System	18 Sep 2020 03:02:10
User entered 'None (0)'	System	18 Sep 2020 03:02:10

US3552412

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 11 Aug 2021 22:53:07

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:25:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7f466cdad72abdb)', Time: '2020-09-17T22:02:01', User OID: 'PatientReportedOutcome (US3552412)', ODM File OID: '92f58466-3666-45af-9cfd-978b9977cdff'	System	18 Sep 2020 03:02:10
User entered 'No (N)'	System	18 Sep 2020 03:02:10

US3552412

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 11 Aug 2021 22:53:07

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:25:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7f466cdad72abddb)', Time: '2020-09-17T22:02:03', User OID: 'PatientReportedOutcome (US3552412)', ODM File OID: '92f58466-3666-45af-9cfd-978b9977cdff'	System	18 Sep 2020 03:02:10
User entered '17 Sep 2020 22:02'	System	18 Sep 2020 03:02:10

US3552412

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 11 Aug 2021 22:53:07

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:25:24
User entered '17 Sep 2020 12:00'	System	11 Sep 2020 19:01:06

US3552412

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 11 Aug 2021 22:53:07

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:25:24
User entered '18 Sep 2020 11:59'	System	11 Sep 2020 19:01:06

US3552412

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:53:07

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 11:14:37
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 19:11:21
User entered 'Yes (Y)'	Mikayla Frye (b) (4) (b) (4)	18 Sep 2020 17:03:54

US3552412

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:53:07

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 11:14:37
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:11:21
User entered '18 Sep 2020'	(b) (4) Mikayla Frye (b) (4) (b) (4)	18 Sep 2020 17:03:54

US3552412

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:53:07

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 11:14:37
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 19:11:21
User entered 'Contact Made (CONTACT MADE)'	Mikayla Frye (b) (4) (b) (4)	18 Sep 2020 17:03:54

US3552412

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:53:07

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 11:14:37
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 19:11:21
User entered empty.	Mikayla Frye (b) (4) (b) (4)	18 Sep 2020 17:03:54

US3552412

Folder: Safety Call Day 8 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:53:07

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 11:14:37
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 19:11:21
User entered 'Yes (Y)'	Mikayla Frye (b) (4) (b) (4)	25 Sep 2020 18:09:16

US3552412

Folder: Safety Call Day 8 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:53:07

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 11:14:37
User entered 'l'	System	25 Sep 2020 18:09:16

US3552412

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:53:07

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 11:14:37
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:11:21
User entered 'Yes (Y)'	(b) (4) Mikayla Frye (b) (4) (b) (4)	25 Sep 2020 18:09:27

US3552412

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:53:07

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 11:14:37
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:11:21
User entered '25 Sep 2020'	(b) (4) Mikayla Frye (b) (4) (b) (4)	25 Sep 2020 18:09:27

US3552412

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:53:07

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 11:14:37
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 19:11:21
User entered 'Contact Made (CONTACT MADE)'	Mikayla Frye (b) (4) (b) (4)	25 Sep 2020 18:09:27

US3552412

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:53:07

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 11:14:37
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 19:11:21
User entered empty.	Mikayla Frye (b) (4) (b) (4)	25 Sep 2020 18:09:27

US3552412

Folder: Safety Call Day 15 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:53:07

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 11:14:37
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 19:11:21
User entered 'Yes (Y)'	Mikayla Frye (b) (4) (b) (4)	02 Oct 2020 16:54:04

**US3552412**

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

**Form: Continuing**

**Generated On: 11 Aug 2021 22:53:07**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 11:14:37
User entered 'l'	System	02 Oct 2020 16:54:04

US3552412

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:53:07

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 11:14:37
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 19:11:21
User entered 'Yes (Y)'	Mikayla Frye (b) (4) (b) (4)	02 Oct 2020 16:54:11

US3552412

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:53:07

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 11:14:37
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 19:11:21
User entered '02 Oct 2020' reason for change: Data Entry Error	Heather Douds (b) (4) (b) (4)	09 Nov 2020 20:58:37
User entered '2 Oct 2020'	Mikayla Frye (b) (4) (b) (4)	02 Oct 2020 16:54:11

US3552412

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:53:07

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 11:14:37
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 19:11:21
User entered 'Contact Made (CONTACT MADE)'	Mikayla Frye (b) (4) (b) (4)	02 Oct 2020 16:54:11

US3552412

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:53:07

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 11:14:37
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 19:11:21
User entered empty.	Mikayla Frye (b) (4) (b) (4)	02 Oct 2020 16:54:11

US3552412

Folder: Safety Call Day 22 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:53:07

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 11:14:37
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:11:21
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	09 Oct 2020 14:36:48

US3552412

Folder: Safety Call Day 22 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:53:07

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 11:14:37
User entered 'l'	System	09 Oct 2020 14:36:48

US3552412

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:53:07

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 11:14:37
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 19:11:21
User entered 'Yes (Y)'	Stanley Dublin (b) (4) (b) (4)	09 Oct 2020 15:23:23

US3552412

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:53:07

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 11:14:37
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 19:11:21
User entered '09 Oct 2020' reason for change: Data Entry Error	Heather Douds (b) (4) (b) (4)	09 Nov 2020 20:58:44
User entered '9 Oct 2020'	Stanley Dublin (b) (4) (b) (4)	09 Oct 2020 15:23:23

US3552412

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:53:07

[Was visit performed at the participant's home or at the clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 11:14:37
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 19:11:21
User entered 'Clinic (Clinic)'	Stanley Dublin (b) (4) (b) (4)	09 Oct 2020 15:23:23

US3552412

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:53:07

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 11:14:37
User entered 'VISIT2'	System	09 Oct 2020 15:23:23

US3552412

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:53:07

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 11:14:37
User accepted default value 'Pre-Dose (PREDOSE)'	Stanley Doublin (b) (4) (b) (4)	09 Oct 2020 15:23:52

US3552412

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:53:07

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 11:14:37
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 19:11:21
User entered 'Yes (Y)'	Stanley Dublin (b) (4) (b) (4)	09 Oct 2020 15:23:52

US3552412

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:53:07

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 11:14:37
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 19:11:21
User entered '09 Oct 2020' reason for change: Data Entry Error	Heather Douds (b) (4) (b) (4)	09 Nov 2020 20:58:52
User entered '9 Oct 2020'	Stanley Dublin (b) (4) (b) (4)	09 Oct 2020 15:23:52

US3552412

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:53:07

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 11:14:37
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 19:11:21
User entered '08:38'	Stanley Dublin (b) (4) (b) (4)	09 Oct 2020 15:23:52

US3552412

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:53:07

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 11:14:37
User entered '09 Oct 2020 08:38'	System	09 Nov 2020 20:58:52
User entered '9 Oct 2020 08:38'	System	09 Oct 2020 15:23:52

US3552412

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:53:07

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 11:14:37
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 19:11:21
User entered '97.8' F	Stanley Dublin (b) (4) (b) (4)	09 Oct 2020 15:23:52

US3552412

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:53:07

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 11:14:37
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 19:11:21
User entered 'Oral (Oral)'	Stanley Dublin (b) (4) (b) (4)	09 Oct 2020 15:23:52

US3552412

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:53:07

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 11:14:37
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 19:11:21
User entered empty.	Stanley Dublin (b) (4) (b) (4)	09 Oct 2020 15:23:52

US3552412

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:53:07

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 11:14:37
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 19:11:21
User entered '90'	Stanley Dublin (b) (4) (b) (4)	09 Oct 2020 15:23:52

US3552412

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:53:07

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 11:14:37
User entered 'bpm'	System	09 Oct 2020 15:23:52

US3552412

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:53:07

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 11:14:37
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 19:11:21
User entered '12'	Stanley Dublin (b) (4) (b) (4)	09 Oct 2020 15:23:52

US3552412

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:53:07

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 11:14:37
User entered 'breaths/min'	System	09 Oct 2020 15:23:52

US3552412

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:53:07

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 11:14:37
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 19:11:21
User entered '90'	Stanley Dublin (b) (4) (b) (4)	09 Oct 2020 15:23:52

US3552412

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:53:07

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 11:14:37
User entered 'mmHg'	System	09 Oct 2020 15:23:52

US3552412

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:53:07

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 11:14:37
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 19:11:21
User entered '60'	Stanley Dublin (b) (4) (b) (4)	09 Oct 2020 15:23:52

US3552412

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:53:07

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 11:14:37
User entered 'mmHg'	System	09 Oct 2020 15:23:52

US3552412

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:53:07

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 11:14:37
User accepted default value 'Post-Dose (POSTDOSE)'	Stanley Doublin (b) (4) (b) (4)	09 Oct 2020 15:24:16

US3552412

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:53:07

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 11:14:37
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 19:11:21
User entered 'Yes (Y)'	Stanley Dublin (b) (4) (b) (4)	09 Oct 2020 15:24:16

US3552412

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:53:07

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 11:14:37
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 19:11:21
User entered '09 Oct 2020' reason for change: Data Entry Error	Heather Douds (b) (4) (b) (4)	09 Nov 2020 20:58:52
User entered '9 Oct 2020'	Stanley Dublin (b) (4) (b) (4)	09 Oct 2020 15:24:16

US3552412

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:53:07

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 11:14:37
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 19:11:21
User entered '10:02'	Stanley Dublin (b) (4) (b) (4)	09 Oct 2020 15:24:16

US3552412

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:53:07

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 11:14:37
User entered '09 Oct 2020 10:02'	System	09 Nov 2020 20:58:52
User entered '9 Oct 2020 10:02'	System	09 Oct 2020 15:24:16

US3552412

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:53:07

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 11:14:37
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 19:11:21
User entered '97.8' F	Stanley Dublin (b) (4) (b) (4)	09 Oct 2020 15:24:16

US3552412

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:53:07

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 11:14:37
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 19:11:21
User entered 'Oral (Oral)'	Stanley Dublin (b) (4) (b) (4)	09 Oct 2020 15:24:16

US3552412

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:53:07

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 11:14:37
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 19:11:21
User entered empty.	Stanley Dublin (b) (4) (b) (4)	09 Oct 2020 15:24:16

US3552412

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:53:07

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 11:14:37
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 19:11:21
User entered '72'	Stanley Dublin (b) (4) (b) (4)	09 Oct 2020 15:24:16

US3552412

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:53:07

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 11:14:37
User entered 'bpm'	System	09 Oct 2020 15:24:16

US3552412

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:53:07

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 11:14:37
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 19:11:21
User entered '14'	Stanley Doublin (b) (4) (b) (4)	09 Oct 2020 15:24:16

US3552412

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:53:07

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 11:14:37
User entered 'breaths/min'	System	09 Oct 2020 15:24:16

US3552412

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:53:07

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 11:14:37
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 19:11:21
User entered '97'	Stanley Dublin (b) (4) (b) (4)	09 Oct 2020 15:24:16

US3552412

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:53:07

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 11:14:37
User entered 'mmHg'	System	09 Oct 2020 15:24:16

US3552412

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:53:07

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 11:14:37
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 19:11:21
User entered '62'	Stanley Dublin (b) (4) (b) (4)	09 Oct 2020 15:24:16

US3552412

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:53:07

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 11:14:37
User entered 'mmHg'	System	09 Oct 2020 15:24:16

US3552412

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Generated On: 11 Aug 2021 22:53:07

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 11:14:37
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:11:21
User entered 'Yes (Y)'	(b) (4) Stanley Dublin (b) (4) (b) (4)	09 Oct 2020 15:24:23

US3552412

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Generated On: 11 Aug 2021 22:53:07

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 11:14:37
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 19:11:21
User entered '09 Oct 2020' reason for change: Data Entry Error	Heather Douds (b) (4) (b) (4)	09 Nov 2020 20:58:57
User entered '9 Oct 2020'	Stanley Dublin (b) (4) (b) (4)	09 Oct 2020 15:24:23

US3552412

Folder: Visit 2 Day 29 (1)

Form: Pregnancy Test

Generated On: 11 Aug 2021 22:53:07

[Was the pregnancy test performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 11:14:37
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 19:11:21
User entered 'Yes (Y)'	Stanley Dublin (b) (4) (b) (4)	09 Oct 2020 15:24:34

US3552412

Folder: Visit 2 Day 29 (1)

Form: Pregnancy Test

Generated On: 11 Aug 2021 22:53:07

Date of test (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 11:14:37
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 19:11:21
User entered '09 Oct 2020' reason for change: Data Entry Error	Heather Douds (b) (4) (b) (4)	09 Nov 2020 20:59:03
User entered '9 Oct 2020'	Stanley Dublin (b) (4) (b) (4)	09 Oct 2020 15:24:34

US3552412

Folder: Visit 2 Day 29 (1)

Form: Pregnancy Test

Generated On: 11 Aug 2021 22:53:07

[Test performed](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 11:14:37
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 19:11:21
User entered 'Urine (URINE)'	Stanley Dublin (b) (4) (b) (4)	09 Oct 2020 15:24:34

US3552412

Folder: Visit 2 Day 29 (1)

Form: Pregnancy Test

Generated On: 11 Aug 2021 22:53:07

[Result](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 11:14:37
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 19:11:21
User entered 'Negative (NEGATIVE)'	Stanley Dublin (b) (4) (b) (4)	09 Oct 2020 15:24:34

US3552412

Folder: Visit 2 Day 29 (1)

Form: Pregnancy Test

Generated On: 11 Aug 2021 22:53:07

[Was FSH sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 11:14:37
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 19:11:21
User entered 'No (N)'	Stanley Dublin (b) (4) (b) (4)	09 Oct 2020 15:24:34

US3552412

Folder: Visit 2 Day 29 (1)

Form: Pregnancy Test

Generated On: 11 Aug 2021 22:53:07

[Collection date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 11:14:37
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 19:11:21
User entered empty.	Stanley Dublin (b) (4) (b) (4)	09 Oct 2020 15:24:34

US3552412

Folder: Visit 2 Day 29 (1)

Form: Pregnancy Test

Generated On: 11 Aug 2021 22:53:07

[Collection time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 11:14:37
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 19:11:21
User entered empty.	Stanley Dublin (b) (4) (b) (4)	09 Oct 2020 15:24:34

US3552412

Folder: Visit 2 Day 29 (1)

Form: Pregnancy Test

Generated On: 11 Aug 2021 22:53:07

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 11:14:37
User entered empty.	System	09 Oct 2020 15:24:34

US3552412

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 11 Aug 2021 22:53:07

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 11:14:37
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:11:21
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	09 Oct 2020 14:37:10

US3552412

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 11 Aug 2021 22:53:07

[If No, reason not given](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 11:14:37
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:11:21
User entered empty.	(b) (4) (b) (4), (b) (6)	09 Oct 2020 14:37:10

US3552412

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 11 Aug 2021 22:53:07

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 11:14:37
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:11:21
User entered empty.	(b) (4), (b) (6)	09 Oct 2020 14:37:10

US3552412

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 11 Aug 2021 22:53:07

[What was the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 11:14:37
User entered 'MRNA-1273 OR PLACEBO'	System	09 Oct 2020 14:37:10

US3552412

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 11 Aug 2021 22:53:07

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 11:14:37
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 19:11:21
User entered '09 Oct 2020' reason for change: Data Entry Error	Heather Douds (b) (4) (b) (4)	09 Nov 2020 20:59:17
User entered '9 Oct 2020'	(b) (4), (b) (6)	09 Oct 2020 14:37:10

US3552412

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 11 Aug 2021 22:53:07

[What was the treatment time? \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 11:14:37
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 19:11:21
User entered '09:32'	(b) (4), (b) (6)	09 Oct 2020 14:37:10

US3552412

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 11 Aug 2021 22:53:07

[Treatment Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 11:14:37
User entered '09 Oct 2020 09:32'	System	09 Nov 2020 20:59:17
User entered '9 Oct 2020 09:32'	System	09 Oct 2020 14:37:10

US3552412

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 11 Aug 2021 22:53:07

[Which arm was used to give treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 11:14:37
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:11:21
User entered 'Left Arm (LEFT ARM)'	(b) (4) (b) (4), (b) (6)	09 Oct 2020 14:37:10

US3552412

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 11 Aug 2021 22:53:07

[What was the frequency of the study treatment dosing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 11:14:37
User entered 'ONCE'	System	09 Oct 2020 14:37:10

US3552412

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 11 Aug 2021 22:53:07

What was the route of administration for the study treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 11:14:37
User entered 'INTRAMUSCULAR'	System	09 Oct 2020 14:37:10

US3552412

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:53:07

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 11:14:37
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 19:11:21
User entered 'Yes (Y)'	Stanley Dublin (b) (4) (b) (4)	09 Oct 2020 15:24:50

US3552412

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:53:07

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 11:14:37
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 19:11:21
User entered '09 Oct 2020' reason for change: Data Entry Error	Heather Douds (b) (4) (b) (4)	09 Nov 2020 20:59:22
User entered '9 Oct 2020'	Stanley Dublin (b) (4) (b) (4)	09 Oct 2020 15:24:50

US3552412

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:53:07

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 11:14:37
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:11:21
User entered '09:01'	(b) (4) Stanley Dublin (b) (4) (b) (4)	09 Oct 2020 15:24:50

US3552412

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:53:07

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 11:14:37
User entered '09 Oct 2020 09:01'	System	09 Nov 2020 20:59:22
User entered '9 Oct 2020 09:01'	System	09 Oct 2020 15:24:50

US3552412

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 11 Aug 2021 22:53:07

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 11:14:37
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 19:11:21
User entered '09 Oct 2020' reason for change: Data Entry Error	Heather Douds (b) (4) (b) (4)	09 Nov 2020 20:59:28
User entered '9 Oct 2020'	Stanley Dublin (b) (4) (b) (4)	09 Oct 2020 15:25:02

US3552412

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 11 Aug 2021 22:53:07

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 11:14:37
User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)'	Stanley Doublin (b) (4) (b) (4)	09 Oct 2020 15:25:02

US3552412

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 11 Aug 2021 22:53:07

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 11:14:37
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 19:11:21
User entered 'Yes (Y)'	Stanley Dublin (b) (4) (b) (4)	09 Oct 2020 15:25:02

US3552412

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 11 Aug 2021 22:53:07

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 11:14:37
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 19:11:21
User entered '09:08'	Stanley Dublin (b) (4) (b) (4)	09 Oct 2020 15:25:02

US3552412

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 11 Aug 2021 22:53:07

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 11:14:37
User entered '09 Oct 2020 09:08'	System	09 Nov 2020 20:59:28
User entered '9 Oct 2020 09:08'	System	09 Oct 2020 15:25:02

US3552412

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 11 Aug 2021 22:53:07

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 11:14:37
User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)'	Stanley Dublin (b) (4) (b) (4)	09 Oct 2020 15:25:02

US3552412

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 11 Aug 2021 22:53:07

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 11:14:37
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 19:11:21
User entered 'No (N)'	Stanley Dublin (b) (4) (b) (4)	09 Oct 2020 15:25:02

US3552412

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 11 Aug 2021 22:53:07

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 11:14:37
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 19:11:21
User entered empty.	Stanley Dublin (b) (4) (b) (4)	09 Oct 2020 15:25:02

US3552412

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 11 Aug 2021 22:53:07

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 11:14:37
User entered empty.	System	09 Oct 2020 15:25:02

US3552412

Folder: Visit 2 Day 29 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:53:07

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 11:14:37
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 19:11:21
User entered 'Yes (Y)'	Stanley Dublin (b) (4) (b) (4)	16 Oct 2020 17:40:53

US3552412

Folder: Visit 2 Day 29 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:53:07

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 11:14:37
User entered 'l'	System	16 Oct 2020 17:40:53

US3552412

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/1)

Generated On: 11 Aug 2021 22:53:07

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:25:24
Data entry locked.	System	09 Oct 2020 14:37:10
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	09 Oct 2020 14:37:10

US3552412

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/1)

Generated On: 11 Aug 2021 22:53:07

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:25:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7f466cdad72abdb)', Time: '2020-10-09T10:02:43', User OID: 'PatientReportedOutcome (US3552412)', ODM File OID: '6a6ee5de-7cc4-4e65-b518-e08714c8d6d5'	System	09 Oct 2020 15:02:57
User entered 'Yes (Y)'	System	09 Oct 2020 15:02:57

US3552412

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/1)

Generated On: 11 Aug 2021 22:53:07

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:25:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7f466cdad72abdb)', Time: '2020-10-09T10:02:47', User OID: 'PatientReportedOutcome (US3552412)', ODM File OID: '6a6ee5de-7cc4-4e65-b518-e08714c8d6d5'	System	09 Oct 2020 15:02:57
User entered '97.8'	System	09 Oct 2020 15:02:57

US3552412

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/1)

Generated On: 11 Aug 2021 22:53:07

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:25:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7f466cdad72abdb)', Time: '2020-10-09T10:02:50', User OID: 'PatientReportedOutcome (US3552412)', ODM File OID: '6a6ee5de-7cc4-4e65-b518-e08714c8d6d5'	System	09 Oct 2020 15:02:57
User entered 'No (N)'	System	09 Oct 2020 15:02:57

US3552412

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/1)

Generated On: 11 Aug 2021 22:53:07

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:25:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7f466cdad72abdb)', Time: '2020-10-09T10:02:53', User OID: 'PatientReportedOutcome (US3552412)', ODM File OID: '6a6ee5de-7cc4-4e65-b518-e08714c8d6d5'	System	09 Oct 2020 15:02:57
User entered '09 Oct 2020 10:02'	System	09 Oct 2020 15:02:57

US3552412

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/1)

Generated On: 11 Aug 2021 22:53:07

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:25:24
User entered '09 Oct 2020 09:52'	System	09 Oct 2020 14:37:10

US3552412

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/1)

Generated On: 11 Aug 2021 22:53:07

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:25:24
User entered '09 Oct 2020 12:22'	System	09 Oct 2020 14:37:10

US3552412

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/2)

Generated On: 11 Aug 2021 22:53:07

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:25:24
Data entry locked.	System	09 Oct 2020 14:37:10
User entered 'Day 1, after vaccination (at home)'	System	09 Oct 2020 14:37:10

US3552412

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/2)

Generated On: 11 Aug 2021 22:53:07

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:25:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7f466cdad72abdb)', Time: '2020-10-09T18:45:22', User OID: 'PatientReportedOutcome (US3552412)', ODM File OID: '7bfef587-13fe-479c-aa47-f150e4f2ef0d'	System	09 Oct 2020 23:46:03
User entered 'Yes (Y)'	System	09 Oct 2020 23:46:03

US3552412

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/2)

Generated On: 11 Aug 2021 22:53:07

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:25:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7f466cdad72abdb)', Time: '2020-10-09T18:45:26', User OID: 'PatientReportedOutcome (US3552412)', ODM File OID: '7bfef587-13fe-479c-aa47-f150e4f2ef0d'	System	09 Oct 2020 23:46:03
User entered '100.0'	System	09 Oct 2020 23:46:03

US3552412

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/2)

Generated On: 11 Aug 2021 22:53:07

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:25:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7f466cdad72abdb)', Time: '2020-10-09T18:45:49', User OID: 'PatientReportedOutcome (US3552412)', ODM File OID: '7bfef587-13fe-479c-aa47-f150e4f2ef0d'	System	09 Oct 2020 23:46:03
User entered 'Yes (Y)'	System	09 Oct 2020 23:46:03

US3552412

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/2)

Generated On: 11 Aug 2021 22:53:07

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:25:24
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 'Subject contacted and data updated accordingly. Thank you.' (Site from System).	(b) (4)	15 Oct 2020 07:04:27
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).	Cassandra Zehenny (b) (4)	12 Oct 2020 16:34:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7f466cdad72abdb)', Time: '2020-10-09T18:45:56', User OID: 'PatientReportedOutcome (US3552412)', ODM File OID: '7bfef587-13fe-479c-aa47-f150e4f2ef0d'	System	09 Oct 2020 23:46:03
User entered '1'	System	09 Oct 2020 23:46:03

US3552412

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/2)

Generated On: 11 Aug 2021 22:53:07

To **PREVENT** pain or fever from occurring

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:25:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7f466cdad72abdb)', Time: '2020-10-09T18:45:56', User OID: 'PatientReportedOutcome (US3552412)', ODM File OID: '7bfef587-13fe-479c-aa47-f150e4f2ef0d'	System	09 Oct 2020 23:46:03
User entered '0'	System	09 Oct 2020 23:46:03

US3552412

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/2)

Generated On: 11 Aug 2021 22:53:07

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:25:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7f466cdad72abdb)', Time: '2020-10-09T18:46:00', User OID: 'PatientReportedOutcome (US3552412)', ODM File OID: '7bfef587-13fe-479c-aa47-f150e4f2ef0d'	System	09 Oct 2020 23:46:03
User entered '09 Oct 2020 18:46'	System	09 Oct 2020 23:46:03

US3552412

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/2)

Generated On: 11 Aug 2021 22:53:07

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:25:24
User entered '09 Oct 2020 13:17'	System	09 Oct 2020 14:37:10

US3552412

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/2)

Generated On: 11 Aug 2021 22:53:07

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:25:24
User entered '10 Oct 2020 11:59'	System	09 Oct 2020 14:37:10

US3552412

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(2)

Generated On: 11 Aug 2021 22:53:07

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:25:24
Data entry locked.	System	09 Oct 2020 14:37:10
User entered 'Day 2'	System	09 Oct 2020 14:37:10

US3552412

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(2)

Generated On: 11 Aug 2021 22:53:07

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:25:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7f466cdad72abdb)', Time: '2020-10-10T19:32:50', User OID: 'PatientReportedOutcome (US3552412)', ODM File OID: '78af9d6a-a35e-4ee7-a6fc-f3cecf48dd4'	System	11 Oct 2020 00:33:14
User entered 'Yes (Y)'	System	11 Oct 2020 00:33:14

US3552412

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(2)

Generated On: 11 Aug 2021 22:53:07

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:25:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7f466cdad72abdb)', Time: '2020-10-10T19:32:55', User OID: 'PatientReportedOutcome (US3552412)', ODM File OID: '78af9d6a-a35e-4ee7-a6fc-f3cecff48dd4'	System	11 Oct 2020 00:33:14
User entered '99.0'	System	11 Oct 2020 00:33:14

US3552412

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(2)

Generated On: 11 Aug 2021 22:53:07

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:25:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7f466cdad72abdb)', Time: '2020-10-10T19:32:58', User OID: 'PatientReportedOutcome (US3552412)', ODM File OID: '78af9d6a-a35e-4ee7-a6fc-f3cecf48dd4'	System	11 Oct 2020 00:33:14
User entered 'Yes (Y)'	System	11 Oct 2020 00:33:14

US3552412

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(2)

Generated On: 11 Aug 2021 22:53:07

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:25:24
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 'Subject contacted and data updated accordingly. Thank you.' (Site from System).	(b) (4), (b) (6)	15 Oct 2020 07:04:04
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 (7f466cdad72abddb)', Time: '2020-10-10T19:33:01', User OID: 'PatientReportedOutcome (US3552412)', ODM File OID: '78af9d6a-a35e-4ee7-a6fc-f3cecff48dd4'	Cassandra Zehenny (b) (4)	12 Oct 2020 16:34:58
User entered '1'	System	11 Oct 2020 00:33:14
	System	11 Oct 2020 00:33:14
	System	11 Oct 2020 00:33:14

US3552412

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(2)

Generated On: 11 Aug 2021 22:53:07

To **PREVENT** pain or fever from occurring

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:25:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7f466cdad72abddb)', Time: '2020-10-10T19:33:01', User OID: 'PatientReportedOutcome (US3552412)', ODM File OID: '78af9d6a-a35e-4ee7-a6fc-f3cecff48dd4'	System	11 Oct 2020 00:33:14
User entered '0'	System	11 Oct 2020 00:33:14

US3552412

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(2)

Generated On: 11 Aug 2021 22:53:07

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:25:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7f466cdad72abdb)', Time: '2020-10-10T19:33:08', User OID: 'PatientReportedOutcome (US3552412)', ODM File OID: '78af9d6a-a35e-4ee7-a6fc-f3cecf48dd4'	System	11 Oct 2020 00:33:14
User entered '10 Oct 2020 19:33'	System	11 Oct 2020 00:33:14

US3552412

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(2)

Generated On: 11 Aug 2021 22:53:07

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:25:24
User entered '10 Oct 2020 12:00'	System	09 Oct 2020 14:37:10

US3552412

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(2)

Generated On: 11 Aug 2021 22:53:07

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:25:24
User entered '11 Oct 2020 11:59'	System	09 Oct 2020 14:37:10

US3552412

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(3)

Generated On: 11 Aug 2021 22:53:07

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:25:24
Data entry locked.	System	09 Oct 2020 14:37:10
User entered 'Day 3'	System	09 Oct 2020 14:37:10

US3552412

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(3)

Generated On: 11 Aug 2021 22:53:07

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:25:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7f466cdad72abdb)', Time: '2020-10-11T20:05:29', User OID: 'PatientReportedOutcome (US3552412)', ODM File OID: 'aacb01b1-5d96-4903-a1a1-6040c5b4c686'	System	12 Oct 2020 01:05:40
User entered 'Yes (Y)'	System	12 Oct 2020 01:05:40

US3552412

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(3)

Generated On: 11 Aug 2021 22:53:07

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:25:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7f466cdad72abdb)', Time: '2020-10-11T20:05:33', User OID: 'PatientReportedOutcome (US3552412)', ODM File OID: 'aacb01b1-5d96-4903-a1a1-6040c5b4c686'	System	12 Oct 2020 01:05:40
User entered '98.3'	System	12 Oct 2020 01:05:40

US3552412

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(3)

Generated On: 11 Aug 2021 22:53:07

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:25:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7f466cdad72abdb)', Time: '2020-10-11T20:05:35', User OID: 'PatientReportedOutcome (US3552412)', ODM File OID: 'aacb01b1-5d96-4903-a1a1-6040c5b4c686'	System	12 Oct 2020 01:05:40
User entered 'No (N)'	System	12 Oct 2020 01:05:40

US3552412

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(3)

Generated On: 11 Aug 2021 22:53:07

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:25:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7f466cdad72abdb)', Time: '2020-10-11T20:05:37', User OID: 'PatientReportedOutcome (US3552412)', ODM File OID: 'aacb01b1-5d96-4903-a1a1-6040c5b4c686'	System	12 Oct 2020 01:05:40
User entered '11 Oct 2020 20:05'	System	12 Oct 2020 01:05:40

US3552412

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(3)

Generated On: 11 Aug 2021 22:53:07

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:25:24
User entered '11 Oct 2020 12:00'	System	09 Oct 2020 14:37:10

US3552412

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(3)

Generated On: 11 Aug 2021 22:53:07

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:25:24
User entered '12 Oct 2020 11:59'	System	09 Oct 2020 14:37:10

US3552412

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(4)

Generated On: 11 Aug 2021 22:53:07

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:25:24
Data entry locked.	System	09 Oct 2020 14:37:10
User entered 'Day 4'	System	09 Oct 2020 14:37:10

US3552412

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(4)

Generated On: 11 Aug 2021 22:53:07

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:25:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7f466cdad72abdb)', Time: '2020-10-12T19:23:44', User OID: 'PatientReportedOutcome (US3552412)', ODM File OID: '3ac450f6-5c30-4149-8e73-56989d9ea6a5'	System	13 Oct 2020 00:23:54
User entered 'Yes (Y)'	System	13 Oct 2020 00:23:54

US3552412

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(4)

Generated On: 11 Aug 2021 22:53:07

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:25:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7f466cdad72abdb)', Time: '2020-10-12T19:23:47', User OID: 'PatientReportedOutcome (US3552412)', ODM File OID: '3ac450f6-5c30-4149-8e73-56989d9ea6a5'	System	13 Oct 2020 00:23:54
User entered '98.1'	System	13 Oct 2020 00:23:54

US3552412

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(4)

Generated On: 11 Aug 2021 22:53:07

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:25:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7f466cdad72abdb)', Time: '2020-10-12T19:23:49', User OID: 'PatientReportedOutcome (US3552412)', ODM File OID: '3ac450f6-5c30-4149-8e73-56989d9ea6a5'	System	13 Oct 2020 00:23:54
User entered 'No (N)'	System	13 Oct 2020 00:23:54

US3552412

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(4)

Generated On: 11 Aug 2021 22:53:07

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:25:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7f466cdad72abddb)', Time: '2020-10-12T19:23:51', User OID: 'PatientReportedOutcome (US3552412)', ODM File OID: '3ac450f6-5c30-4149-8e73-56989d9ea6a5'	System	13 Oct 2020 00:23:54
User entered '12 Oct 2020 19:23'	System	13 Oct 2020 00:23:54

US3552412

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(4)

Generated On: 11 Aug 2021 22:53:07

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:25:24
User entered '12 Oct 2020 12:00'	System	09 Oct 2020 14:37:10

US3552412

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(4)

Generated On: 11 Aug 2021 22:53:07

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:25:24
User entered '13 Oct 2020 11:59'	System	09 Oct 2020 14:37:10

US3552412

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(5)

Generated On: 11 Aug 2021 22:53:07

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:25:24
Data entry locked.	System	09 Oct 2020 14:37:10
User entered 'Day 5'	System	09 Oct 2020 14:37:10

US3552412

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(5)

Generated On: 11 Aug 2021 22:53:07

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:25:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7f466cdad72abdb)', Time: '2020-10-13T21:19:00', User OID: 'PatientReportedOutcome (US3552412)', ODM File OID: '07417329-e5db-4b40-af84-b2fb6ca6a5c9'	System	14 Oct 2020 02:19:10
User entered 'Yes (Y)'	System	14 Oct 2020 02:19:10

US3552412

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(5)

Generated On: 11 Aug 2021 22:53:07

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:25:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7f466cdad72abddb)', Time: '2020-10-13T21:19:04', User OID: 'PatientReportedOutcome (US3552412)', ODM File OID: '07417329-e5db-4b40-af84-b2fb6ca6a5c9'	System	14 Oct 2020 02:19:10
User entered '98.5'	System	14 Oct 2020 02:19:10

US3552412

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(5)

Generated On: 11 Aug 2021 22:53:07

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:25:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7f466cdad72abdb)', Time: '2020-10-13T21:19:06', User OID: 'PatientReportedOutcome (US3552412)', ODM File OID: '07417329-e5db-4b40-af84-b2fb6ca6a5c9'	System	14 Oct 2020 02:19:10
User entered 'No (N)'	System	14 Oct 2020 02:19:10

US3552412

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(5)

Generated On: 11 Aug 2021 22:53:07

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:25:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7f466cdad72abdb)', Time: '2020-10-13T21:19:08', User OID: 'PatientReportedOutcome (US3552412)', ODM File OID: '07417329-e5db-4b40-af84-b2fb6ca6a5c9'	System	14 Oct 2020 02:19:10
User entered '13 Oct 2020 21:19'	System	14 Oct 2020 02:19:10

US3552412

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(5)

Generated On: 11 Aug 2021 22:53:07

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:25:24
User entered '13 Oct 2020 12:00'	System	09 Oct 2020 14:37:10

US3552412

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(5)

Generated On: 11 Aug 2021 22:53:07

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:25:24
User entered '14 Oct 2020 11:59'	System	09 Oct 2020 14:37:10

US3552412

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(6)

Generated On: 11 Aug 2021 22:53:07

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:25:24
Data entry locked.	System	09 Oct 2020 14:37:10
User entered 'Day 6'	System	09 Oct 2020 14:37:10

US3552412

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(6)

Generated On: 11 Aug 2021 22:53:07

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:25:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7f466cdad72abdb)', Time: '2020-10-15T07:14:58', User OID: 'PatientReportedOutcome (US3552412)', ODM File OID: 'ab841107-553c-426f-8fbf-7c8991ac223c'	System	15 Oct 2020 12:15:13
User entered 'Yes (Y)'	System	15 Oct 2020 12:15:13

US3552412

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(6)

Generated On: 11 Aug 2021 22:53:07

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:25:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7f466cdad72abdb)', Time: '2020-10-15T07:15:03', User OID: 'PatientReportedOutcome (US3552412)', ODM File OID: 'ab841107-553c-426f-8fbf-7c8991ac223c'	System	15 Oct 2020 12:15:13
User entered '98.1'	System	15 Oct 2020 12:15:13

US3552412

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(6)

Generated On: 11 Aug 2021 22:53:07

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:25:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7f466cdad72abdb)', Time: '2020-10-15T07:15:05', User OID: 'PatientReportedOutcome (US3552412)', ODM File OID: 'ab841107-553c-426f-8fbf-7c8991ac223c'	System	15 Oct 2020 12:15:13
User entered 'No (N)'	System	15 Oct 2020 12:15:13

US3552412

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(6)

Generated On: 11 Aug 2021 22:53:07

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:25:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7f466cdad72abdb)', Time: '2020-10-15T07:15:08', User OID: 'PatientReportedOutcome (US3552412)', ODM File OID: 'ab841107-553c-426f-8fbf-7c8991ac223c'	System	15 Oct 2020 12:15:13
User entered '15 Oct 2020 07:15'	System	15 Oct 2020 12:15:13

US3552412

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(6)

Generated On: 11 Aug 2021 22:53:07

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:25:24
User entered '14 Oct 2020 12:00'	System	09 Oct 2020 14:37:10

US3552412

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(6)

Generated On: 11 Aug 2021 22:53:07

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:25:24
User entered '15 Oct 2020 11:59'	System	09 Oct 2020 14:37:10

US3552412

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(7)

Generated On: 11 Aug 2021 22:53:07

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:25:24
Data entry locked.	System	09 Oct 2020 14:37:10
User entered 'Day 7'	System	09 Oct 2020 14:37:10

US3552412

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(7)

Generated On: 11 Aug 2021 22:53:07

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:25:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7f466cdad72abdb)', Time: '2020-10-15T21:12:07', User OID: 'PatientReportedOutcome (US3552412)', ODM File OID: '7c7dde69-e6c9-4dbf-98c1-5aad905d1fde'	System	16 Oct 2020 02:12:24
User entered 'Yes (Y)'	System	16 Oct 2020 02:12:24

US3552412

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(7)

Generated On: 11 Aug 2021 22:53:07

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:25:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7f466cdad72abdb)', Time: '2020-10-15T21:12:09', User OID: 'PatientReportedOutcome (US3552412)', ODM File OID: '7c7dde69-e6c9-4dbf-98c1-5aad905d1fde'	System	16 Oct 2020 02:12:24
User entered '97.3'	System	16 Oct 2020 02:12:24

US3552412

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(7)

Generated On: 11 Aug 2021 22:53:07

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:25:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7f466cdad72abdb)', Time: '2020-10-15T21:12:13', User OID: 'PatientReportedOutcome (US3552412)', ODM File OID: '7c7dde69-e6c9-4dbf-98c1-5aad905d1fde'	System	16 Oct 2020 02:12:24
User entered 'Yes (Y)'	System	16 Oct 2020 02:12:24

US3552412

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(7)

Generated On: 11 Aug 2021 22:53:07

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:25:24
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 'done' (Site from System).	(b) (4)	19 Oct 2020 05:57:31
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).	Heather Douds (b) (4)	16 Oct 2020 17:49:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7f466cdad72abdb)', Time: '2020-10-15T21:12:17', User OID: 'PatientReportedOutcome (US3552412)', ODM File OID: '7c7dde69-e6c9-4dbf-98c1-5aad905d1fde'	System	16 Oct 2020 02:12:24
User entered '1'	System	16 Oct 2020 02:12:24

US3552412

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(7)

Generated On: 11 Aug 2021 22:53:07

To **PREVENT** pain or fever from occurring

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:25:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7f466cdad72abdb)', Time: '2020-10-15T21:12:17', User OID: 'PatientReportedOutcome (US3552412)', ODM File OID: '7c7dde69-e6c9-4dbf-98c1-5aad905d1fde'	System	16 Oct 2020 02:12:24
User entered '0'	System	16 Oct 2020 02:12:24

US3552412

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(7)

Generated On: 11 Aug 2021 22:53:07

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:25:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7f466cdad72abdb)', Time: '2020-10-15T21:12:20', User OID: 'PatientReportedOutcome (US3552412)', ODM File OID: '7c7dde69-e6c9-4dbf-98c1-5aad905d1fde'	System	16 Oct 2020 02:12:24
User entered '15 Oct 2020 21:12'	System	16 Oct 2020 02:12:24

US3552412

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(7)

Generated On: 11 Aug 2021 22:53:07

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:25:24
User entered '15 Oct 2020 12:00'	System	09 Oct 2020 14:37:10

US3552412

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(7)

Generated On: 11 Aug 2021 22:53:07

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:25:24
User entered '16 Oct 2020 11:59'	System	09 Oct 2020 14:37:10

US3552412

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(8)

Generated On: 11 Aug 2021 22:53:07

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:25:24
Data entry locked.	System	16 Oct 2020 02:12:24
User entered 'Day 8'	System	16 Oct 2020 02:12:24

US3552412

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(8)

Generated On: 11 Aug 2021 22:53:07

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:25:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7f466cdad72abdb)', Time: '2020-10-16T22:12:33', User OID: 'PatientReportedOutcome (US3552412)', ODM File OID: '6fa8e909-d2e5-4971-b07a-12017d17be97'	System	17 Oct 2020 03:12:45
User entered 'Yes (Y)'	System	17 Oct 2020 03:12:45

US3552412

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(8)

Generated On: 11 Aug 2021 22:53:07

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:25:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7f466cdad72abdb)', Time: '2020-10-16T22:12:36', User OID: 'PatientReportedOutcome (US3552412)', ODM File OID: '6fa8e909-d2e5-4971-b07a-12017d17be97'	System	17 Oct 2020 03:12:45
User entered '97.1'	System	17 Oct 2020 03:12:45

US3552412

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(8)

Generated On: 11 Aug 2021 22:53:07

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:25:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7f466cdad72abdb)', Time: '2020-10-16T22:12:38', User OID: 'PatientReportedOutcome (US3552412)', ODM File OID: '6fa8e909-d2e5-4971-b07a-12017d17be97'	System	17 Oct 2020 03:12:45
User entered 'No (N)'	System	17 Oct 2020 03:12:45

US3552412

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(8)

Generated On: 11 Aug 2021 22:53:07

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:25:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7f466cdad72abdb)', Time: '2020-10-16T22:12:40', User OID: 'PatientReportedOutcome (US3552412)', ODM File OID: '6fa8e909-d2e5-4971-b07a-12017d17be97'	System	17 Oct 2020 03:12:45
User entered '16 Oct 2020 22:12'	System	17 Oct 2020 03:12:45

US3552412

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(8)

Generated On: 11 Aug 2021 22:53:07

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:25:24
User entered '16 Oct 2020 12:00'	System	16 Oct 2020 02:12:24

US3552412

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(8)

Generated On: 11 Aug 2021 22:53:07

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:25:24
User entered '17 Oct 2020 11:59'	System	16 Oct 2020 02:12:24

US3552412

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/1)

Generated On: 11 Aug 2021 22:53:07

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:25:24
Data entry locked.	System	09 Oct 2020 14:37:10
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	09 Oct 2020 14:37:10

US3552412

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/1)

Generated On: 11 Aug 2021 22:53:07

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:25:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7f466cdad72abdb)', Time: '2020-10-09T10:03:00', User OID: 'PatientReportedOutcome (US3552412)', ODM File OID: '247fddc4-aed4-44b0-861e-fe71bd4e2d77'	System	09 Oct 2020 15:03:47
User entered 'None (1)'	System	09 Oct 2020 15:03:47

US3552412

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/1)

Generated On: 11 Aug 2021 22:53:07

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:25:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7f466cdad72abdb)', Time: '2020-10-09T10:03:06', User OID: 'PatientReportedOutcome (US3552412)', ODM File OID: '247fddc4-aed4-44b0-861e-fe71bd4e2d77'	System	09 Oct 2020 15:03:47
User entered 'No (N)'	System	09 Oct 2020 15:03:47

US3552412

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/1)

Generated On: 11 Aug 2021 22:53:07

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:25:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7f466cdad72abdb)', Time: '2020-10-09T10:03:11', User OID: 'PatientReportedOutcome (US3552412)', ODM File OID: '247fddc4-aed4-44b0-861e-fe71bd4e2d77'	System	09 Oct 2020 15:03:47
User entered 'No (N)'	System	09 Oct 2020 15:03:47

US3552412

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/1)

Generated On: 11 Aug 2021 22:53:07

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:25:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7f466cdad72abdb)', Time: '2020-10-09T10:03:18', User OID: 'PatientReportedOutcome (US3552412)', ODM File OID: '247fddc4-aed4-44b0-861e-fe71bd4e2d77'	System	09 Oct 2020 15:03:47
User entered 'None (1)'	System	09 Oct 2020 15:03:47

US3552412

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/1)

Generated On: 11 Aug 2021 22:53:07

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:25:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7f466cdad72abdb)', Time: '2020-10-09T10:03:20', User OID: 'PatientReportedOutcome (US3552412)', ODM File OID: '247fddc4-aed4-44b0-861e-fe71bd4e2d77'	System	09 Oct 2020 15:03:47
User entered '09 Oct 2020 10:03'	System	09 Oct 2020 15:03:47

US3552412

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/1)

Generated On: 11 Aug 2021 22:53:07

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:25:24
User entered '09 Oct 2020 09:52'	System	09 Oct 2020 14:37:10

US3552412

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/1)

Generated On: 11 Aug 2021 22:53:07

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:25:24
User entered '09 Oct 2020 12:22'	System	09 Oct 2020 14:37:10

US3552412

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/2)

Generated On: 11 Aug 2021 22:53:07

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:25:24
Data entry locked.	System	09 Oct 2020 14:37:10
User entered 'Day 1, after vaccination (at home)'	System	09 Oct 2020 14:37:10

US3552412

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/2)

Generated On: 11 Aug 2021 22:53:07

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:25:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7f466cdad72abdb)', Time: '2020-10-09T18:46:52', User OID: 'PatientReportedOutcome (US3552412)', ODM File OID: '822f6fa5-d05d-4a45-926d-dd684175b2d2'	System	09 Oct 2020 23:47:13
User entered 'Does not interfere with activity (2)'	System	09 Oct 2020 23:47:13

US3552412

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/2)

Generated On: 11 Aug 2021 22:53:07

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:25:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7f466cdad72abdb)', Time: '2020-10-09T18:46:54', User OID: 'PatientReportedOutcome (US3552412)', ODM File OID: '822f6fa5-d05d-4a45-926d-dd684175b2d2'	System	09 Oct 2020 23:47:13
User entered 'No (N)'	System	09 Oct 2020 23:47:13

US3552412

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/2)

Generated On: 11 Aug 2021 22:53:07

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:25:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7f466cdad72abdb)', Time: '2020-10-09T18:47:01', User OID: 'PatientReportedOutcome (US3552412)', ODM File OID: '822f6fa5-d05d-4a45-926d-dd684175b2d2'	System	09 Oct 2020 23:47:13
User entered 'No (N)'	System	09 Oct 2020 23:47:13

US3552412

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/2)

Generated On: 11 Aug 2021 22:53:07

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:25:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7f466cdad72abdb)', Time: '2020-10-09T18:47:09', User OID: 'PatientReportedOutcome (US3552412)', ODM File OID: '822f6fa5-d05d-4a45-926d-dd684175b2d2'	System	09 Oct 2020 23:47:13
User entered 'None (1)'	System	09 Oct 2020 23:47:13

US3552412

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/2)

Generated On: 11 Aug 2021 22:53:07

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:25:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7f466cdad72abdb)', Time: '2020-10-09T18:47:11', User OID: 'PatientReportedOutcome (US3552412)', ODM File OID: '822f6fa5-d05d-4a45-926d-dd684175b2d2'	System	09 Oct 2020 23:47:13
User entered '09 Oct 2020 18:47'	System	09 Oct 2020 23:47:13

US3552412

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/2)

Generated On: 11 Aug 2021 22:53:07

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:25:24
User entered '09 Oct 2020 13:17'	System	09 Oct 2020 14:37:10

US3552412

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/2)

Generated On: 11 Aug 2021 22:53:07

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:25:24
User entered '10 Oct 2020 11:59'	System	09 Oct 2020 14:37:10

US3552412

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(2)

Generated On: 11 Aug 2021 22:53:07

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:25:24
Data entry locked.	System	09 Oct 2020 14:37:10
User entered 'Day 2'	System	09 Oct 2020 14:37:10

US3552412

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(2)

Generated On: 11 Aug 2021 22:53:07

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:25:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7f466cdad72abddb)', Time: '2020-10-10T19:29:50', User OID: 'PatientReportedOutcome (US3552412)', ODM File OID: '60287cd3-0505-4c62-b4b7-77ad93ab2335'	System	11 Oct 2020 00:30:24
User entered 'Does not interfere with activity (2)'	System	11 Oct 2020 00:30:24

US3552412

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(2)

Generated On: 11 Aug 2021 22:53:07

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:25:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7f466cdad72abdb)', Time: '2020-10-10T19:29:52', User OID: 'PatientReportedOutcome (US3552412)', ODM File OID: '60287cd3-0505-4c62-b4b7-77ad93ab2335'	System	11 Oct 2020 00:30:24
User entered 'Yes (Y)'	System	11 Oct 2020 00:30:24

US3552412

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(2)

Generated On: 11 Aug 2021 22:53:07

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

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:25:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7f466cdad72abdb)', Time: '2020-10-10T19:30:03', User OID: 'PatientReportedOutcome (US3552412)', ODM File OID: '60287cd3-0505-4c62-b4b7-77ad93ab2335'	System	11 Oct 2020 00:30:24
User entered '50'	System	11 Oct 2020 00:30:24

US3552412

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(2)

Generated On: 11 Aug 2021 22:53:07

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:25:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7f466cdad72abdb)', Time: '2020-10-10T19:30:06', User OID: 'PatientReportedOutcome (US3552412)', ODM File OID: '60287cd3-0505-4c62-b4b7-77ad93ab2335'	System	11 Oct 2020 00:30:24
User entered 'No (N)'	System	11 Oct 2020 00:30:24

US3552412

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(2)

Generated On: 11 Aug 2021 22:53:07

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:25:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7f466cdad72abddb)', Time: '2020-10-10T19:30:17', User OID: 'PatientReportedOutcome (US3552412)', ODM File OID: '60287cd3-0505-4c62-b4b7-77ad93ab2335'	System	11 Oct 2020 00:30:24
User entered 'None (1)'	System	11 Oct 2020 00:30:24

US3552412

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(2)

Generated On: 11 Aug 2021 22:53:07

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:25:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7f466cdad72abdb)', Time: '2020-10-10T19:30:19', User OID: 'PatientReportedOutcome (US3552412)', ODM File OID: '60287cd3-0505-4c62-b4b7-77ad93ab2335'	System	11 Oct 2020 00:30:24
User entered '10 Oct 2020 19:30'	System	11 Oct 2020 00:30:24

US3552412

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(2)

Generated On: 11 Aug 2021 22:53:07

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:25:24
User entered '10 Oct 2020 12:00'	System	09 Oct 2020 14:37:10

US3552412

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(2)

Generated On: 11 Aug 2021 22:53:07

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:25:24
User entered '11 Oct 2020 11:59'	System	09 Oct 2020 14:37:10

US3552412

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(3)

Generated On: 11 Aug 2021 22:53:07

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:25:24
Data entry locked.	System	09 Oct 2020 14:37:10
User entered 'Day 3'	System	09 Oct 2020 14:37:10

US3552412

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(3)

Generated On: 11 Aug 2021 22:53:07

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:25:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7f466cdad72abdb)', Time: '2020-10-11T20:05:41', User OID: 'PatientReportedOutcome (US3552412)', ODM File OID: '96d3d311-e2a5-4676-bf85-4305ce7363a5'	System	12 Oct 2020 01:05:56
User entered 'Does not interfere with activity (2)'	System	12 Oct 2020 01:05:56

US3552412

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(3)

Generated On: 11 Aug 2021 22:53:07

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:25:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7f466cdad72abdb)', Time: '2020-10-11T20:05:43', User OID: 'PatientReportedOutcome (US3552412)', ODM File OID: '96d3d311-e2a5-4676-bf85-4305ce7363a5'	System	12 Oct 2020 01:05:56
User entered 'No (N)'	System	12 Oct 2020 01:05:56

US3552412

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(3)

Generated On: 11 Aug 2021 22:53:07

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:25:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7f466cdad72abdb)', Time: '2020-10-11T20:05:46', User OID: 'PatientReportedOutcome (US3552412)', ODM File OID: '96d3d311-e2a5-4676-bf85-4305ce7363a5'	System	12 Oct 2020 01:05:56
User entered 'No (N)'	System	12 Oct 2020 01:05:56

US3552412

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(3)

Generated On: 11 Aug 2021 22:53:07

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:25:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7f466cdad72abdb)', Time: '2020-10-11T20:05:53', User OID: 'PatientReportedOutcome (US3552412)', ODM File OID: '96d3d311-e2a5-4676-bf85-4305ce7363a5'	System	12 Oct 2020 01:05:56
User entered 'None (1)'	System	12 Oct 2020 01:05:56

US3552412

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(3)

Generated On: 11 Aug 2021 22:53:07

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:25:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7f466cdad72abddb)', Time: '2020-10-11T20:05:55', User OID: 'PatientReportedOutcome (US3552412)', ODM File OID: '96d3d311-e2a5-4676-bf85-4305ce7363a5'	System	12 Oct 2020 01:05:56
User entered '11 Oct 2020 20:05'	System	12 Oct 2020 01:05:56

US3552412

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(3)

Generated On: 11 Aug 2021 22:53:07

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:25:24
User entered '11 Oct 2020 12:00'	System	09 Oct 2020 14:37:10

US3552412

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(3)

Generated On: 11 Aug 2021 22:53:07

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:25:24
User entered '12 Oct 2020 11:59'	System	09 Oct 2020 14:37:10

US3552412

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(4)

Generated On: 11 Aug 2021 22:53:07

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:25:24
Data entry locked.	System	09 Oct 2020 14:37:10
User entered 'Day 4'	System	09 Oct 2020 14:37:10

US3552412

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(4)

Generated On: 11 Aug 2021 22:53:07

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:25:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7f466cdad72abddb)', Time: '2020-10-12T19:23:59', User OID: 'PatientReportedOutcome (US3552412)', ODM File OID: '83320b98-0557-405f-9b27-2c8b78f34d0a'	System	13 Oct 2020 00:24:18
User entered 'Does not interfere with activity (2)'	System	13 Oct 2020 00:24:18

US3552412

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(4)

Generated On: 11 Aug 2021 22:53:07

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:25:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7f466cdad72abdb)', Time: '2020-10-12T19:24:01', User OID: 'PatientReportedOutcome (US3552412)', ODM File OID: '83320b98-0557-405f-9b27-2c8b78f34d0a'	System	13 Oct 2020 00:24:18
User entered 'No (N)'	System	13 Oct 2020 00:24:18

US3552412

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(4)

Generated On: 11 Aug 2021 22:53:07

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:25:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7f466cdad72abdb)', Time: '2020-10-12T19:24:03', User OID: 'PatientReportedOutcome (US3552412)', ODM File OID: '83320b98-0557-405f-9b27-2c8b78f34d0a'	System	13 Oct 2020 00:24:18
User entered 'No (N)'	System	13 Oct 2020 00:24:18

US3552412

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(4)

Generated On: 11 Aug 2021 22:53:07

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:25:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7f466cdad72abdb)', Time: '2020-10-12T19:24:12', User OID: 'PatientReportedOutcome (US3552412)', ODM File OID: '83320b98-0557-405f-9b27-2c8b78f34d0a'	System	13 Oct 2020 00:24:18
User entered 'None (1)'	System	13 Oct 2020 00:24:18

US3552412

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(4)

Generated On: 11 Aug 2021 22:53:07

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:25:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7f466cdad72abdb)', Time: '2020-10-12T19:24:14', User OID: 'PatientReportedOutcome (US3552412)', ODM File OID: '83320b98-0557-405f-9b27-2c8b78f34d0a'	System	13 Oct 2020 00:24:18
User entered '12 Oct 2020 19:24'	System	13 Oct 2020 00:24:18

US3552412

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(4)

Generated On: 11 Aug 2021 22:53:07

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:25:24
User entered '12 Oct 2020 12:00'	System	09 Oct 2020 14:37:10

US3552412

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(4)

Generated On: 11 Aug 2021 22:53:07

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:25:24
User entered '13 Oct 2020 11:59'	System	09 Oct 2020 14:37:10

US3552412

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(5)

Generated On: 11 Aug 2021 22:53:07

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:25:24
Data entry locked.	System	09 Oct 2020 14:37:10
User entered 'Day 5'	System	09 Oct 2020 14:37:10

US3552412

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(5)

Generated On: 11 Aug 2021 22:53:07

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:25:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7f466cdad72abdb)', Time: '2020-10-13T21:18:29', User OID: 'PatientReportedOutcome (US3552412)', ODM File OID: 'cf6bf88c-bf39-4414-8df8-29dee5fdcabe'	System	14 Oct 2020 02:18:40
User entered 'None (1)'	System	14 Oct 2020 02:18:40

US3552412

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(5)

Generated On: 11 Aug 2021 22:53:07

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:25:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7f466cdad72abdb)', Time: '2020-10-13T21:18:31', User OID: 'PatientReportedOutcome (US3552412)', ODM File OID: 'cf6bf88c-bf39-4414-8df8-29dee5fdcabe'	System	14 Oct 2020 02:18:40
User entered 'No (N)'	System	14 Oct 2020 02:18:40

US3552412

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(5)

Generated On: 11 Aug 2021 22:53:07

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:25:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7f466cdad72abdb)', Time: '2020-10-13T21:18:33', User OID: 'PatientReportedOutcome (US3552412)', ODM File OID: 'cf6bf88c-bf39-4414-8df8-29dee5fdcab'	System	14 Oct 2020 02:18:40
User entered 'No (N)'	System	14 Oct 2020 02:18:40

US3552412

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(5)

Generated On: 11 Aug 2021 22:53:07

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:25:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7f466cdad72abdb)', Time: '2020-10-13T21:18:35', User OID: 'PatientReportedOutcome (US3552412)', ODM File OID: 'cf6bf88c-bf39-4414-8df8-29dee5fdcabe'	System	14 Oct 2020 02:18:40
User entered 'None (1)'	System	14 Oct 2020 02:18:40

US3552412

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(5)

Generated On: 11 Aug 2021 22:53:07

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:25:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7f466cdad72abddb)', Time: '2020-10-13T21:18:38', User OID: 'PatientReportedOutcome (US3552412)', ODM File OID: 'cf6bf88c-bf39-4414-8df8-29dee5fdcabe'	System	14 Oct 2020 02:18:40
User entered '13 Oct 2020 21:18'	System	14 Oct 2020 02:18:40

US3552412

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(5)

Generated On: 11 Aug 2021 22:53:07

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:25:24
User entered '13 Oct 2020 12:00'	System	09 Oct 2020 14:37:10

US3552412

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(5)

Generated On: 11 Aug 2021 22:53:07

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:25:24
User entered '14 Oct 2020 11:59'	System	09 Oct 2020 14:37:10

US3552412

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(6)

Generated On: 11 Aug 2021 22:53:07

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:25:24
Data entry locked.	System	09 Oct 2020 14:37:10
User entered 'Day 6'	System	09 Oct 2020 14:37:10

US3552412

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(6)

Generated On: 11 Aug 2021 22:53:07

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:25:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7f466cdad72abdb)', Time: '2020-10-15T07:15:12', User OID: 'PatientReportedOutcome (US3552412)', ODM File OID: 'cb68ea68-830e-4e59-be43-ad63bef0429e'	System	15 Oct 2020 12:15:26
User entered 'None (1)'	System	15 Oct 2020 12:15:26

US3552412

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(6)

Generated On: 11 Aug 2021 22:53:07

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:25:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7f466cdad72abdb)', Time: '2020-10-15T07:15:14', User OID: 'PatientReportedOutcome (US3552412)', ODM File OID: 'cb68ea68-830e-4e59-be43-ad63bef0429e'	System	15 Oct 2020 12:15:26
User entered 'No (N)'	System	15 Oct 2020 12:15:26

US3552412

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(6)

Generated On: 11 Aug 2021 22:53:07

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:25:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7f466cdad72abdb)', Time: '2020-10-15T07:15:16', User OID: 'PatientReportedOutcome (US3552412)', ODM File OID: 'cb68ea68-830e-4e59-be43-ad63bef0429e'	System	15 Oct 2020 12:15:26
User entered 'No (N)'	System	15 Oct 2020 12:15:26

US3552412

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(6)

Generated On: 11 Aug 2021 22:53:07

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:25:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7f466cdad72abdb)', Time: '2020-10-15T07:15:18', User OID: 'PatientReportedOutcome (US3552412)', ODM File OID: 'cb68ea68-830e-4e59-be43-ad63bef0429e'	System	15 Oct 2020 12:15:26
User entered 'None (1)'	System	15 Oct 2020 12:15:26

US3552412

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(6)

Generated On: 11 Aug 2021 22:53:07

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:25:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7f466cdad72abddb)', Time: '2020-10-15T07:15:21', User OID: 'PatientReportedOutcome (US3552412)', ODM File OID: 'cb68ea68-830e-4e59-be43-ad63bef0429e'	System	15 Oct 2020 12:15:26
User entered '15 Oct 2020 07:15'	System	15 Oct 2020 12:15:26

US3552412

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(6)

Generated On: 11 Aug 2021 22:53:07

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:25:24
User entered '14 Oct 2020 12:00'	System	09 Oct 2020 14:37:10

US3552412

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(6)

Generated On: 11 Aug 2021 22:53:07

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:25:24
User entered '15 Oct 2020 11:59'	System	09 Oct 2020 14:37:10

US3552412

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(7)

Generated On: 11 Aug 2021 22:53:07

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:25:24
Data entry locked.	System	09 Oct 2020 14:37:10
User entered 'Day 7'	System	09 Oct 2020 14:37:10

US3552412

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(7)

Generated On: 11 Aug 2021 22:53:07

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:25:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7f466cdad72abddb)', Time: '2020-10-15T21:12:24', User OID: 'PatientReportedOutcome (US3552412)', ODM File OID: '9f400064-283c-459e-b108-9fbf80f992d1'	System	16 Oct 2020 02:12:37
User entered 'None (1)'	System	16 Oct 2020 02:12:37

US3552412

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(7)

Generated On: 11 Aug 2021 22:53:07

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:25:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7f466cdad72abdb)', Time: '2020-10-15T21:12:26', User OID: 'PatientReportedOutcome (US3552412)', ODM File OID: '9f400064-283c-459e-b108-9fbf80f992d1'	System	16 Oct 2020 02:12:37
User entered 'No (N)'	System	16 Oct 2020 02:12:37

US3552412

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(7)

Generated On: 11 Aug 2021 22:53:07

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:25:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7f466cdad72abdb)', Time: '2020-10-15T21:12:27', User OID: 'PatientReportedOutcome (US3552412)', ODM File OID: '9f400064-283c-459e-b108-9fbf80f992d1'	System	16 Oct 2020 02:12:37
User entered 'No (N)'	System	16 Oct 2020 02:12:37

US3552412

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(7)

Generated On: 11 Aug 2021 22:53:07

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:25:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7f466cdad72abdb)', Time: '2020-10-15T21:12:29', User OID: 'PatientReportedOutcome (US3552412)', ODM File OID: '9f400064-283c-459e-b108-9fbf80f992d1'	System	16 Oct 2020 02:12:37
User entered 'None (1)'	System	16 Oct 2020 02:12:37

US3552412

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(7)

Generated On: 11 Aug 2021 22:53:07

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:25:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7f466cdad72abddb)', Time: '2020-10-15T21:12:31', User OID: 'PatientReportedOutcome (US3552412)', ODM File OID: '9f400064-283c-459e-b108-9fbf80f992d1'	System	16 Oct 2020 02:12:37
User entered '15 Oct 2020 21:12'	System	16 Oct 2020 02:12:37

US3552412

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(7)

Generated On: 11 Aug 2021 22:53:07

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:25:24
User entered '15 Oct 2020 12:00'	System	09 Oct 2020 14:37:10

US3552412

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(7)

Generated On: 11 Aug 2021 22:53:07

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:25:24
User entered '16 Oct 2020 11:59'	System	09 Oct 2020 14:37:10

US3552412

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 11 Aug 2021 22:53:07

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:25:24
Data entry locked.	System	09 Oct 2020 14:37:10
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	09 Oct 2020 14:37:10

US3552412

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 11 Aug 2021 22:53:07

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:25:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7f466cdad72abdb)', Time: '2020-10-09T10:03:23', User OID: 'PatientReportedOutcome (US3552412)', ODM File OID: 'e4362f0c-04a3-406a-8bd9-95b1cd7c225a'	System	09 Oct 2020 15:03:48
User entered 'None (0)'	System	09 Oct 2020 15:03:48

US3552412

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 11 Aug 2021 22:53:07

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:25:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7f466cdad72abdb)', Time: '2020-10-09T10:03:25', User OID: 'PatientReportedOutcome (US3552412)', ODM File OID: 'e4362f0c-04a3-406a-8bd9-95b1cd7c225a'	System	09 Oct 2020 15:03:48
User entered 'None (0)'	System	09 Oct 2020 15:03:48

US3552412

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 11 Aug 2021 22:53:07

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:25:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7f466cdad72abdb)', Time: '2020-10-09T10:03:26', User OID: 'PatientReportedOutcome (US3552412)', ODM File OID: 'e4362f0c-04a3-406a-8bd9-95b1cd7c225a'	System	09 Oct 2020 15:03:48
User entered 'None (0)'	System	09 Oct 2020 15:03:48

US3552412

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 11 Aug 2021 22:53:07

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:25:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7f466cdad72abdb)', Time: '2020-10-09T10:03:28', User OID: 'PatientReportedOutcome (US3552412)', ODM File OID: 'e4362f0c-04a3-406a-8bd9-95b1cd7c225a'	System	09 Oct 2020 15:03:48
User entered 'None (0)'	System	09 Oct 2020 15:03:48

US3552412

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 11 Aug 2021 22:53:07

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:25:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7f466cdad72abdb)', Time: '2020-10-09T10:03:29', User OID: 'PatientReportedOutcome (US3552412)', ODM File OID: 'e4362f0c-04a3-406a-8bd9-95b1cd7c225a'	System	09 Oct 2020 15:03:48
User entered 'None (0)'	System	09 Oct 2020 15:03:48

US3552412

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 11 Aug 2021 22:53:07

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:25:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7f466cdad72abdb)', Time: '2020-10-09T10:03:31', User OID: 'PatientReportedOutcome (US3552412)', ODM File OID: 'e4362f0c-04a3-406a-8bd9-95b1cd7c225a'	System	09 Oct 2020 15:03:48
User entered 'None (0)'	System	09 Oct 2020 15:03:48

US3552412

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 11 Aug 2021 22:53:07

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:25:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7f466cdad72abdb)', Time: '2020-10-09T10:03:33', User OID: 'PatientReportedOutcome (US3552412)', ODM File OID: 'e4362f0c-04a3-406a-8bd9-95b1cd7c225a'	System	09 Oct 2020 15:03:48
User entered 'No (N)'	System	09 Oct 2020 15:03:48

US3552412

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 11 Aug 2021 22:53:07

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:25:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7f466cdad72abdb)', Time: '2020-10-09T10:03:35', User OID: 'PatientReportedOutcome (US3552412)', ODM File OID: 'e4362f0c-04a3-406a-8bd9-95b1cd7c225a'	System	09 Oct 2020 15:03:48
User entered '09 Oct 2020 10:03'	System	09 Oct 2020 15:03:48

US3552412

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 11 Aug 2021 22:53:07

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:25:24
User entered '09 Oct 2020 09:52'	System	09 Oct 2020 14:37:10

US3552412

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 11 Aug 2021 22:53:07

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:25:24
User entered '09 Oct 2020 12:22'	System	09 Oct 2020 14:37:10

US3552412

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 11 Aug 2021 22:53:07

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:25:24
Data entry locked.	System	09 Oct 2020 14:37:10
User entered 'Day 1, after vaccination (at home)'	System	09 Oct 2020 14:37:10

US3552412

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 11 Aug 2021 22:53:07

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:25:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7f466cdad72abdb)', Time: '2020-10-09T18:44:33', User OID: 'PatientReportedOutcome (US3552412)', ODM File OID: '866230a7-5186-4b46-89f8-d39f67d17dbd'	System	09 Oct 2020 23:45:07
User entered 'No interference with activity (1)'	System	09 Oct 2020 23:45:07

US3552412

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 11 Aug 2021 22:53:07

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:25:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7f466cdad72abdb)', Time: '2020-10-09T18:44:36', User OID: 'PatientReportedOutcome (US3552412)', ODM File OID: '866230a7-5186-4b46-89f8-d39f67d17dbd'	System	09 Oct 2020 23:45:07
User entered 'Some interference with activity (2)'	System	09 Oct 2020 23:45:07

US3552412

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 11 Aug 2021 22:53:07

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:25:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7f466cdad72abdb)', Time: '2020-10-09T18:44:42', User OID: 'PatientReportedOutcome (US3552412)', ODM File OID: '866230a7-5186-4b46-89f8-d39f67d17dbd'	System	09 Oct 2020 23:45:07
User entered 'Some interference with activity (2)'	System	09 Oct 2020 23:45:07

US3552412

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 11 Aug 2021 22:53:07

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:25:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7f466cdad72abdb)', Time: '2020-10-09T18:44:47', User OID: 'PatientReportedOutcome (US3552412)', ODM File OID: '866230a7-5186-4b46-89f8-d39f67d17dbd'	System	09 Oct 2020 23:45:07
User entered 'Some interference with activity (2)'	System	09 Oct 2020 23:45:07

US3552412

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 11 Aug 2021 22:53:07

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:25:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7f466cdad72abdb)', Time: '2020-10-09T18:44:52', User OID: 'PatientReportedOutcome (US3552412)', ODM File OID: '866230a7-5186-4b46-89f8-d39f67d17dbd'	System	09 Oct 2020 23:45:07
User entered 'None (0)'	System	09 Oct 2020 23:45:07

US3552412

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 11 Aug 2021 22:53:07

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:25:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7f466cdad72abdb)', Time: '2020-10-09T18:44:55', User OID: 'PatientReportedOutcome (US3552412)', ODM File OID: '866230a7-5186-4b46-89f8-d39f67d17dbd'	System	09 Oct 2020 23:45:07
User entered 'No interference with activity (1)'	System	09 Oct 2020 23:45:07

US3552412

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 11 Aug 2021 22:53:07

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:25:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7f466cdad72abdb)', Time: '2020-10-09T18:44:58', User OID: 'PatientReportedOutcome (US3552412)', ODM File OID: '866230a7-5186-4b46-89f8-d39f67d17dbd'	System	09 Oct 2020 23:45:07
User entered 'No (N)'	System	09 Oct 2020 23:45:07

US3552412

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 11 Aug 2021 22:53:07

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:25:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7f466cdad72abdb)', Time: '2020-10-09T18:45:02', User OID: 'PatientReportedOutcome (US3552412)', ODM File OID: '866230a7-5186-4b46-89f8-d39f67d17dbd'	System	09 Oct 2020 23:45:07
User entered '09 Oct 2020 18:45'	System	09 Oct 2020 23:45:07

US3552412

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 11 Aug 2021 22:53:07

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:25:24
User entered '09 Oct 2020 13:17'	System	09 Oct 2020 14:37:10

US3552412

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 11 Aug 2021 22:53:07

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:25:24
User entered '10 Oct 2020 11:59'	System	09 Oct 2020 14:37:10

US3552412

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 11 Aug 2021 22:53:07

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:25:24
Data entry locked.	System	09 Oct 2020 14:37:10
User entered 'Day 2'	System	09 Oct 2020 14:37:10

US3552412

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 11 Aug 2021 22:53:07

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:25:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7f466cdad72abdb)', Time: '2020-10-10T19:26:21', User OID: 'PatientReportedOutcome (US3552412)', ODM File OID: 'd1d8fcb1-5a10-49ec-b997-072ad36bb627'	System	11 Oct 2020 00:26:52
User entered 'No interference with activity (1)'	System	11 Oct 2020 00:26:52

US3552412

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 11 Aug 2021 22:53:07

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:25:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7f466cdad72abdb)', Time: '2020-10-10T19:26:27', User OID: 'PatientReportedOutcome (US3552412)', ODM File OID: 'd1d8fcb1-5a10-49ec-b997-072ad36bb627'	System	11 Oct 2020 00:26:52
User entered 'Some interference with activity (2)'	System	11 Oct 2020 00:26:52

US3552412

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 11 Aug 2021 22:53:07

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:25:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7f466cdad72abdb)', Time: '2020-10-10T19:26:30', User OID: 'PatientReportedOutcome (US3552412)', ODM File OID: 'd1d8fcb1-5a10-49ec-b997-072ad36bb627'	System	11 Oct 2020 00:26:52
User entered 'Some interference with activity (2)'	System	11 Oct 2020 00:26:52

US3552412

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 11 Aug 2021 22:53:07

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:25:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7f466cdad72abdb)', Time: '2020-10-10T19:26:32', User OID: 'PatientReportedOutcome (US3552412)', ODM File OID: 'd1d8fcb1-5a10-49ec-b997-072ad36bb627'	System	11 Oct 2020 00:26:52
User entered 'No interference with activity (1)'	System	11 Oct 2020 00:26:52

US3552412

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 11 Aug 2021 22:53:07

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:25:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7f466cdad72abdb)', Time: '2020-10-10T19:26:34', User OID: 'PatientReportedOutcome (US3552412)', ODM File OID: 'd1d8fcb1-5a10-49ec-b997-072ad36bb627'	System	11 Oct 2020 00:26:52
User entered 'None (0)'	System	11 Oct 2020 00:26:52

US3552412

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 11 Aug 2021 22:53:07

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:25:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7f466cdad72abdb)', Time: '2020-10-10T19:26:39', User OID: 'PatientReportedOutcome (US3552412)', ODM File OID: 'd1d8fcb1-5a10-49ec-b997-072ad36bb627'	System	11 Oct 2020 00:26:52
User entered 'No interference with activity (1)'	System	11 Oct 2020 00:26:52

US3552412

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 11 Aug 2021 22:53:07

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:25:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7f466cdad72abdb)', Time: '2020-10-10T19:26:42', User OID: 'PatientReportedOutcome (US3552412)', ODM File OID: 'd1d8fcb1-5a10-49ec-b997-072ad36bb627'	System	11 Oct 2020 00:26:52
User entered 'No (N)'	System	11 Oct 2020 00:26:52

US3552412

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 11 Aug 2021 22:53:07

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:25:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7f466cdad72abdb)', Time: '2020-10-10T19:26:48', User OID: 'PatientReportedOutcome (US3552412)', ODM File OID: 'd1d8fcb1-5a10-49ec-b997-072ad36bb627'	System	11 Oct 2020 00:26:52
User entered '10 Oct 2020 19:26'	System	11 Oct 2020 00:26:52

US3552412

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 11 Aug 2021 22:53:07

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:25:24
User entered '10 Oct 2020 12:00'	System	09 Oct 2020 14:37:10

US3552412

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 11 Aug 2021 22:53:07

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:25:24
User entered '11 Oct 2020 11:59'	System	09 Oct 2020 14:37:10

US3552412

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 11 Aug 2021 22:53:07

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:25:24
Data entry locked.	System	09 Oct 2020 14:37:10
User entered 'Day 3'	System	09 Oct 2020 14:37:10

US3552412

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 11 Aug 2021 22:53:07

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:25:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7f466cdad72abdb)', Time: '2020-10-11T20:05:59', User OID: 'PatientReportedOutcome (US3552412)', ODM File OID: 'e8bb2a45-615d-4ec6-913a-ece0e5d28e6e'	System	12 Oct 2020 01:06:22
User entered 'None (0)'	System	12 Oct 2020 01:06:22

US3552412

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 11 Aug 2021 22:53:07

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:25:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7f466cdad72abdb)', Time: '2020-10-11T20:06:05', User OID: 'PatientReportedOutcome (US3552412)', ODM File OID: 'e8bb2a45-615d-4ec6-913a-ece0e5d28e6e'	System	12 Oct 2020 01:06:22
User entered 'No interference with activity (1)'	System	12 Oct 2020 01:06:22

US3552412

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 11 Aug 2021 22:53:07

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:25:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7f466cdad72abdb)', Time: '2020-10-11T20:06:07', User OID: 'PatientReportedOutcome (US3552412)', ODM File OID: 'e8bb2a45-615d-4ec6-913a-ece0e5d28e6e'	System	12 Oct 2020 01:06:22
User entered 'None (0)'	System	12 Oct 2020 01:06:22

US3552412

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 11 Aug 2021 22:53:07

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:25:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7f466cdad72abdb)', Time: '2020-10-11T20:06:10', User OID: 'PatientReportedOutcome (US3552412)', ODM File OID: 'e8bb2a45-615d-4ec6-913a-ece0e5d28e6e'	System	12 Oct 2020 01:06:22
User entered 'None (0)'	System	12 Oct 2020 01:06:22

US3552412

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 11 Aug 2021 22:53:07

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:25:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7f466cdad72abdb)', Time: '2020-10-11T20:06:12', User OID: 'PatientReportedOutcome (US3552412)', ODM File OID: 'e8bb2a45-615d-4ec6-913a-ece0e5d28e6e'	System	12 Oct 2020 01:06:22
User entered 'None (0)'	System	12 Oct 2020 01:06:22

US3552412

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 11 Aug 2021 22:53:07

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:25:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7f466cdad72abdb)', Time: '2020-10-11T20:06:15', User OID: 'PatientReportedOutcome (US3552412)', ODM File OID: 'e8bb2a45-615d-4ec6-913a-ece0e5d28e6e'	System	12 Oct 2020 01:06:22
User entered 'No interference with activity (1)'	System	12 Oct 2020 01:06:22

US3552412

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 11 Aug 2021 22:53:07

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:25:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7f466cdad72abdb)', Time: '2020-10-11T20:06:17', User OID: 'PatientReportedOutcome (US3552412)', ODM File OID: 'e8bb2a45-615d-4ec6-913a-ece0e5d28e6e'	System	12 Oct 2020 01:06:22
User entered 'No (N)'	System	12 Oct 2020 01:06:22

US3552412

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 11 Aug 2021 22:53:07

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:25:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7f466cdad72abdb)', Time: '2020-10-11T20:06:19', User OID: 'PatientReportedOutcome (US3552412)', ODM File OID: 'e8bb2a45-615d-4ec6-913a-ece0e5d28e6e'	System	12 Oct 2020 01:06:22
User entered '11 Oct 2020 20:06'	System	12 Oct 2020 01:06:22

US3552412

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 11 Aug 2021 22:53:07

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:25:24
User entered '11 Oct 2020 12:00'	System	09 Oct 2020 14:37:10

US3552412

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 11 Aug 2021 22:53:07

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:25:24
User entered '12 Oct 2020 11:59'	System	09 Oct 2020 14:37:10

US3552412

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 11 Aug 2021 22:53:07

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:25:24
Data entry locked.	System	09 Oct 2020 14:37:10
User entered 'Day 4'	System	09 Oct 2020 14:37:10

US3552412

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 11 Aug 2021 22:53:07

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:25:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7f466cdad72abdb)', Time: '2020-10-12T19:24:17', User OID: 'PatientReportedOutcome (US3552412)', ODM File OID: '1a37f8a0-87bb-4c2e-8890-73c669bfc15b'	System	13 Oct 2020 00:24:37
User entered 'None (0)'	System	13 Oct 2020 00:24:37

US3552412

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 11 Aug 2021 22:53:07

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:25:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7f466cdad72abdb)', Time: '2020-10-12T19:24:19', User OID: 'PatientReportedOutcome (US3552412)', ODM File OID: '1a37f8a0-87bb-4c2e-8890-73c669bfc15b'	System	13 Oct 2020 00:24:37
User entered 'None (0)'	System	13 Oct 2020 00:24:37

US3552412

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 11 Aug 2021 22:53:07

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:25:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7f466cdad72abdb)', Time: '2020-10-12T19:24:20', User OID: 'PatientReportedOutcome (US3552412)', ODM File OID: '1a37f8a0-87bb-4c2e-8890-73c669bfc15b'	System	13 Oct 2020 00:24:37
User entered 'None (0)'	System	13 Oct 2020 00:24:37

US3552412

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 11 Aug 2021 22:53:07

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:25:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7f466cdad72abdb)', Time: '2020-10-12T19:24:23', User OID: 'PatientReportedOutcome (US3552412)', ODM File OID: '1a37f8a0-87bb-4c2e-8890-73c669bfc15b'	System	13 Oct 2020 00:24:37
User entered 'No interference with activity (1)'	System	13 Oct 2020 00:24:37

US3552412

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 11 Aug 2021 22:53:07

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:25:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7f466cdad72abdb)', Time: '2020-10-12T19:24:25', User OID: 'PatientReportedOutcome (US3552412)', ODM File OID: '1a37f8a0-87bb-4c2e-8890-73c669bfc15b'	System	13 Oct 2020 00:24:37
User entered 'None (0)'	System	13 Oct 2020 00:24:37

US3552412

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 11 Aug 2021 22:53:07

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:25:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7f466cdad72abdb)', Time: '2020-10-12T19:24:27', User OID: 'PatientReportedOutcome (US3552412)', ODM File OID: '1a37f8a0-87bb-4c2e-8890-73c669bfc15b'	System	13 Oct 2020 00:24:37
User entered 'None (0)'	System	13 Oct 2020 00:24:37

US3552412

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 11 Aug 2021 22:53:07

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:25:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7f466cdad72abdb)', Time: '2020-10-12T19:24:29', User OID: 'PatientReportedOutcome (US3552412)', ODM File OID: '1a37f8a0-87bb-4c2e-8890-73c669bfc15b'	System	13 Oct 2020 00:24:37
User entered 'No (N)'	System	13 Oct 2020 00:24:37

US3552412

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 11 Aug 2021 22:53:07

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:25:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7f466cdad72abdb)', Time: '2020-10-12T19:24:31', User OID: 'PatientReportedOutcome (US3552412)', ODM File OID: '1a37f8a0-87bb-4c2e-8890-73c669bfc15b'	System	13 Oct 2020 00:24:37
User entered '12 Oct 2020 19:24'	System	13 Oct 2020 00:24:37

US3552412

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 11 Aug 2021 22:53:07

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:25:24
User entered '12 Oct 2020 12:00'	System	09 Oct 2020 14:37:10

US3552412

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 11 Aug 2021 22:53:07

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:25:24
User entered '13 Oct 2020 11:59'	System	09 Oct 2020 14:37:10

US3552412

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 11 Aug 2021 22:53:07

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:25:24
Data entry locked.	System	09 Oct 2020 14:37:10
User entered 'Day 5'	System	09 Oct 2020 14:37:10

US3552412

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 11 Aug 2021 22:53:07

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:25:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7f466cdad72abdb)', Time: '2020-10-13T21:18:41', User OID: 'PatientReportedOutcome (US3552412)', ODM File OID: 'd656d4d2-1909-4f8a-a4a1-5a4d4e4018a1' User entered 'None (0)'	System	14 Oct 2020 02:18:59
	System	14 Oct 2020 02:18:59

US3552412

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 11 Aug 2021 22:53:07

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:25:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7f466cdad72abdb)', Time: '2020-10-13T21:18:42', User OID: 'PatientReportedOutcome (US3552412)', ODM File OID: 'd656d4d2-1909-4f8a-a4a1-5a4d4e4018a1'	System	14 Oct 2020 02:18:59
User entered 'None (0)'	System	14 Oct 2020 02:18:59

US3552412

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 11 Aug 2021 22:53:07

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:25:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7f466cdad72abdb)', Time: '2020-10-13T21:18:43', User OID: 'PatientReportedOutcome (US3552412)', ODM File OID: 'd656d4d2-1909-4f8a-a4a1-5a4d4e4018a1'	System	14 Oct 2020 02:18:59
User entered 'None (0)'	System	14 Oct 2020 02:18:59

US3552412

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 11 Aug 2021 22:53:07

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:25:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7f466cdad72abdb)', Time: '2020-10-13T21:18:45', User OID: 'PatientReportedOutcome (US3552412)', ODM File OID: 'd656d4d2-1909-4f8a-a4a1-5a4d4e4018a1' User entered 'None (0)'	System	14 Oct 2020 02:18:59
	System	14 Oct 2020 02:18:59

US3552412

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 11 Aug 2021 22:53:07

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:25:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7f466cdad72abdb)', Time: '2020-10-13T21:18:46', User OID: 'PatientReportedOutcome (US3552412)', ODM File OID: 'd656d4d2-1909-4f8a-a4a1-5a4d4e4018a1'	System	14 Oct 2020 02:18:59
User entered 'None (0)'	System	14 Oct 2020 02:18:59

US3552412

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 11 Aug 2021 22:53:07

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:25:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7f466cdad72abddb)', Time: '2020-10-13T21:18:47', User OID: 'PatientReportedOutcome (US3552412)', ODM File OID: 'd656d4d2-1909-4f8a-a4a1-5a4d4e4018a1'	System	14 Oct 2020 02:18:59
User entered 'None (0)'	System	14 Oct 2020 02:18:59

US3552412

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 11 Aug 2021 22:53:07

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:25:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7f466cdad72abdb)', Time: '2020-10-13T21:18:50', User OID: 'PatientReportedOutcome (US3552412)', ODM File OID: 'd656d4d2-1909-4f8a-a4a1-5a4d4e4018a1'	System	14 Oct 2020 02:18:59
User entered 'No (N)'	System	14 Oct 2020 02:18:59

US3552412

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 11 Aug 2021 22:53:07

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:25:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7f466cdad72abdb)', Time: '2020-10-13T21:18:55', User OID: 'PatientReportedOutcome (US3552412)', ODM File OID: 'd656d4d2-1909-4f8a-a4a1-5a4d4e4018a1'	System	14 Oct 2020 02:18:59
User entered '13 Oct 2020 21:18'	System	14 Oct 2020 02:18:59

US3552412

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 11 Aug 2021 22:53:07

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:25:24
User entered '13 Oct 2020 12:00'	System	09 Oct 2020 14:37:10

US3552412

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 11 Aug 2021 22:53:07

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:25:24
User entered '14 Oct 2020 11:59'	System	09 Oct 2020 14:37:10

US3552412

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 11 Aug 2021 22:53:07

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:25:24
Data entry locked.	System	09 Oct 2020 14:37:10
User entered 'Day 6'	System	09 Oct 2020 14:37:10

US3552412

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 11 Aug 2021 22:53:07

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:25:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7f466cdad72abdb)', Time: '2020-10-15T07:15:28', User OID: 'PatientReportedOutcome (US3552412)', ODM File OID: '3466d3a8-9719-4145-a7d7-689039bc67ed'	System	15 Oct 2020 12:15:51
User entered 'None (0)'	System	15 Oct 2020 12:15:51

US3552412

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 11 Aug 2021 22:53:07

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:25:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7f466cdad72abdb)', Time: '2020-10-15T07:15:30', User OID: 'PatientReportedOutcome (US3552412)', ODM File OID: '3466d3a8-9719-4145-a7d7-689039bc67ed' User entered 'None (0)'	System	15 Oct 2020 12:15:51
	System	15 Oct 2020 12:15:51

US3552412

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 11 Aug 2021 22:53:07

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:25:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7f466cdad72abdb)', Time: '2020-10-15T07:15:32', User OID: 'PatientReportedOutcome (US3552412)', ODM File OID: '3466d3a8-9719-4145-a7d7-689039bc67ed' User entered 'None (0)'	System	15 Oct 2020 12:15:51
	System	15 Oct 2020 12:15:51

US3552412

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 11 Aug 2021 22:53:07

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:25:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7f466cdad72abdb)', Time: '2020-10-15T07:15:36', User OID: 'PatientReportedOutcome (US3552412)', ODM File OID: '3466d3a8-9719-4145-a7d7-689039bc67ed' User entered 'None (0)'	System	15 Oct 2020 12:15:51
	System	15 Oct 2020 12:15:51

US3552412

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 11 Aug 2021 22:53:07

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:25:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7f466cdad72abddb)', Time: '2020-10-15T07:15:38', User OID: 'PatientReportedOutcome (US3552412)', ODM File OID: '3466d3a8-9719-4145-a7d7-689039bc67ed'	System	15 Oct 2020 12:15:51
User entered 'None (0)'	System	15 Oct 2020 12:15:51

US3552412

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 11 Aug 2021 22:53:07

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:25:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7f466cdad72abdb)', Time: '2020-10-15T07:15:40', User OID: 'PatientReportedOutcome (US3552412)', ODM File OID: '3466d3a8-9719-4145-a7d7-689039bc67ed'	System	15 Oct 2020 12:15:51
User entered 'None (0)'	System	15 Oct 2020 12:15:51

US3552412

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 11 Aug 2021 22:53:07

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:25:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7f466cdad72abdb)', Time: '2020-10-15T07:15:43', User OID: 'PatientReportedOutcome (US3552412)', ODM File OID: '3466d3a8-9719-4145-a7d7-689039bc67ed'	System	15 Oct 2020 12:15:51
User entered 'No (N)'	System	15 Oct 2020 12:15:51

US3552412

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 11 Aug 2021 22:53:07

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:25:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7f466cdad72abddb)', Time: '2020-10-15T07:15:45', User OID: 'PatientReportedOutcome (US3552412)', ODM File OID: '3466d3a8-9719-4145-a7d7-689039bc67ed' User entered '15 Oct 2020 07:15'	System	15 Oct 2020 12:15:51
	System	15 Oct 2020 12:15:51

US3552412

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 11 Aug 2021 22:53:07

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:25:24
User entered '14 Oct 2020 12:00'	System	09 Oct 2020 14:37:10

US3552412

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 11 Aug 2021 22:53:07

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:25:24
User entered '15 Oct 2020 11:59'	System	09 Oct 2020 14:37:10

US3552412

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 11 Aug 2021 22:53:07

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:25:24
Data entry locked.	System	09 Oct 2020 14:37:10
User entered 'Day 7'	System	09 Oct 2020 14:37:10

US3552412

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 11 Aug 2021 22:53:07

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:25:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7f466cdad72abdb)', Time: '2020-10-15T21:12:39', User OID: 'PatientReportedOutcome (US3552412)', ODM File OID: 'd230bb90-d37a-4337-b2c4-89012aafac2'	System	16 Oct 2020 02:12:57
User entered 'Repeated use of over-the-counter pain reliever > 24 hours or some interference with activity (2)'	System	16 Oct 2020 02:12:57

US3552412

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 11 Aug 2021 22:53:07

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:25:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7f466cdad72abdb)', Time: '2020-10-15T21:12:41', User OID: 'PatientReportedOutcome (US3552412)', ODM File OID: 'd230bb90-d37a-4337-b2c4-89012aafaf2'	System	16 Oct 2020 02:12:57
User entered 'None (0)'	System	16 Oct 2020 02:12:57

US3552412

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 11 Aug 2021 22:53:07

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:25:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7f466cdad72abdb)', Time: '2020-10-15T21:12:42', User OID: 'PatientReportedOutcome (US3552412)', ODM File OID: 'd230bb90-d37a-4337-b2c4-89012aafaf2'	System	16 Oct 2020 02:12:57
User entered 'None (0)'	System	16 Oct 2020 02:12:57

US3552412

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 11 Aug 2021 22:53:07

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:25:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7f466cdad72abdb)', Time: '2020-10-15T21:12:43', User OID: 'PatientReportedOutcome (US3552412)', ODM File OID: 'd230bb90-d37a-4337-b2c4-89012aafaf2'	System	16 Oct 2020 02:12:57
User entered 'None (0)'	System	16 Oct 2020 02:12:57

US3552412

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 11 Aug 2021 22:53:07

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:25:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7f466cdad72abdb)', Time: '2020-10-15T21:12:47', User OID: 'PatientReportedOutcome (US3552412)', ODM File OID: 'd230bb90-d37a-4337-b2c4-89012aafaf2'	System	16 Oct 2020 02:12:57
User entered 'No interference with activity or 1-2 episodes/24 hours (1)'	System	16 Oct 2020 02:12:57

US3552412

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 11 Aug 2021 22:53:07

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:25:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7f466cdad72abddb)', Time: '2020-10-15T21:12:49', User OID: 'PatientReportedOutcome (US3552412)', ODM File OID: 'd230bb90-d37a-4337-b2c4-89012aafaf2'	System	16 Oct 2020 02:12:57
User entered 'None (0)'	System	16 Oct 2020 02:12:57

US3552412

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 11 Aug 2021 22:53:07

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:25:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7f466cdad72abdb)', Time: '2020-10-15T21:12:50', User OID: 'PatientReportedOutcome (US3552412)', ODM File OID: 'd230bb90-d37a-4337-b2c4-89012aafac2'	System	16 Oct 2020 02:12:57
User entered 'No (N)'	System	16 Oct 2020 02:12:57

US3552412

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 11 Aug 2021 22:53:07

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:25:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7f466cdad72abdb)', Time: '2020-10-15T21:12:53', User OID: 'PatientReportedOutcome (US3552412)', ODM File OID: 'd230bb90-d37a-4337-b2c4-89012aafaf2'	System	16 Oct 2020 02:12:57
User entered '15 Oct 2020 21:12'	System	16 Oct 2020 02:12:57

US3552412

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 11 Aug 2021 22:53:07

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:25:24
User entered '15 Oct 2020 12:00'	System	09 Oct 2020 14:37:10

US3552412

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 11 Aug 2021 22:53:07

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:25:24
User entered '16 Oct 2020 11:59'	System	09 Oct 2020 14:37:10

US3552412

Folder: Diary Dose 2 (1)

Form: Headache\_Day(8)

Generated On: 11 Aug 2021 22:53:07

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:25:24
Data entry locked.	System	16 Oct 2020 02:12:57
User entered 'Day 8'	System	16 Oct 2020 02:12:57

US3552412

Folder: Diary Dose 2 (1)

Form: Headache\_Day(8)

Generated On: 11 Aug 2021 22:53:07

Select one response below to indicate the intensity of your **HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:25:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7f466cdad72abdb)', Time: '2020-10-16T22:12:44', User OID: 'PatientReportedOutcome (US3552412)', ODM File OID: '23da6373-f8e0-4106-a507-a84bb2df767b'	System	17 Oct 2020 03:12:51
User entered 'None (0)'	System	17 Oct 2020 03:12:51

US3552412

Folder: Diary Dose 2 (1)

Form: Headache\_Day(8)

Generated On: 11 Aug 2021 22:53:07

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:25:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7f466cdad72abdb)', Time: '2020-10-16T22:12:46', User OID: 'PatientReportedOutcome (US3552412)', ODM File OID: '23da6373-f8e0-4106-a507-a84bb2df767b'	System	17 Oct 2020 03:12:51
User entered '16 Oct 2020 22:12'	System	17 Oct 2020 03:12:51

US3552412

Folder: Diary Dose 2 (1)

Form: Headache\_Day(8)

Generated On: 11 Aug 2021 22:53:07

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:25:24
User entered '16 Oct 2020 12:00'	System	16 Oct 2020 02:12:57

US3552412

Folder: Diary Dose 2 (1)

Form: Headache\_Day(8)

Generated On: 11 Aug 2021 22:53:07

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:25:24
User entered '17 Oct 2020 11:59'	System	16 Oct 2020 02:12:57

US3552412

Folder: Diary Dose 2 (1)

Form: Nausea\_Day(8)

Generated On: 11 Aug 2021 22:53:07

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:25:24
Data entry locked.	System	16 Oct 2020 02:12:57
User entered 'Day 8'	System	16 Oct 2020 02:12:57

US3552412

Folder: Diary Dose 2 (1)

Form: Nausea\_Day(8)

Generated On: 11 Aug 2021 22:53:07

Select one response below to indicate the level of your **NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:25:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7f466cdad72abdb)', Time: '2020-10-16T22:12:49', User OID: 'PatientReportedOutcome (US3552412)', ODM File OID: '94e77343-5feb-4ab8-8f98-bcfa016cac36'	System	17 Oct 2020 03:12:58
User entered 'None (0)'	System	17 Oct 2020 03:12:58

US3552412

Folder: Diary Dose 2 (1)

Form: Nausea\_Day(8)

Generated On: 11 Aug 2021 22:53:07

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:25:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7f466cdad72abdb)', Time: '2020-10-16T22:12:51', User OID: 'PatientReportedOutcome (US3552412)', ODM File OID: '94e77343-5feb-4ab8-8f98-bcfa016cac36'	System	17 Oct 2020 03:12:58
User entered '16 Oct 2020 22:12'	System	17 Oct 2020 03:12:58

US3552412

Folder: Diary Dose 2 (1)

Form: Nausea\_Day(8)

Generated On: 11 Aug 2021 22:53:07

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:25:24
User entered '16 Oct 2020 12:00'	System	16 Oct 2020 02:12:57

US3552412

Folder: Diary Dose 2 (1)

Form: Nausea\_Day(8)

Generated On: 11 Aug 2021 22:53:07

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:25:24
User entered '17 Oct 2020 11:59'	System	16 Oct 2020 02:12:57

US3552412

Folder: Diary Dose 2 (1)

Form: Medical Attention\_Day(8)

Generated On: 11 Aug 2021 22:53:07

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:25:24
Data entry locked.	System	16 Oct 2020 02:12:24
User entered 'Day 8'	System	16 Oct 2020 02:12:24

US3552412

Folder: Diary Dose 2 (1)

Form: Medical Attention\_Day(8)

Generated On: 11 Aug 2021 22:53:07

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:25:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7f466cdad72abdb)', Time: '2020-10-16T22:12:55', User OID: 'PatientReportedOutcome (US3552412)', ODM File OID: '4039e835-54ab-42d4-a091-ecf8b65644a8'	System	17 Oct 2020 03:13:03
User entered 'No (N)'	System	17 Oct 2020 03:13:03

US3552412

Folder: Diary Dose 2 (1)

Form: Medical Attention\_Day(8)

Generated On: 11 Aug 2021 22:53:07

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:25:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7f466cdad72abdb)', Time: '2020-10-16T22:12:57', User OID: 'PatientReportedOutcome (US3552412)', ODM File OID: '4039e835-54ab-42d4-a091-ecf8b65644a8'	System	17 Oct 2020 03:13:03
User entered '16 Oct 2020 22:12'	System	17 Oct 2020 03:13:03

US3552412

Folder: Diary Dose 2 (1)

Form: Medical Attention\_Day(8)

Generated On: 11 Aug 2021 22:53:07

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:25:24
User entered '16 Oct 2020 12:00'	System	16 Oct 2020 02:12:24

US3552412

Folder: Diary Dose 2 (1)

Form: Medical Attention\_Day(8)

Generated On: 11 Aug 2021 22:53:07

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:25:24
User entered '17 Oct 2020 11:59'	System	16 Oct 2020 02:12:24

US3552412

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:53:07

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 11:14:37
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 19:11:21
User entered 'Yes (Y)'	Stanley Dublin (b) (4) (b) (4)	16 Oct 2020 17:41:54

US3552412

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:53:07

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 11:14:37
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:11:21
User entered '16 Oct 2020'	(b) (4) Stanley Dublin (b) (4) (b) (4)	16 Oct 2020 17:41:54

US3552412

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:53:07

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 11:14:37
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 19:11:21
User entered 'Contact Made (CONTACT MADE)'	Stanley Dublin (b) (4) (b) (4)	16 Oct 2020 17:41:54

US3552412

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:53:07

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 11:14:37
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 19:11:21
User entered empty.	Stanley Dublin (b) (4) (b) (4)	16 Oct 2020 17:41:54

US3552412

Folder: Safety Call Day 36 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:53:07

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 11:14:37
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:11:21
User entered 'Yes (Y)'	(b) (4) Mikayla Frye (b) (4) (b) (4)	23 Oct 2020 15:35:27

US3552412

Folder: Safety Call Day 36 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:53:07

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 11:14:37
User entered 'l'	System	23 Oct 2020 15:35:27

US3552412

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:53:07

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 11:14:37
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 19:11:21
User entered 'Yes (Y)'	Mikayla Frye (b) (4) (b) (4)	23 Oct 2020 15:35:37

US3552412

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:53:07

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 11:14:37
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:11:21
User entered '23 Oct 2020'	(b) (4) Mikayla Frye (b) (4) (b) (4)	23 Oct 2020 15:35:37

US3552412

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:53:07

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 11:14:37
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 19:11:21
User entered 'Contact Made (CONTACT MADE)'	Mikayla Frye (b) (4) (b) (4)	23 Oct 2020 15:35:37

US3552412

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:53:07

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 11:14:37
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:11:21
User entered empty.	(b) (4) Mikayla Frye (b) (4) (b) (4)	23 Oct 2020 15:35:37

US3552412

Folder: Safety Call Day 43 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:53:07

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 11:14:37
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 19:11:21
User entered 'Yes (Y)'	Stanley Dublin (b) (4) (b) (4)	30 Oct 2020 15:50:16

US3552412

Folder: Safety Call Day 43 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:53:07

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 11:14:37
User entered 'l'	System	30 Oct 2020 15:50:16

US3552412

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:53:07

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 11:14:37
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:11:21
User entered 'Yes (Y)'	(b) (4) Stanley Dublin (b) (4) (b) (4)	30 Oct 2020 15:50:27

US3552412

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:53:07

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 11:14:37
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:11:21
User entered '30 Oct 2020'	(b) (4) Stanley Dublin (b) (4) (b) (4)	30 Oct 2020 15:50:27

US3552412

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:53:07

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 11:14:37
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 19:11:21
User entered 'Contact Made (CONTACT MADE)'	Stanley Dublin (b) (4) (b) (4)	30 Oct 2020 15:50:27

US3552412

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:53:07

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 11:14:37
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 19:11:21
User entered empty.	Stanley Dublin (b) (4) (b) (4)	30 Oct 2020 15:50:27

US3552412

Folder: Safety Call Day 50 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:53:07

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 11:14:37
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:11:21
User entered 'Yes (Y)'	(b) (4) Stanley Dublin (b) (4) (b) (4)	11 Nov 2020 14:16:24

US3552412

Folder: Safety Call Day 50 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:53:07

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 11:14:37
User entered 'l'	System	11 Nov 2020 14:16:24

US3552412

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:53:07

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 11:14:37
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 19:11:21
User entered 'Yes (Y)'	Stanley Dublin (b) (4) (b) (4)	11 Nov 2020 14:16:34

US3552412

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:53:07

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 11:14:37
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:11:21
User entered '10 Nov 2020'	(b) (4) Stanley Dublin (b) (4) (b) (4)	11 Nov 2020 14:16:34

US3552412

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:53:07

[Was visit performed at the participant's home or at the clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 11:14:37
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:11:21
User entered 'Clinic (Clinic)'	(b) (4) Stanley Dublin (b) (4) (b) (4)	11 Nov 2020 14:16:34

US3552412

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:53:07

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 11:14:37
User entered 'VISIT3'	System	11 Nov 2020 14:16:34

US3552412

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:53:07

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 11:14:37
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:11:21
User entered 'No (N)'	(b) (4) Stanley Dublin (b) (4) (b) (4)	11 Nov 2020 14:16:39

US3552412

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:53:07

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 11:14:37
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 19:11:21
User entered empty.	Stanley Dublin (b) (4) (b) (4)	11 Nov 2020 14:16:39

US3552412

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:53:07

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 11:14:37
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:11:21
User entered empty.	(b) (4) Stanley Dublin (b) (4) (b) (4)	11 Nov 2020 14:16:39

US3552412

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:53:07

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 11:14:37
User entered empty.	System	11 Nov 2020 14:16:39

US3552412

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:53:07

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 11:14:37
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 19:11:21
User entered empty.	Stanley Dublin (b) (4) (b) (4)	11 Nov 2020 14:16:39

US3552412

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:53:07

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 11:14:37
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 19:11:21
User entered empty.	Stanley Dublin (b) (4) (b) (4)	11 Nov 2020 14:16:39

US3552412

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:53:07

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 11:14:37
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 19:11:21
User entered empty.	Stanley Dublin (b) (4) (b) (4)	11 Nov 2020 14:16:39

US3552412

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:53:07

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 11:14:37
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 19:11:21
User entered empty.	Stanley Dublin (b) (4) (b) (4)	11 Nov 2020 14:16:39

US3552412

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:53:07

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 11:14:37
User entered empty.	System	11 Nov 2020 14:16:39

US3552412

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:53:07

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 11:14:37
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 19:11:21
User entered empty.	Stanley Dublin (b) (4) (b) (4)	11 Nov 2020 14:16:39

US3552412

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:53:07

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 11:14:37
User entered empty.	System	11 Nov 2020 14:16:39

US3552412

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:53:07

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 11:14:37
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 19:11:21
User entered empty.	Stanley Dublin (b) (4) (b) (4)	11 Nov 2020 14:16:39

US3552412

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:53:07

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 11:14:37
User entered empty.	System	11 Nov 2020 14:16:39

US3552412

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:53:07

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 11:14:37
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 19:11:21
User entered empty.	Stanley Dublin (b) (4) (b) (4)	11 Nov 2020 14:16:39

US3552412

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:53:07

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 11:14:37
User entered empty.	System	11 Nov 2020 14:16:39

US3552412

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:53:07

Height (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 11:14:37

US3552412

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:53:07

Weight (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 11:14:37

US3552412

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Generated On: 11 Aug 2021 22:53:07

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 11:14:37
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:11:21
User entered 'No (N)'	(b) (4) Stanley Dublin (b) (4) (b) (4)	11 Nov 2020 14:16:45

US3552412

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Generated On: 11 Aug 2021 22:53:07

Date of examination (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 11:14:37
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 19:11:21
User entered empty.	Stanley Dublin (b) (4) (b) (4)	11 Nov 2020 14:16:45

US3552412

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:53:07

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 11:14:37
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:11:21
User entered 'Yes (Y)'	(b) (4) Stanley Dublin (b) (4) (b) (4)	11 Nov 2020 14:16:57

US3552412

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:53:07

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 11:14:37
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:11:21
User entered '10 Nov 2020'	(b) (4) Stanley Dublin (b) (4) (b) (4)	11 Nov 2020 14:16:57

US3552412

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:53:07

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 11:14:37
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:11:21
User entered '15:12'	(b) (4) Stanley Dublin (b) (4) (b) (4)	11 Nov 2020 14:16:57

US3552412

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:53:07

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 11:14:37
User entered '10 Nov 2020 15:12'	System	11 Nov 2020 14:16:57

US3552412

Folder: Visit 3 Day 57 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:53:07

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 11:14:37
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 19:11:21
User entered 'Yes (Y)'	Mikayla Frye (b) (4) (b) (4)	07 Jan 2021 21:33:58

US3552412

Folder: Visit 3 Day 57 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:53:07

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 11:14:37
User entered 'l'	System	07 Jan 2021 21:33:58

US3552412

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:53:07

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:25:24
Data entry locked.	System	11 Sep 2020 19:01:06
User entered 'Day 64'	System	11 Sep 2020 19:01:06

US3552412

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:53:07

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:25:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7f466cdad72abdb)', Time: '2020-11-12T19:09:08', User OID: 'PatientReportedOutcome (US3552412)', ODM File OID: '0c6d6e44-9dc6-4800-9cc6-a9b33228070c'	System	13 Nov 2020 01:09:29
User entered 'No (N)'	System	13 Nov 2020 01:09:29

US3552412

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:53:07**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:25:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7f466cdad72abdb)', Time: '2020-11-12T19:09:19', User OID: 'PatientReportedOutcome (US3552412)', ODM File OID: '0c6d6e44-9dc6-4800-9cc6-a9b33228070c'	System	13 Nov 2020 01:09:29
User entered 'No (N)'	System	13 Nov 2020 01:09:29

US3552412

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:53:07

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:25:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7f466cdad72abdb)', Time: '2020-11-12T19:09:26', User OID: 'PatientReportedOutcome (US3552412)', ODM File OID: '0c6d6e44-9dc6-4800-9cc6-a9b33228070c'	System	13 Nov 2020 01:09:29
User entered '12 Nov 2020 19:09:26'	System	13 Nov 2020 01:09:29

US3552412

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:53:07

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:25:24
Data entry locked.	System	11 Sep 2020 19:01:06
User entered '11 Nov 2020 00:01'	System	11 Sep 2020 19:01:06

US3552412

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:53:07

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:25:24
Data entry locked.	System	11 Sep 2020 19:01:06
User entered '15 Nov 2020 23:59'	System	11 Sep 2020 19:01:06

US3552412

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:53:07

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:25:24
Data entry locked.	System	11 Sep 2020 19:01:06
User entered 'Day 71'	System	11 Sep 2020 19:01:06

US3552412

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:53:07

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:25:24
User closed query 'Per DM CLR: Any changes since last questionnaire or contact with study clinic?; and Have you contacted a healthcare provider since last questionnaire or study contact? = YES, however, there is no corresponding AE recorded for this information in the AE eCRF page. Please confirm and update if a Medically-attended AE should be recorded, otherwise provide clarification.' (Site from DM).		28 Dec 2020 12:21:09
Query 'Per DM CLR: Any changes since last questionnaire or contact with study clinic?; and Have you contacted a healthcare provider since last questionnaire or study contact? = YES, however, there is no corresponding AE recorded for this information in the AE eCRF page. Please confirm and update if a Medically-attended AE should be recorded, otherwise provide clarification.' answered with 'Subject contacted and no related AE' (Site from DM).	Cassandra Zehenny (b) (4)	23 Dec 2020 22:19:39
User opened query 'Per DM CLR: Any changes since last questionnaire or contact with study clinic?; and Have you contacted a healthcare provider since last questionnaire or study contact? = YES, however, there is no corresponding AE recorded for this information in the AE eCRF page. Please confirm and update if a Medically-attended AE should be recorded, otherwise provide clarification.' (Site from DM).	(b) (4), (b) (6)	19 Dec 2020 10:49:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7f466cdad72abdb)', Time: '2020-11-18T21:24:08', User OID: 'PatientReportedOutcome (US3552412)', ODM File OID: '84efe2f9-dda6-4c5e-908e-875a4d391cff'	System	19 Nov 2020 03:25:01
User entered 'Yes (Y)'	System	19 Nov 2020 03:25:01

US3552412

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:53:07

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:25:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7f466cdad72abdb)', Time: '2020-11-18T21:24:14', User OID: 'PatientReportedOutcome (US3552412)', ODM File OID: '84efe2f9-dda6-4c5e-908e-875a4d391cff'	System	19 Nov 2020 03:25:01
User entered 'Yes (Y)'	System	19 Nov 2020 03:25:01

US3552412

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:53:07**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:25:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7f466cdad72abdb)', Time: '2020-11-18T21:24:19', User OID: 'PatientReportedOutcome (US3552412)', ODM File OID: '84efe2f9-dda6-4c5e-908e-875a4d391cff'	System	19 Nov 2020 03:25:01
User entered 'I confirm I have read this message and will call the study clinic immediately (9)'	System	19 Nov 2020 03:25:01

US3552412

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:53:07

Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:25:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7f466cdad72abdb)', Time: '2020-11-18T21:24:26', User OID: 'PatientReportedOutcome (US3552412)', ODM File OID: '84efe2f9-dda6-4c5e-908e-875a4d391cff'	System	19 Nov 2020 03:25:01
User entered 'No (N)'	System	19 Nov 2020 03:25:01

US3552412

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:53:07

[Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:25:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7f466cdad72abdb)', Time: '2020-11-18T21:24:32', User OID: 'PatientReportedOutcome (US3552412)', ODM File OID: '84efe2f9-dda6-4c5e-908e-875a4d391cff'	System	19 Nov 2020 03:25:01
User entered 'Yes (Y)'	System	19 Nov 2020 03:25:01

US3552412

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:53:07**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:25:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7f466cdad72abdb)', Time: '2020-11-18T21:24:45', User OID: 'PatientReportedOutcome (US3552412)', ODM File OID: '84efe2f9-dda6-4c5e-908e-875a4d391cff'	System	19 Nov 2020 03:25:01
User entered 'I confirm I have read this message and will call the study clinic immediately (9)'	System	19 Nov 2020 03:25:01

US3552412

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:53:07

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:25:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7f466cdad72abdb)', Time: '2020-11-18T21:24:48', User OID: 'PatientReportedOutcome (US3552412)', ODM File OID: '84efe2f9-dda6-4c5e-908e-875a4d391cff'	System	19 Nov 2020 03:25:01
User entered '18 Nov 2020 21:24:48'	System	19 Nov 2020 03:25:01

US3552412

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:53:07

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:25:24
Data entry locked.	System	11 Sep 2020 19:01:06
User entered '18 Nov 2020 00:01'	System	11 Sep 2020 19:01:06

US3552412

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:53:07

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:25:24
Data entry locked.	System	11 Sep 2020 19:01:06
User entered '22 Nov 2020 23:59'	System	11 Sep 2020 19:01:06

**US3552412**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:53:07**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:49:24
Amendment Manager: User entered 'Day 75'	System	20 Nov 2020 07:49:24

**US3552412**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:53:07**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:49:24
Amendment Manager: User entered '22 Nov 2020 00:01'	System	20 Nov 2020 07:49:24

**US3552412**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:53:07**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:49:24
Amendment Manager: User entered '26 Nov 2020 23:59'	System	20 Nov 2020 07:49:24

**US3552412**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:53:07**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:49:24
Amendment Manager: User entered 'Day 82'	System	20 Nov 2020 07:49:24

**US3552412**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:53:07**

[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 (7f466cdad72abdb)', Time: '2020-12-03T12:08:55', User OID: 'PatientReportedOutcome (US3552412)', ODM File OID: '903b279e-3949-48b1-83ed-f2c1ac0563c4'	System	03 Dec 2020 18:09:06
User entered 'No (N)'	System	03 Dec 2020 18:09:06

**US3552412**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:53:07**

[Have you been exposed to someone with 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 (7f466cdad72abdb)', Time: '2020-12-03T12:08:58', User OID: 'PatientReportedOutcome (US3552412)', ODM File OID: '903b279e-3949-48b1-83ed-f2c1ac0563c4'	System	03 Dec 2020 18:09:06
User entered 'No (N)'	System	03 Dec 2020 18:09:06

**US3552412**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:53:07**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7f466cdad72abdb)', Time: '2020-12-03T12:09:01', User OID: 'PatientReportedOutcome (US3552412)', ODM File OID: '903b279e-3949-48b1-83ed-f2c1ac0563c4'	System	03 Dec 2020 18:09:06
User entered '03 Dec 2020 12:09:01'	System	03 Dec 2020 18:09:06

**US3552412**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:53:07**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:49:24
Amendment Manager: User entered '29 Nov 2020 00:01'	System	20 Nov 2020 07:49:24

**US3552412**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:53:07**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:49:24
Amendment Manager: User entered '03 Dec 2020 23:59'	System	20 Nov 2020 07:49:24

**US3552412**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:53:07**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:49:24
Amendment Manager: User entered 'Day 89'	System	20 Nov 2020 07:49:24

**US3552412**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:53:07**

[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 (7f466cdad72abdb)', Time: '2020-12-09T17:56:29', User OID: 'PatientReportedOutcome (US3552412)', ODM File OID: '61ebc8ee-8276-4920-965c-96b11920e7d6'	System	09 Dec 2020 23:56:39
User entered 'No (N)'	System	09 Dec 2020 23:56:39

**US3552412**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:53:07**

[Have you been exposed to someone with 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 (7f466cdad72abdb)', Time: '2020-12-09T17:56:32', User OID: 'PatientReportedOutcome (US3552412)', ODM File OID: '61ebc8ee-8276-4920-965c-96b11920e7d6'	System	09 Dec 2020 23:56:39
User entered 'No (N)'	System	09 Dec 2020 23:56:39

**US3552412**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:53:07**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7f466cdad72abdb)', Time: '2020-12-09T17:56:34', User OID: 'PatientReportedOutcome (US3552412)', ODM File OID: '61ebc8ee-8276-4920-965c-96b11920e7d6'	System	09 Dec 2020 23:56:39
User entered '09 Dec 2020 17:56:34'	System	09 Dec 2020 23:56:39

**US3552412**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:53:07**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:49:24
Amendment Manager: User entered '06 Dec 2020 00:01'	System	20 Nov 2020 07:49:24

**US3552412**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:53:07**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:49:24
Amendment Manager: User entered '10 Dec 2020 23:59'	System	20 Nov 2020 07:49:24

**US3552412**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:53:07**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:49:24
Amendment Manager: User entered 'Day 96'	System	20 Nov 2020 07:49:24

**US3552412**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:53:07**

[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 (7f466cdad72abdb)', Time: '2020-12-16T13:28:14', User OID: 'PatientReportedOutcome (US3552412)', ODM File OID: '9608629e-de12-47c5-ab10-1da1c1fca4f5'	System	16 Dec 2020 19:28:26
User entered 'No (N)'	System	16 Dec 2020 19:28:26

**US3552412**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:53:07**

[Have you been exposed to someone with 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 (7f466cdad72abdb)', Time: '2020-12-16T13:28:18', User OID: 'PatientReportedOutcome (US3552412)', ODM File OID: '9608629e-de12-47c5-ab10-1da1c1fca4f5'	System	16 Dec 2020 19:28:26
User entered 'No (N)'	System	16 Dec 2020 19:28:26

**US3552412**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:53:07**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7f466cdad72abdb)', Time: '2020-12-16T13:28:20', User OID: 'PatientReportedOutcome (US3552412)', ODM File OID: '9608629e-de12-47c5-ab10-1da1c1fca4f5' User entered '16 Dec 2020 13:28:20'	System	16 Dec 2020 19:28:26
	System	16 Dec 2020 19:28:26

**US3552412**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:53:07**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:49:24
Amendment Manager: User entered '13 Dec 2020 00:01'	System	20 Nov 2020 07:49:24

**US3552412**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:53:07**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:49:24
Amendment Manager: User entered '17 Dec 2020 23:59'	System	20 Nov 2020 07:49:24

**US3552412**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:53:07**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:49:24
Amendment Manager: User entered 'Day 103'	System	20 Nov 2020 07:49:24

**US3552412**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:53:07**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:49:24
Amendment Manager: User entered '20 Dec 2020 00:01'	System	20 Nov 2020 07:49:24

**US3552412**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:53:07**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:49:24
Amendment Manager: User entered '24 Dec 2020 23:59'	System	20 Nov 2020 07:49:24

**US3552412**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:53:07**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:49:24
Amendment Manager: User entered 'Day 110'	System	20 Nov 2020 07:49:24

**US3552412**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:53:07**

[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 (7f466cdad72abdb)', Time: '2020-12-28T10:01:21', User OID: 'PatientReportedOutcome (US3552412)', ODM File OID: '57b85a68-99a3-466f-a9a8-9de8115483a4'	System	28 Dec 2020 16:01:28
User entered 'No (N)'	System	28 Dec 2020 16:01:28

**US3552412**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:53:07**

Have you been exposed to someone with 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 (7f466cdad72abdb)', Time: '2020-12-28T10:01:22', User OID: 'PatientReportedOutcome (US3552412)', ODM File OID: '57b85a68-99a3-466f-a9a8-9de8115483a4'	System	28 Dec 2020 16:01:28
User entered 'No (N)'	System	28 Dec 2020 16:01:28

**US3552412**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:53:07**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7f466cdad72abdb)', Time: '2020-12-28T10:01:25', User OID: 'PatientReportedOutcome (US3552412)', ODM File OID: '57b85a68-99a3-466f-a9a8-9de8115483a4' User entered '28 Dec 2020 10:01:25'	System	28 Dec 2020 16:01:28
	System	28 Dec 2020 16:01:28

**US3552412**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:53:07**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:49:24
Amendment Manager: User entered '27 Dec 2020 00:01'	System	20 Nov 2020 07:49:24

**US3552412**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:53:07**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:49:24
Amendment Manager: User entered '31 Dec 2020 23:59'	System	20 Nov 2020 07:49:24

**US3552412**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:53:07**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:49:24
Amendment Manager: User entered 'Day 117'	System	20 Nov 2020 07:49:24

**US3552412**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:53:07**

[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 (7f466cdad72abdb)', Time: '2021-01-04T06:22:10', User OID: 'PatientReportedOutcome (US3552412)', ODM File OID: 'b3293310-9a24-41fb-af5f-4f7a73da0155'	System	04 Jan 2021 12:22:20
User entered 'No (N)'	System	04 Jan 2021 12:22:20

**US3552412**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:53:07**

[Have you been exposed to someone with 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 (7f466cdad72abdb)', Time: '2021-01-04T06:22:12', User OID: 'PatientReportedOutcome (US3552412)', ODM File OID: 'b3293310-9a24-41fb-af5f-4f7a73da0155'	System	04 Jan 2021 12:22:20
User entered 'No (N)'	System	04 Jan 2021 12:22:20

**US3552412**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:53:07**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7f466cdad72abdb)', Time: '2021-01-04T06:22:17', User OID: 'PatientReportedOutcome (US3552412)', ODM File OID: 'b3293310-9a24-41fb-af5f-4f7a73da0155'	System	04 Jan 2021 12:22:20
User entered '04 Jan 2021 06:22:17'	System	04 Jan 2021 12:22:20

**US3552412**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:53:07**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:49:24
Amendment Manager: User entered '03 Jan 2021 00:01'	System	20 Nov 2020 07:49:24

**US3552412**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:53:07**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:49:24
Amendment Manager: User entered '07 Jan 2021 23:59'	System	20 Nov 2020 07:49:24

**US3552412**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:53:07**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:49:24
Amendment Manager: User entered 'Day 124'	System	20 Nov 2020 07:49:24

**US3552412**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:53:07**

[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 (7f466cdad72abdb)', Time: '2021-01-11T08:18:14', User OID: 'PatientReportedOutcome (US3552412)', ODM File OID: '67c7f526-d922-4c3d-bb79-682ee33aa0e4'	System	11 Jan 2021 14:18:22
User entered 'No (N)'	System	11 Jan 2021 14:18:22

**US3552412**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:53:07**

[Have you been exposed to someone with 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 (7f466cdad72abdb)', Time: '2021-01-11T08:18:17', User OID: 'PatientReportedOutcome (US3552412)', ODM File OID: '67c7f526-d922-4c3d-bb79-682ee33aa0e4'	System	11 Jan 2021 14:18:22
User entered 'No (N)'	System	11 Jan 2021 14:18:22

**US3552412**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:53:07**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7f466cdad72abdb)', Time: '2021-01-11T08:18:19', User OID: 'PatientReportedOutcome (US3552412)', ODM File OID: '67c7f526-d922-4c3d-bb79-682ee33aa0e4' User entered '11 Jan 2021 08:18:19'	System	11 Jan 2021 14:18:22

**US3552412**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:53:07**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:49:24
Amendment Manager: User entered '10 Jan 2021 00:01'	System	20 Nov 2020 07:49:24

**US3552412**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:53:07**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:49:24
Amendment Manager: User entered '14 Jan 2021 23:59'	System	20 Nov 2020 07:49:24

**US3552412**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:53:07**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:49:24
Amendment Manager: User entered 'Day 131'	System	20 Nov 2020 07:49:24

**US3552412**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:53:07**

[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 (7f466cdad72abdb)', Time: '2021-01-21T13:47:31', User OID: 'PatientReportedOutcome (US3552412)', ODM File OID: '237c0ff0-b695-4b5f-91bb-dacd16002fc9'	System	21 Jan 2021 19:47:39
User entered 'No (N)'	System	21 Jan 2021 19:47:39

**US3552412**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:53:07**

[Have you been exposed to someone with 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 (7f466cdad72abdb)', Time: '2021-01-21T13:47:33', User OID: 'PatientReportedOutcome (US3552412)', ODM File OID: '237c0ff0-b695-4b5f-91bb-dacd16002fc9'	System	21 Jan 2021 19:47:39
User entered 'No (N)'	System	21 Jan 2021 19:47:39

**US3552412**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:53:07**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7f466cdad72abdb)', Time: '2021-01-21T13:47:35', User OID: 'PatientReportedOutcome (US3552412)', ODM File OID: '237c0ff0-b695-4b5f-91bb-dacd16002fc9' User entered '21 Jan 2021 13:47:35'	System	21 Jan 2021 19:47:39

**US3552412**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:53:07**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:49:24
Amendment Manager: User entered '17 Jan 2021 00:01'	System	20 Nov 2020 07:49:24

**US3552412**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:53:07**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:49:24
Amendment Manager: User entered '21 Jan 2021 23:59'	System	20 Nov 2020 07:49:24

**US3552412**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:53:07**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:49:24
Amendment Manager: User entered 'Day 138'	System	20 Nov 2020 07:49:24

**US3552412**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:53:07**

[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 (7f466cdad72abdb)', Time: '2021-01-25T06:27:14', User OID: 'PatientReportedOutcome (US3552412)', ODM File OID: '48932981-63b6-4dcb-ad3f-eea9e72cf321'	System	25 Jan 2021 12:27:22
User entered 'No (N)'	System	25 Jan 2021 12:27:22

**US3552412**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:53:07**

[Have you been exposed to someone with 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 (7f466cdad72abdb)', Time: '2021-01-25T06:27:16', User OID: 'PatientReportedOutcome (US3552412)', ODM File OID: '48932981-63b6-4dcb-ad3f-eea9e72cf321'	System	25 Jan 2021 12:27:22
User entered 'No (N)'	System	25 Jan 2021 12:27:22

**US3552412**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:53:07**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7f466cdad72abdb)', Time: '2021-01-25T06:27:18', User OID: 'PatientReportedOutcome (US3552412)', ODM File OID: '48932981-63b6-4dcb-ad3f-eea9e72cf321' User entered '25 Jan 2021 06:27:18'	System	25 Jan 2021 12:27:22

**US3552412**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:53:07**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:49:24
Amendment Manager: User entered '24 Jan 2021 00:01'	System	20 Nov 2020 07:49:24

**US3552412**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:53:07**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:49:24
Amendment Manager: User entered '28 Jan 2021 23:59'	System	20 Nov 2020 07:49:24

**US3552412**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:53:07**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:49:24
Amendment Manager: User entered 'Day 145'	System	20 Nov 2020 07:49:24

**US3552412**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:53:07**

[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 (7f466cdad72abdb)', Time: '2021-01-31T20:44:03', User OID: 'PatientReportedOutcome (US3552412)', ODM File OID: '555fbf18-7bcf-421b-b13c-6162ee6ec421'	System	01 Feb 2021 02:44:11
User entered 'No (N)'	System	01 Feb 2021 02:44:11

**US3552412**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:53:07**

[Have you been exposed to someone with 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 (7f466cdad72abdb)', Time: '2021-01-31T20:44:05', User OID: 'PatientReportedOutcome (US3552412)', ODM File OID: '555fbf18-7bcf-421b-b13c-6162ee6ec421'	System	01 Feb 2021 02:44:11
User entered 'No (N)'	System	01 Feb 2021 02:44:11

**US3552412**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:53:07**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7f466cdad72abdb)', Time: '2021-01-31T20:44:07', User OID: 'PatientReportedOutcome (US3552412)', ODM File OID: '555fbf18-7bcf-421b-b13c-6162ee6ec421' User entered '31 Jan 2021 20:44:07'	System	01 Feb 2021 02:44:11
	System	01 Feb 2021 02:44:11

**US3552412**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:53:07**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:49:24
Amendment Manager: User entered '31 Jan 2021 00:01'	System	20 Nov 2020 07:49:24

**US3552412**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:53:07**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:49:24
Amendment Manager: User entered '04 Feb 2021 23:59'	System	20 Nov 2020 07:49:24

**US3552412**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:53:07**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:49:24
Amendment Manager: User entered 'Day 152'	System	20 Nov 2020 07:49:24

**US3552412**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:53:07**

[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 (7f466cdad72abdb)', Time: '2021-02-08T06:18:08', User OID: 'PatientReportedOutcome (US3552412)', ODM File OID: 'ff535658-b5cf-439b-bb48-9fa58411748d'	System	08 Feb 2021 12:18:15
User entered 'No (N)'	System	08 Feb 2021 12:18:15

**US3552412**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:53:07**

[Have you been exposed to someone with 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 (7f466cdad72abdb)', Time: '2021-02-08T06:18:10', User OID: 'PatientReportedOutcome (US3552412)', ODM File OID: 'ff535658-b5cf-439b-bb48-9fa58411748d'	System	08 Feb 2021 12:18:15
User entered 'No (N)'	System	08 Feb 2021 12:18:15

**US3552412**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:53:07**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7f466cdad72abdb)', Time: '2021-02-08T06:18:12', User OID: 'PatientReportedOutcome (US3552412)', ODM File OID: 'ff535658-b5cf-439b-bb48-9fa58411748d'	System	08 Feb 2021 12:18:15
User entered '08 Feb 2021 06:18:12'	System	08 Feb 2021 12:18:15

**US3552412**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:53:07**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:49:24
Amendment Manager: User entered '07 Feb 2021 00:01'	System	20 Nov 2020 07:49:24

**US3552412**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:53:07**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:49:24
Amendment Manager: User entered '11 Feb 2021 23:59'	System	20 Nov 2020 07:49:24

**US3552412**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:53:07**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:49:24
Amendment Manager: User entered 'Day 159'	System	20 Nov 2020 07:49:24

**US3552412**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:53:07**

[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 (7f466cdad72abdb)', Time: '2021-02-15T20:57:25', User OID: 'PatientReportedOutcome (US3552412)', ODM File OID: 'c1f7cc45-7877-453f-8bd0-6eacf4031990'	System	16 Feb 2021 02:57:35
User entered 'No (N)'	System	16 Feb 2021 02:57:35

**US3552412**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:53:07**

[Have you been exposed to someone with 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 (7f466cdad72abdb)', Time: '2021-02-15T20:57:26', User OID: 'PatientReportedOutcome (US3552412)', ODM File OID: 'c1f7cc45-7877-453f-8bd0-6eacf4031990'	System	16 Feb 2021 02:57:35
User entered 'No (N)'	System	16 Feb 2021 02:57:35

**US3552412**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:53:07**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7f466cdad72abdb)', Time: '2021-02-15T20:57:29', User OID: 'PatientReportedOutcome (US3552412)', ODM File OID: 'c1f7cc45-7877-453f-8bd0-6eacf4031990'	System	16 Feb 2021 02:57:35
User entered '15 Feb 2021 20:57:29'	System	16 Feb 2021 02:57:35

**US3552412**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:53:07**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:49:24
Amendment Manager: User entered '14 Feb 2021 00:01'	System	20 Nov 2020 07:49:24

**US3552412**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:53:07**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:49:24
Amendment Manager: User entered '18 Feb 2021 23:59'	System	20 Nov 2020 07:49:24

**US3552412**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:53:07**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:49:24
Amendment Manager: User entered 'Day 166'	System	20 Nov 2020 07:49:24

**US3552412**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:53:07**

[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 (7f466cdad72abdb)', Time: '2021-02-22T07:21:58', User OID: 'PatientReportedOutcome (US3552412)', ODM File OID: '4caeb26b-46ba-45b6-a27b-a8ce78b49f2f'	System	22 Feb 2021 13:22:04
User entered 'No (N)'	System	22 Feb 2021 13:22:04

**US3552412**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:53:07**

Have you been exposed to someone with 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 (7f466cdad72abdb)', Time: '2021-02-22T07:21:59', User OID: 'PatientReportedOutcome (US3552412)', ODM File OID: '4caeb26b-46ba-45b6-a27b-a8ce78b49f2f'	System	22 Feb 2021 13:22:04
User entered 'No (N)'	System	22 Feb 2021 13:22:04

**US3552412**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:53:07**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7f466cdad72abdb)', Time: '2021-02-22T07:22:01', User OID: 'PatientReportedOutcome (US3552412)', ODM File OID: '4caeb26b-46ba-45b6-a27b-a8ce78b49f2f'	System	22 Feb 2021 13:22:04
User entered '22 Feb 2021 07:22:01'	System	22 Feb 2021 13:22:04

**US3552412**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:53:07**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:49:24
Amendment Manager: User entered '21 Feb 2021 00:01'	System	20 Nov 2020 07:49:24

**US3552412**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:53:07**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:49:24
Amendment Manager: User entered '25 Feb 2021 23:59'	System	20 Nov 2020 07:49:24

**US3552412**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:53:07**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:49:24
Amendment Manager: User entered 'Day 173'	System	20 Nov 2020 07:49:24

**US3552412**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:53:07**

[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 (7f466cdad72abddb)', Time: '2021-03-01T06:19:22-06:00', User OID: 'PatientReportedOutcome (US3552412)', ODM File OID: '1f13299b-161e-4839-aea4-8e3dae6abcbf' User entered 'No (N)'	System	01 Mar 2021 12:19:28
	System	01 Mar 2021 12:19:28

**US3552412**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:53:07**

[Have you been exposed to someone with 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 (7f466cdad72abdb)', Time: '2021-03-01T06:19:23-06:00', User OID: 'PatientReportedOutcome (US3552412)', ODM File OID: '1f13299b-161e-4839-aea4-8e3dae6abcbf' User entered 'No (N)'	System	01 Mar 2021 12:19:28

**US3552412**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:53:07**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7f466cdad72abddb)', Time: '2021-03-01T06:19:25-06:00', User OID: 'PatientReportedOutcome (US3552412)', ODM File OID: '1f13299b-161e-4839-aea4-8e3dae6abcbf'	System	01 Mar 2021 12:19:28
User entered '01 Mar 2021 06:19:25'	System	01 Mar 2021 12:19:28

**US3552412**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:53:07**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:49:24
Amendment Manager: User entered '28 Feb 2021 00:01'	System	20 Nov 2020 07:49:24

**US3552412**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:53:07**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:49:24
Amendment Manager: User entered '04 Mar 2021 23:59'	System	20 Nov 2020 07:49:24

**US3552412**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:53:07**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:49:24
Amendment Manager: User entered 'Day 180'	System	20 Nov 2020 07:49:24

**US3552412**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:53:07**

[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 (7f466cdad72abdb)', Time: '2021-03-08T09:18:48-06:00', User OID: 'PatientReportedOutcome (US3552412)', ODM File OID: '7dcf10e5-c9f4-4467-8ff4-c14624140a40'	System	08 Mar 2021 15:18:56
User entered 'No (N)'	System	08 Mar 2021 15:18:56

US3552412

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:53:07**

Have you been exposed to someone with 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 (7f466cdad72abdb)', Time: '2021-03-08T09:18:50-06:00', User OID: 'PatientReportedOutcome (US3552412)', ODM File OID: '7dcf10e5-c9f4-4467-8ff4-c14624140a40'	System	08 Mar 2021 15:18:56
User entered 'No (N)'	System	08 Mar 2021 15:18:56

**US3552412**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:53:07**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7f466cdad72abddb)', Time: '2021-03-08T09:18:52-06:00', User OID: 'PatientReportedOutcome (US3552412)', ODM File OID: '7dcf10e5-c9f4-4467-8ff4-c14624140a40'	System	08 Mar 2021 15:18:56
User entered '08 Mar 2021 09:18:52'	System	08 Mar 2021 15:18:56

**US3552412**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:53:07**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:49:24
Amendment Manager: User entered '07 Mar 2021 00:01'	System	20 Nov 2020 07:49:24

**US3552412**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:53:07**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:49:24
Amendment Manager: User entered '11 Mar 2021 23:59'	System	20 Nov 2020 07:49:24

**US3552412**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:53:07**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:49:24
Amendment Manager: User entered 'Day 187'	System	20 Nov 2020 07:49:24

**US3552412**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:53:07**

[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 (7f466cdad72abdb)', Time: '2021-03-15T15:46:46-05:00', User OID: 'PatientReportedOutcome (US3552412)', ODM File OID: '5ab229f1-2078-44af-85c6-51010977f7d5'	System	15 Mar 2021 20:46:52
User entered 'No (N)'	System	15 Mar 2021 20:46:52

**US3552412**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:53:07**

[Have you been exposed to someone with 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 (7f466cdad72abdb)', Time: '2021-03-15T15:46:47-05:00', User OID: 'PatientReportedOutcome (US3552412)', ODM File OID: '5ab229f1-2078-44af-85c6-51010977f7d5'	System	15 Mar 2021 20:46:52
User entered 'No (N)'	System	15 Mar 2021 20:46:52

**US3552412**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:53:07**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7f466cdad72abdb)', Time: '2021-03-15T15:46:49-05:00', User OID: 'PatientReportedOutcome (US3552412)', ODM File OID: '5ab229f1-2078-44af-85c6-51010977f7d5'	System	15 Mar 2021 20:46:52
User entered '15 Mar 2021 15:46:49'	System	15 Mar 2021 20:46:52

**US3552412**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:53:07**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:49:24
Amendment Manager: User entered '14 Mar 2021 00:01'	System	20 Nov 2020 07:49:24

**US3552412**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:53:07**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:49:24
Amendment Manager: User entered '18 Mar 2021 23:59'	System	20 Nov 2020 07:49:24

**US3552412**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:53:07**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:49:24
Amendment Manager: User entered 'Day 194'	System	20 Nov 2020 07:49:24

**US3552412**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:53:07**

[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 (7f466cdad72abddb)', Time: '2021-03-22T06:17:50-05:00', User OID: 'PatientReportedOutcome (US3552412)', ODM File OID: 'e20ccfd0-01d3-4d43-81cf-1fbdea08c771'	System	22 Mar 2021 11:17:57
User entered 'No (N)'	System	22 Mar 2021 11:17:57

**US3552412**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:53:07**

[Have you been exposed to someone with 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 (7f466cdad72abdb)', Time: '2021-03-22T06:17:52-05:00', User OID: 'PatientReportedOutcome (US3552412)', ODM File OID: 'e20ccfd0-01d3-4d43-81cf-1fbdea08c771'	System	22 Mar 2021 11:17:57
User entered 'No (N)'	System	22 Mar 2021 11:17:57

**US3552412**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:53:07**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7f466cdad72abddb)', Time: '2021-03-22T06:17:55-05:00', User OID: 'PatientReportedOutcome (US3552412)', ODM File OID: 'e20ccfd0-01d3-4d43-81cf-1fbdea08c771'	System	22 Mar 2021 11:17:57
User entered '22 Mar 2021 06:17:55'	System	22 Mar 2021 11:17:57

**US3552412**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:53:07**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:49:24
Amendment Manager: User entered '21 Mar 2021 00:01'	System	20 Nov 2020 07:49:24

**US3552412**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:53:07**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:49:24
Amendment Manager: User entered '25 Mar 2021 23:59'	System	20 Nov 2020 07:49:24

**US3552412**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:53:07**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:49:24
Amendment Manager: User entered 'Day 201'	System	20 Nov 2020 07:49:24

**US3552412**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:53:07**

[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 (7f466cdad72abdb)', Time: '2021-03-30T12:00:22-05:00', User OID: 'PatientReportedOutcome (US3552412)', ODM File OID: '4f48c2fd-e096-49bd-9428-2c2165c1802d'	System	30 Mar 2021 17:00:40
User entered 'No (N)'	System	30 Mar 2021 17:00:40

**US3552412**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:53:07**

[Have you been exposed to someone with 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 (7f466cdad72abdb)', Time: '2021-03-30T12:00:23-05:00', User OID: 'PatientReportedOutcome (US3552412)', ODM File OID: '4f48c2fd-e096-49bd-9428-2c2165c1802d'	System	30 Mar 2021 17:00:40
User entered 'No (N)'	System	30 Mar 2021 17:00:40

**US3552412**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:53:07**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7f466cdad72abddb)', Time: '2021-03-30T12:00:25-05:00', User OID: 'PatientReportedOutcome (US3552412)', ODM File OID: '4f48c2fd-e096-49bd-9428-2c2165c1802d' User entered '30 Mar 2021 12:00:25'	System	30 Mar 2021 17:00:40
	System	30 Mar 2021 17:00:40

**US3552412**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:53:07**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:49:24
Amendment Manager: User entered '28 Mar 2021 00:01'	System	20 Nov 2020 07:49:24

**US3552412**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:53:07**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:49:24
Amendment Manager: User entered '01 Apr 2021 23:59'	System	20 Nov 2020 07:49:24

**US3552412**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:53:07**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:49:24
Amendment Manager: User entered 'Day 208'	System	20 Nov 2020 07:49:24

**US3552412**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:53:07**

[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 (7f466cdad72abdb)', Time: '2021-04-05T08:16:55-05:00', User OID: 'PatientReportedOutcome (US3552412)', ODM File OID: 'e29630c8-2cbe-442c-84ab-865bca686243' User entered 'No (N)'	System	05 Apr 2021 13:17:10
	System	05 Apr 2021 13:17:10

US3552412

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:53:07

Have you been exposed to someone with 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 (7f466cdad72abdb)', Time: '2021-04-05T08:16:56-05:00', User OID: 'PatientReportedOutcome (US3552412)', ODM File OID: 'e29630c8-2cbe-442c-84ab-865bca686243'	System	05 Apr 2021 13:17:10
User entered 'No (N)'	System	05 Apr 2021 13:17:10

**US3552412**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:53:07**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7f466cdad72abddb)', Time: '2021-04-05T08:16:58-05:00', User OID: 'PatientReportedOutcome (US3552412)', ODM File OID: 'e29630c8-2cbe-442c-84ab-865bca686243' User entered '05 Apr 2021 08:16:58'	System	05 Apr 2021 13:17:10
	System	05 Apr 2021 13:17:10

**US3552412**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:53:07**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:49:24
Amendment Manager: User entered '04 Apr 2021 00:01'	System	20 Nov 2020 07:49:24

**US3552412**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:53:07**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:49:24
Amendment Manager: User entered '08 Apr 2021 23:59'	System	20 Nov 2020 07:49:24

**US3552412**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:53:07**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:49:24
Amendment Manager: User entered 'Day 215'	System	20 Nov 2020 07:49:24

**US3552412**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:53:07**

[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 (7f466cdad72abdb)', Time: '2021-04-12T08:10:24-05:00', User OID: 'PatientReportedOutcome (US3552412)', ODM File OID: '7fdd30f0-5cbe-4b60-980d-bf8978c5c087'	System	12 Apr 2021 13:10:42
User entered 'No (N)'	System	12 Apr 2021 13:10:42

**US3552412**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:53:07**

[Have you been exposed to someone with 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 (7f466cdad72abdb)', Time: '2021-04-12T08:09:41-05:00', User OID: 'PatientReportedOutcome (US3552412)', ODM File OID: '7fdd30f0-5cbe-4b60-980d-bf8978c5c087'	System	12 Apr 2021 13:10:42
User entered 'No (N)'	System	12 Apr 2021 13:10:42

**US3552412**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:53:07**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7f466cdad72abddb)', Time: '2021-04-12T08:10:28-05:00', User OID: 'PatientReportedOutcome (US3552412)', ODM File OID: '7fdd30f0-5cbe-4b60-980d-bf8978c5c087'	System	12 Apr 2021 13:10:42
User entered '12 Apr 2021 08:10:28'	System	12 Apr 2021 13:10:42

**US3552412**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:53:07**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:49:24
Amendment Manager: User entered '11 Apr 2021 00:01'	System	20 Nov 2020 07:49:24

**US3552412**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:53:07**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:49:24
Amendment Manager: User entered '15 Apr 2021 23:59'	System	20 Nov 2020 07:49:24

**US3552412**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:53:07**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:49:24
Amendment Manager: User entered 'Day 222'	System	20 Nov 2020 07:49:24

**US3552412**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:53:07**

[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 (7f466cdad72abdb)', Time: '2021-04-22T14:11:04-05:00', User OID: 'PatientReportedOutcome (US3552412)', ODM File OID: 'd964923f-81e6-47ad-9dba-4abd880690e3' User entered 'No (N)'	System	22 Apr 2021 19:11:16
	System	22 Apr 2021 19:11:16

US3552412

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:53:07

Have you been exposed to someone with 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 (7f466cdad72abdb)', Time: '2021-04-22T14:11:06-05:00', User OID: 'PatientReportedOutcome (US3552412)', ODM File OID: 'd964923f-81e6-47ad-9dba-4abd880690e3' User entered 'No (N)'	System	22 Apr 2021 19:11:16

**US3552412**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:53:07**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7f466cdad72abddb)', Time: '2021-04-22T14:11:10-05:00', User OID: 'PatientReportedOutcome (US3552412)', ODM File OID: 'd964923f-81e6-47ad-9dba-4abd880690e3' User entered '22 Apr 2021 14:11:10'	System	22 Apr 2021 19:11:16
	System	22 Apr 2021 19:11:16

**US3552412**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:53:07**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:49:24
Amendment Manager: User entered '18 Apr 2021 00:01'	System	20 Nov 2020 07:49:24

**US3552412**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:53:07**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:49:24
Amendment Manager: User entered '22 Apr 2021 23:59'	System	20 Nov 2020 07:49:24

**US3552412**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:53:07**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:49:24
Amendment Manager: User entered 'Day 229'	System	20 Nov 2020 07:49:24

**US3552412**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:53:07**

[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 (7f466cdad72abdb)', Time: '2021-04-25T20:59:07-05:00', User OID: 'PatientReportedOutcome (US3552412)', ODM File OID: 'd3efbe42-b31c-4578-9cab-3e36221e885e' User entered 'No (N)'	System	26 Apr 2021 01:59:13

US3552412

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:53:07

Have you been exposed to someone with 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 (7f466cdad72abdb)', Time: '2021-04-25T20:59:08-05:00', User OID: 'PatientReportedOutcome (US3552412)', ODM File OID: 'd3efbe42-b31c-4578-9cab-3e36221e885e' User entered 'No (N)'	System	26 Apr 2021 01:59:13

**US3552412**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:53:07**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7f466cdad72abddb)', Time: '2021-04-25T20:59:10-05:00', User OID: 'PatientReportedOutcome (US3552412)', ODM File OID: 'd3efbe42-b31c-4578-9cab-3e36221e885e'	System	26 Apr 2021 01:59:13
User entered '25 Apr 2021 20:59:10'	System	26 Apr 2021 01:59:13

**US3552412**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:53:07**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:49:24
Amendment Manager: User entered '25 Apr 2021 00:01'	System	20 Nov 2020 07:49:24

**US3552412**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:53:07**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:49:24
Amendment Manager: User entered '29 Apr 2021 23:59'	System	20 Nov 2020 07:49:24

**US3552412**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:53:07**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:49:24
Amendment Manager: User entered 'Day 236'	System	20 Nov 2020 07:49:24

**US3552412**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:53:07**

[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 (7f466cdad72abdb)', Time: '2021-05-02T20:42:48-05:00', User OID: 'PatientReportedOutcome (US3552412)', ODM File OID: '9656448c-0d08-4e09-906c-96f0a7b53d37'	System	03 May 2021 01:42:57
User entered 'No (N)'	System	03 May 2021 01:42:57

US3552412

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:53:07

Have you been exposed to someone with 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 (7f466cdad72abdb)', Time: '2021-05-02T20:42:50-05:00', User OID: 'PatientReportedOutcome (US3552412)', ODM File OID: '9656448c-0d08-4e09-906c-96f0a7b53d37'	System	03 May 2021 01:42:57
User entered 'No (N)'	System	03 May 2021 01:42:57

**US3552412**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:53:07**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7f466cdad72abddb)', Time: '2021-05-02T20:42:52-05:00', User OID: 'PatientReportedOutcome (US3552412)', ODM File OID: '9656448c-0d08-4e09-906c-96f0a7b53d37'	System	03 May 2021 01:42:57
User entered '02 May 2021 20:42:52'	System	03 May 2021 01:42:57

**US3552412**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:53:07**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:49:24
Amendment Manager: User entered '02 May 2021 00:01'	System	20 Nov 2020 07:49:24

**US3552412**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:53:07**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:49:24
Amendment Manager: User entered '06 May 2021 23:59'	System	20 Nov 2020 07:49:24

**US3552412**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:53:07**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:49:24
Amendment Manager: User entered 'Day 243'	System	20 Nov 2020 07:49:24

**US3552412**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:53:07**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:49:24
Amendment Manager: User entered '09 May 2021 00:01'	System	20 Nov 2020 07:49:24

**US3552412**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:53:07**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:49:24
Amendment Manager: User entered '13 May 2021 23:59'	System	20 Nov 2020 07:49:24

**US3552412**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:53:07**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:49:24
Amendment Manager: User entered 'Day 250'	System	20 Nov 2020 07:49:24

**US3552412**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:53:07**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:49:24
Amendment Manager: User entered '16 May 2021 00:01'	System	20 Nov 2020 07:49:24

**US3552412**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:53:07**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:49:24
Amendment Manager: User entered '20 May 2021 23:59'	System	20 Nov 2020 07:49:24

**US3552412**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:53:07**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:49:24
Amendment Manager: User entered 'Day 257'	System	20 Nov 2020 07:49:24

**US3552412**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:53:07**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:49:24
Amendment Manager: User entered '23 May 2021 00:01'	System	20 Nov 2020 07:49:24

**US3552412**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:53:07**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:49:24
Amendment Manager: User entered '27 May 2021 23:59'	System	20 Nov 2020 07:49:24

**US3552412**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:53:07**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:49:24
Amendment Manager: User entered 'Day 264'	System	20 Nov 2020 07:49:24

**US3552412**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:53:07**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:49:24
Amendment Manager: User entered '30 May 2021 00:01'	System	20 Nov 2020 07:49:24

**US3552412**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:53:07**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:49:24
Amendment Manager: User entered '03 Jun 2021 23:59'	System	20 Nov 2020 07:49:24

**US3552412**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:53:07**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:49:24
Amendment Manager: User entered 'Day 271'	System	20 Nov 2020 07:49:24

**US3552412**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:53:07**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:49:24
Amendment Manager: User entered '06 Jun 2021 00:01'	System	20 Nov 2020 07:49:24

**US3552412**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:53:07**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:49:24
Amendment Manager: User entered '10 Jun 2021 23:59'	System	20 Nov 2020 07:49:24

**US3552412**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:53:07**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:49:24
Amendment Manager: User entered 'Day 278'	System	20 Nov 2020 07:49:24

**US3552412**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:53:07**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:49:24
Amendment Manager: User entered '13 Jun 2021 00:01'	System	20 Nov 2020 07:49:24

**US3552412**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:53:07**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:49:24
Amendment Manager: User entered '17 Jun 2021 23:59'	System	20 Nov 2020 07:49:24

**US3552412**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:53:07**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:49:24
Amendment Manager: User entered 'Day 285'	System	20 Nov 2020 07:49:24

**US3552412**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:53:07**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:49:24
Amendment Manager: User entered '20 Jun 2021 00:01'	System	20 Nov 2020 07:49:24

**US3552412**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:53:07**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:49:24
Amendment Manager: User entered '24 Jun 2021 23:59'	System	20 Nov 2020 07:49:24

**US3552412**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:53:07**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:49:24
Amendment Manager: User entered 'Day 292'	System	20 Nov 2020 07:49:24

**US3552412**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:53:07**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:49:24
Amendment Manager: User entered '27 Jun 2021 00:01'	System	20 Nov 2020 07:49:24

**US3552412**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:53:07**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:49:24
Amendment Manager: User entered '01 Jul 2021 23:59'	System	20 Nov 2020 07:49:24

**US3552412**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:53:07**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:49:24
Amendment Manager: User entered 'Day 299'	System	20 Nov 2020 07:49:24

**US3552412**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:53:07**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:49:24
Amendment Manager: User entered '04 Jul 2021 00:01'	System	20 Nov 2020 07:49:24

**US3552412**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:53:07**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:49:24
Amendment Manager: User entered '08 Jul 2021 23:59'	System	20 Nov 2020 07:49:24

**US3552412**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:53:07**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:49:24
Amendment Manager: User entered 'Day 306'	System	20 Nov 2020 07:49:24

**US3552412**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:53:07**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:49:24
Amendment Manager: User entered '11 Jul 2021 00:01'	System	20 Nov 2020 07:49:24

**US3552412**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:53:07**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:49:24
Amendment Manager: User entered '15 Jul 2021 23:59'	System	20 Nov 2020 07:49:24

**US3552412**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:53:07**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:49:24
Amendment Manager: User entered 'Day 313'	System	20 Nov 2020 07:49:24

**US3552412**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:53:07**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:49:24
Amendment Manager: User entered '18 Jul 2021 00:01'	System	20 Nov 2020 07:49:24

**US3552412**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:53:07**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:49:24
Amendment Manager: User entered '22 Jul 2021 23:59'	System	20 Nov 2020 07:49:24

**US3552412**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:53:07**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:49:24
Amendment Manager: User entered 'Day 320'	System	20 Nov 2020 07:49:24

**US3552412**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:53:07**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:49:24
Amendment Manager: User entered '25 Jul 2021 00:01'	System	20 Nov 2020 07:49:24

**US3552412**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:53:07**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:49:24
Amendment Manager: User entered '29 Jul 2021 23:59'	System	20 Nov 2020 07:49:24

**US3552412**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:53:07**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:49:24
Amendment Manager: User entered 'Day 327'	System	20 Nov 2020 07:49:24

**US3552412**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:53:07**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:49:24
Amendment Manager: User entered '01 Aug 2021 00:01'	System	20 Nov 2020 07:49:24

**US3552412**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:53:07**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:49:24
Amendment Manager: User entered '05 Aug 2021 23:59'	System	20 Nov 2020 07:49:24

**US3552412**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:53:07**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:49:24
Amendment Manager: User entered 'Day 334'	System	20 Nov 2020 07:49:24

**US3552412**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:53:07**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:49:24
Amendment Manager: User entered '08 Aug 2021 00:01'	System	20 Nov 2020 07:49:24

**US3552412**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:53:07**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:49:24
Amendment Manager: User entered '12 Aug 2021 23:59'	System	20 Nov 2020 07:49:24

**US3552412**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:53:07**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:49:24
Amendment Manager: User entered 'Day 341'	System	20 Nov 2020 07:49:24

**US3552412**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:53:07**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:49:24
Amendment Manager: User entered '15 Aug 2021 00:01'	System	20 Nov 2020 07:49:24

**US3552412**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:53:07**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:49:24
Amendment Manager: User entered '19 Aug 2021 23:59'	System	20 Nov 2020 07:49:24

**US3552412**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:53:07**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:49:24
Amendment Manager: User entered 'Day 348'	System	20 Nov 2020 07:49:24

**US3552412**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:53:07**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:49:24
Amendment Manager: User entered '22 Aug 2021 00:01'	System	20 Nov 2020 07:49:24

**US3552412**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:53:07**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:49:24
Amendment Manager: User entered '26 Aug 2021 23:59'	System	20 Nov 2020 07:49:24

**US3552412**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:53:07**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:49:24
Amendment Manager: User entered 'Day 355'	System	20 Nov 2020 07:49:24

**US3552412**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:53:07**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:49:24
Amendment Manager: User entered '29 Aug 2021 00:01'	System	20 Nov 2020 07:49:24

**US3552412**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:53:07**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:49:24
Amendment Manager: User entered '02 Sep 2021 23:59'	System	20 Nov 2020 07:49:24

**US3552412**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:53:07**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:49:24
Amendment Manager: User entered 'Day 362'	System	20 Nov 2020 07:49:24

**US3552412**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:53:07**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:49:24
Amendment Manager: User entered '05 Sep 2021 00:01'	System	20 Nov 2020 07:49:24

**US3552412**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:53:07**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:49:24
Amendment Manager: User entered '09 Sep 2021 23:59'	System	20 Nov 2020 07:49:24

**US3552412**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:53:07**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:49:24
Amendment Manager: User entered 'Day 369'	System	20 Nov 2020 07:49:24

**US3552412**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:53:07**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:49:24
Amendment Manager: User entered '12 Sep 2021 00:01'	System	20 Nov 2020 07:49:24

**US3552412**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:53:07**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:49:24
Amendment Manager: User entered '16 Sep 2021 23:59'	System	20 Nov 2020 07:49:24

**US3552412**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:53:07**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:49:24
Amendment Manager: User entered 'Day 376'	System	20 Nov 2020 07:49:24

**US3552412**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:53:07**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:49:24
Amendment Manager: User entered '19 Sep 2021 00:01'	System	20 Nov 2020 07:49:24

**US3552412**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:53:07**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:49:24
Amendment Manager: User entered '23 Sep 2021 23:59'	System	20 Nov 2020 07:49:24

**US3552412**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:53:07**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:49:24
Amendment Manager: User entered 'Day 383'	System	20 Nov 2020 07:49:24

**US3552412**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:53:07**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:49:24
Amendment Manager: User entered '26 Sep 2021 00:01'	System	20 Nov 2020 07:49:24

**US3552412**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:53:07**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:49:24
Amendment Manager: User entered '30 Sep 2021 23:59'	System	20 Nov 2020 07:49:24

**US3552412**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:53:07**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:49:24
Amendment Manager: User entered 'Day 390'	System	20 Nov 2020 07:49:24

**US3552412**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:53:07**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:49:24
Amendment Manager: User entered '03 Oct 2021 00:01'	System	20 Nov 2020 07:49:24

**US3552412**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:53:07**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:49:24
Amendment Manager: User entered '07 Oct 2021 23:59'	System	20 Nov 2020 07:49:24

**US3552412**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:53:07**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:49:24
Amendment Manager: User entered 'Day 397'	System	20 Nov 2020 07:49:24

**US3552412**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:53:07**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:49:24
Amendment Manager: User entered '10 Oct 2021 00:01'	System	20 Nov 2020 07:49:24

**US3552412**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:53:07**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:49:24
Amendment Manager: User entered '14 Oct 2021 23:59'	System	20 Nov 2020 07:49:24

**US3552412**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:53:07**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:49:24
Amendment Manager: User entered 'Day 404'	System	20 Nov 2020 07:49:24

**US3552412**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:53:07**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:49:24
Amendment Manager: User entered '17 Oct 2021 00:01'	System	20 Nov 2020 07:49:24

**US3552412**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:53:07**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:49:24
Amendment Manager: User entered '21 Oct 2021 23:59'	System	20 Nov 2020 07:49:24

**US3552412**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:53:07**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:49:24
Amendment Manager: User entered 'Day 411'	System	20 Nov 2020 07:49:24

**US3552412**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:53:07**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:49:24
Amendment Manager: User entered '24 Oct 2021 00:01'	System	20 Nov 2020 07:49:24

**US3552412**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:53:07**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:49:24
Amendment Manager: User entered '28 Oct 2021 23:59'	System	20 Nov 2020 07:49:24

**US3552412**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:53:07**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:49:24
Amendment Manager: User entered 'Day 418'	System	20 Nov 2020 07:49:24

**US3552412**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:53:07**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:49:24
Amendment Manager: User entered '31 Oct 2021 00:01'	System	20 Nov 2020 07:49:24

**US3552412**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:53:07**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:49:24
Amendment Manager: User entered '04 Nov 2021 23:59'	System	20 Nov 2020 07:49:24

**US3552412**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:53:07**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:49:24
Amendment Manager: User entered 'Day 425'	System	20 Nov 2020 07:49:24

**US3552412**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:53:07**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:49:24
Amendment Manager: User entered '07 Nov 2021 00:01'	System	20 Nov 2020 07:49:24

**US3552412**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:53:07**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:49:24
Amendment Manager: User entered '11 Nov 2021 23:59'	System	20 Nov 2020 07:49:24

**US3552412**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:53:07**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:49:24
Amendment Manager: User entered 'Day 432'	System	20 Nov 2020 07:49:24

**US3552412**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:53:07**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:49:24
Amendment Manager: User entered '14 Nov 2021 00:01'	System	20 Nov 2020 07:49:24

**US3552412**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:53:07**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:49:24
Amendment Manager: User entered '18 Nov 2021 23:59'	System	20 Nov 2020 07:49:24

**US3552412**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:53:07**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:49:24
Amendment Manager: User entered 'Day 439'	System	20 Nov 2020 07:49:24

**US3552412**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:53:07**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:49:24
Amendment Manager: User entered '21 Nov 2021 00:01'	System	20 Nov 2020 07:49:24

**US3552412**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:53:07**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:49:24
Amendment Manager: User entered '25 Nov 2021 23:59'	System	20 Nov 2020 07:49:24

**US3552412**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:53:07**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:49:24
Amendment Manager: User entered 'Day 446'	System	20 Nov 2020 07:49:24

**US3552412**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:53:07**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:49:24
Amendment Manager: User entered '28 Nov 2021 00:01'	System	20 Nov 2020 07:49:24

**US3552412**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:53:07**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:49:24
Amendment Manager: User entered '02 Dec 2021 23:59'	System	20 Nov 2020 07:49:24

**US3552412**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:53:07**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:49:24
Amendment Manager: User entered 'Day 453'	System	20 Nov 2020 07:49:24

**US3552412**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:53:07**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:49:24
Amendment Manager: User entered '05 Dec 2021 00:01'	System	20 Nov 2020 07:49:24

**US3552412**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:53:07**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:49:24
Amendment Manager: User entered '09 Dec 2021 23:59'	System	20 Nov 2020 07:49:24

**US3552412**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:53:07**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:49:24
Amendment Manager: User entered 'Day 460'	System	20 Nov 2020 07:49:24

**US3552412**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:53:07**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:49:24
Amendment Manager: User entered '12 Dec 2021 00:01'	System	20 Nov 2020 07:49:24

**US3552412**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:53:07**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:49:24
Amendment Manager: User entered '16 Dec 2021 23:59'	System	20 Nov 2020 07:49:24

**US3552412**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:53:07**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:49:24
Amendment Manager: User entered 'Day 467'	System	20 Nov 2020 07:49:24

**US3552412**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:53:07**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:49:24
Amendment Manager: User entered '19 Dec 2021 00:01'	System	20 Nov 2020 07:49:24

**US3552412**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:53:07**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:49:24
Amendment Manager: User entered '23 Dec 2021 23:59'	System	20 Nov 2020 07:49:24

**US3552412**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:53:07**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:49:24
Amendment Manager: User entered 'Day 474'	System	20 Nov 2020 07:49:24

**US3552412**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:53:07**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:49:24
Amendment Manager: User entered '26 Dec 2021 00:01'	System	20 Nov 2020 07:49:24

**US3552412**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:53:07**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:49:24
Amendment Manager: User entered '30 Dec 2021 23:59'	System	20 Nov 2020 07:49:24

**US3552412**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:53:07**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:49:24
Amendment Manager: User entered 'Day 481'	System	20 Nov 2020 07:49:24

**US3552412**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:53:07**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:49:24
Amendment Manager: User entered '02 Jan 2022 00:01'	System	20 Nov 2020 07:49:24

**US3552412**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:53:07**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:49:24
Amendment Manager: User entered '06 Jan 2022 23:59'	System	20 Nov 2020 07:49:24

**US3552412**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:53:07**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:49:24
Amendment Manager: User entered 'Day 488'	System	20 Nov 2020 07:49:24

**US3552412**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:53:07**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:49:24
Amendment Manager: User entered '09 Jan 2022 00:01'	System	20 Nov 2020 07:49:24

**US3552412**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:53:07**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:49:24
Amendment Manager: User entered '13 Jan 2022 23:59'	System	20 Nov 2020 07:49:24

**US3552412**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:53:07**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:49:24
Amendment Manager: User entered 'Day 495'	System	20 Nov 2020 07:49:24

**US3552412**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:53:07**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:49:24
Amendment Manager: User entered '16 Jan 2022 00:01'	System	20 Nov 2020 07:49:24

**US3552412**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:53:07**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:49:24
Amendment Manager: User entered '20 Jan 2022 23:59'	System	20 Nov 2020 07:49:24

**US3552412**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:53:07**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:49:24
Amendment Manager: User entered 'Day 502'	System	20 Nov 2020 07:49:24

**US3552412**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:53:07**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:49:24
Amendment Manager: User entered '23 Jan 2022 00:01'	System	20 Nov 2020 07:49:24

**US3552412**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:53:07**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:49:24
Amendment Manager: User entered '27 Jan 2022 23:59'	System	20 Nov 2020 07:49:24

**US3552412**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:53:07**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:49:24
Amendment Manager: User entered 'Day 509'	System	20 Nov 2020 07:49:24

**US3552412**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:53:07**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:49:24
Amendment Manager: User entered '30 Jan 2022 00:01'	System	20 Nov 2020 07:49:24

**US3552412**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:53:07**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:49:24
Amendment Manager: User entered '03 Feb 2022 23:59'	System	20 Nov 2020 07:49:24

**US3552412**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:53:07**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:49:24
Amendment Manager: User entered 'Day 516'	System	20 Nov 2020 07:49:24

**US3552412**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:53:07**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:49:24
Amendment Manager: User entered '06 Feb 2022 00:01'	System	20 Nov 2020 07:49:24

**US3552412**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:53:07**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:49:24
Amendment Manager: User entered '10 Feb 2022 23:59'	System	20 Nov 2020 07:49:24

**US3552412**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:53:07**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:49:24
Amendment Manager: User entered 'Day 523'	System	20 Nov 2020 07:49:24

**US3552412**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:53:07**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:49:24
Amendment Manager: User entered '13 Feb 2022 00:01'	System	20 Nov 2020 07:49:24

**US3552412**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:53:07**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:49:24
Amendment Manager: User entered '17 Feb 2022 23:59'	System	20 Nov 2020 07:49:24

**US3552412**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:53:07**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:49:24
Amendment Manager: User entered 'Day 530'	System	20 Nov 2020 07:49:24

**US3552412**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:53:07**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:49:24
Amendment Manager: User entered '20 Feb 2022 00:01'	System	20 Nov 2020 07:49:24

**US3552412**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:53:07**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:49:24
Amendment Manager: User entered '24 Feb 2022 23:59'	System	20 Nov 2020 07:49:24

**US3552412**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:53:07**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:49:24
Amendment Manager: User entered 'Day 537'	System	20 Nov 2020 07:49:24

**US3552412**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:53:07**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:49:24
Amendment Manager: User entered '27 Feb 2022 00:01'	System	20 Nov 2020 07:49:24

**US3552412**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:53:07**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:49:24
Amendment Manager: User entered '03 Mar 2022 23:59'	System	20 Nov 2020 07:49:24

**US3552412**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:53:07**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:49:24
Amendment Manager: User entered 'Day 544'	System	20 Nov 2020 07:49:24

**US3552412**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:53:07**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:49:24
Amendment Manager: User entered '06 Mar 2022 00:01'	System	20 Nov 2020 07:49:24

**US3552412**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:53:07**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:49:24
Amendment Manager: User entered '10 Mar 2022 23:59'	System	20 Nov 2020 07:49:24

**US3552412**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:53:07**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:49:24
Amendment Manager: User entered 'Day 551'	System	20 Nov 2020 07:49:24

**US3552412**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:53:07**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:49:24
Amendment Manager: User entered '13 Mar 2022 00:01'	System	20 Nov 2020 07:49:24

**US3552412**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:53:07**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:49:24
Amendment Manager: User entered '17 Mar 2022 23:59'	System	20 Nov 2020 07:49:24

**US3552412**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:53:07**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:49:24
Amendment Manager: User entered 'Day 558'	System	20 Nov 2020 07:49:24

**US3552412**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:53:07**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:49:24
Amendment Manager: User entered '20 Mar 2022 00:01'	System	20 Nov 2020 07:49:24

**US3552412**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:53:07**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:49:24
Amendment Manager: User entered '24 Mar 2022 23:59'	System	20 Nov 2020 07:49:24

**US3552412**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:53:07**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:49:24
Amendment Manager: User entered 'Day 565'	System	20 Nov 2020 07:49:24

**US3552412**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:53:07**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:49:24
Amendment Manager: User entered '27 Mar 2022 00:01'	System	20 Nov 2020 07:49:24

**US3552412**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:53:07**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:49:24
Amendment Manager: User entered '31 Mar 2022 23:59'	System	20 Nov 2020 07:49:24

**US3552412**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:53:07**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:49:24
Amendment Manager: User entered 'Day 572'	System	20 Nov 2020 07:49:24

**US3552412**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:53:07**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:49:24
Amendment Manager: User entered '03 Apr 2022 00:01'	System	20 Nov 2020 07:49:24

**US3552412**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:53:07**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:49:24
Amendment Manager: User entered '07 Apr 2022 23:59'	System	20 Nov 2020 07:49:24

**US3552412**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:53:07**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:49:24
Amendment Manager: User entered 'Day 579'	System	20 Nov 2020 07:49:24

**US3552412**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:53:07**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:49:24
Amendment Manager: User entered '10 Apr 2022 00:01'	System	20 Nov 2020 07:49:24

**US3552412**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:53:07**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:49:24
Amendment Manager: User entered '14 Apr 2022 23:59'	System	20 Nov 2020 07:49:24

**US3552412**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:53:07**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:49:24
Amendment Manager: User entered 'Day 586'	System	20 Nov 2020 07:49:24

**US3552412**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:53:07**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:49:24
Amendment Manager: User entered '17 Apr 2022 00:01'	System	20 Nov 2020 07:49:24

**US3552412**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:53:07**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:49:24
Amendment Manager: User entered '21 Apr 2022 23:59'	System	20 Nov 2020 07:49:24

**US3552412**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:53:07**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:49:24
Amendment Manager: User entered 'Day 593'	System	20 Nov 2020 07:49:24

**US3552412**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:53:07**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:49:24
Amendment Manager: User entered '24 Apr 2022 00:01'	System	20 Nov 2020 07:49:24

**US3552412**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:53:07**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:49:24
Amendment Manager: User entered '28 Apr 2022 23:59'	System	20 Nov 2020 07:49:24

**US3552412**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:53:07**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:49:24
Amendment Manager: User entered 'Day 600'	System	20 Nov 2020 07:49:24

**US3552412**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:53:07**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:49:24
Amendment Manager: User entered '01 May 2022 00:01'	System	20 Nov 2020 07:49:24

**US3552412**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:53:07**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:49:24
Amendment Manager: User entered '05 May 2022 23:59'	System	20 Nov 2020 07:49:24

**US3552412**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:53:07**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:49:24
Amendment Manager: User entered 'Day 607'	System	20 Nov 2020 07:49:24

**US3552412**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:53:07**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:49:24
Amendment Manager: User entered '08 May 2022 00:01'	System	20 Nov 2020 07:49:24

**US3552412**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:53:07**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:49:24
Amendment Manager: User entered '12 May 2022 23:59'	System	20 Nov 2020 07:49:24

**US3552412**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:53:07**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:49:24
Amendment Manager: User entered 'Day 614'	System	20 Nov 2020 07:49:24

**US3552412**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:53:07**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:49:24
Amendment Manager: User entered '15 May 2022 00:01'	System	20 Nov 2020 07:49:24

**US3552412**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:53:07**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:49:24
Amendment Manager: User entered '19 May 2022 23:59'	System	20 Nov 2020 07:49:24

**US3552412**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:53:07**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:49:24
Amendment Manager: User entered 'Day 621'	System	20 Nov 2020 07:49:24

**US3552412**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:53:07**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:49:24
Amendment Manager: User entered '22 May 2022 00:01'	System	20 Nov 2020 07:49:24

**US3552412**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:53:07**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:49:24
Amendment Manager: User entered '26 May 2022 23:59'	System	20 Nov 2020 07:49:24

**US3552412**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:53:07**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:49:24
Amendment Manager: User entered 'Day 628'	System	20 Nov 2020 07:49:24

**US3552412**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:53:07**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:49:24
Amendment Manager: User entered '29 May 2022 00:01'	System	20 Nov 2020 07:49:24

**US3552412**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:53:07**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:49:24
Amendment Manager: User entered '02 Jun 2022 23:59'	System	20 Nov 2020 07:49:24

**US3552412**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:53:07**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:49:24
Amendment Manager: User entered 'Day 635'	System	20 Nov 2020 07:49:24

**US3552412**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:53:07**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:49:24
Amendment Manager: User entered '05 Jun 2022 00:01'	System	20 Nov 2020 07:49:24

**US3552412**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:53:07**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:49:24
Amendment Manager: User entered '09 Jun 2022 23:59'	System	20 Nov 2020 07:49:24

**US3552412**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:53:07**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:49:24
Amendment Manager: User entered 'Day 642'	System	20 Nov 2020 07:49:24

**US3552412**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:53:07**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:49:24
Amendment Manager: User entered '12 Jun 2022 00:01'	System	20 Nov 2020 07:49:24

**US3552412**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:53:07**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:49:24
Amendment Manager: User entered '16 Jun 2022 23:59'	System	20 Nov 2020 07:49:24

**US3552412**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:53:07**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:49:24
Amendment Manager: User entered 'Day 649'	System	20 Nov 2020 07:49:24

**US3552412**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:53:07**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:49:24
Amendment Manager: User entered '19 Jun 2022 00:01'	System	20 Nov 2020 07:49:24

**US3552412**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:53:07**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:49:24
Amendment Manager: User entered '23 Jun 2022 23:59'	System	20 Nov 2020 07:49:24

**US3552412**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:53:07**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:49:24
Amendment Manager: User entered 'Day 656'	System	20 Nov 2020 07:49:24

**US3552412**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:53:07**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:49:24
Amendment Manager: User entered '26 Jun 2022 00:01'	System	20 Nov 2020 07:49:24

**US3552412**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:53:07**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:49:24
Amendment Manager: User entered '30 Jun 2022 23:59'	System	20 Nov 2020 07:49:24

**US3552412**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:53:07**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:49:24
Amendment Manager: User entered 'Day 663'	System	20 Nov 2020 07:49:24

**US3552412**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:53:07**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:49:24
Amendment Manager: User entered '03 Jul 2022 00:01'	System	20 Nov 2020 07:49:24

**US3552412**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:53:07**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:49:24
Amendment Manager: User entered '07 Jul 2022 23:59'	System	20 Nov 2020 07:49:24

**US3552412**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:53:07**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:49:24
Amendment Manager: User entered 'Day 670'	System	20 Nov 2020 07:49:24

**US3552412**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:53:07**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:49:24
Amendment Manager: User entered '10 Jul 2022 00:01'	System	20 Nov 2020 07:49:24

**US3552412**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:53:07**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:49:24
Amendment Manager: User entered '14 Jul 2022 23:59'	System	20 Nov 2020 07:49:24

**US3552412**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:53:07**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:49:24
Amendment Manager: User entered 'Day 677'	System	20 Nov 2020 07:49:24

**US3552412**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:53:07**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:49:24
Amendment Manager: User entered '17 Jul 2022 00:01'	System	20 Nov 2020 07:49:24

**US3552412**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:53:07**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:49:24
Amendment Manager: User entered '21 Jul 2022 23:59'	System	20 Nov 2020 07:49:24

**US3552412**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:53:07**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:49:24
Amendment Manager: User entered 'Day 684'	System	20 Nov 2020 07:49:24

**US3552412**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:53:07**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:49:24
Amendment Manager: User entered '24 Jul 2022 00:01'	System	20 Nov 2020 07:49:24

**US3552412**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:53:07**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:49:24
Amendment Manager: User entered '28 Jul 2022 23:59'	System	20 Nov 2020 07:49:24

**US3552412**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:53:07**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:49:24
Amendment Manager: User entered 'Day 691'	System	20 Nov 2020 07:49:24

**US3552412**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:53:07**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:49:24
Amendment Manager: User entered '31 Jul 2022 00:01'	System	20 Nov 2020 07:49:24

**US3552412**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:53:07**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:49:24
Amendment Manager: User entered '04 Aug 2022 23:59'	System	20 Nov 2020 07:49:24

**US3552412**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:53:07**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:49:24
Amendment Manager: User entered 'Day 698'	System	20 Nov 2020 07:49:24

**US3552412**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:53:07**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:49:24
Amendment Manager: User entered '07 Aug 2022 00:01'	System	20 Nov 2020 07:49:24

**US3552412**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:53:07**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:49:24
Amendment Manager: User entered '11 Aug 2022 23:59'	System	20 Nov 2020 07:49:24

**US3552412**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:53:07**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:49:24
Amendment Manager: User entered 'Day 705'	System	20 Nov 2020 07:49:24

**US3552412**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:53:07**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:49:24
Amendment Manager: User entered '14 Aug 2022 00:01'	System	20 Nov 2020 07:49:24

**US3552412**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:53:07**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:49:24
Amendment Manager: User entered '18 Aug 2022 23:59'	System	20 Nov 2020 07:49:24

**US3552412**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:53:07**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:49:24
Amendment Manager: User entered 'Day 712'	System	20 Nov 2020 07:49:24

**US3552412**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:53:07**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:49:24
Amendment Manager: User entered '21 Aug 2022 00:01'	System	20 Nov 2020 07:49:24

**US3552412**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:53:07**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:49:24
Amendment Manager: User entered '25 Aug 2022 23:59'	System	20 Nov 2020 07:49:24

**US3552412**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:53:07**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:49:24
Amendment Manager: User entered 'Day 719'	System	20 Nov 2020 07:49:24

**US3552412**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:53:07**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:49:24
Amendment Manager: User entered '28 Aug 2022 00:01'	System	20 Nov 2020 07:49:24

**US3552412**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:53:07**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:49:24
Amendment Manager: User entered '01 Sep 2022 23:59'	System	20 Nov 2020 07:49:24

**US3552412**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:53:07**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:49:24
Amendment Manager: User entered 'Day 726'	System	20 Nov 2020 07:49:24

**US3552412**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:53:07**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:49:24
Amendment Manager: User entered '04 Sep 2022 00:01'	System	20 Nov 2020 07:49:24

**US3552412**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:53:07**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:49:24
Amendment Manager: User entered '08 Sep 2022 23:59'	System	20 Nov 2020 07:49:24

**US3552412**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:53:07**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:49:24
Amendment Manager: User entered 'Day 733'	System	20 Nov 2020 07:49:24

**US3552412**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:53:07**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:49:24
Amendment Manager: User entered '11 Sep 2022 00:01'	System	20 Nov 2020 07:49:24

**US3552412**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:53:07**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:49:24
Amendment Manager: User entered '15 Sep 2022 23:59'	System	20 Nov 2020 07:49:24

**US3552412**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:53:07**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:49:24
Amendment Manager: User entered 'Day 740'	System	20 Nov 2020 07:49:24

**US3552412**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:53:07**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:49:24
Amendment Manager: User entered '18 Sep 2022 00:01'	System	20 Nov 2020 07:49:24

**US3552412**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:53:07**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:49:24
Amendment Manager: User entered '22 Sep 2022 23:59'	System	20 Nov 2020 07:49:24

**US3552412**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:53:07**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:49:24
Amendment Manager: User entered 'Day 747'	System	20 Nov 2020 07:49:24

**US3552412**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:53:07**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:49:24
Amendment Manager: User entered '25 Sep 2022 00:01'	System	20 Nov 2020 07:49:24

**US3552412**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:53:07**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:49:24
Amendment Manager: User entered '29 Sep 2022 23:59'	System	20 Nov 2020 07:49:24

**US3552412**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:53:07**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:49:24
Amendment Manager: User entered 'Day 754'	System	20 Nov 2020 07:49:24

**US3552412**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:53:07**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:49:24
Amendment Manager: User entered '02 Oct 2022 00:01'	System	20 Nov 2020 07:49:24

**US3552412**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:53:07**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:49:24
Amendment Manager: User entered '06 Oct 2022 23:59'	System	20 Nov 2020 07:49:24

**US3552412**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:53:07**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:49:24
Amendment Manager: User entered 'Day 761'	System	20 Nov 2020 07:49:24

**US3552412**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:53:07**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:49:24
Amendment Manager: User entered '09 Oct 2022 00:01'	System	20 Nov 2020 07:49:24

**US3552412**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:53:07**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:49:24
Amendment Manager: User entered '13 Oct 2022 23:59'	System	20 Nov 2020 07:49:24

**US3552412**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:53:07**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:49:24
Amendment Manager: User entered 'Day 768'	System	20 Nov 2020 07:49:24

**US3552412**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:53:07**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:49:24
Amendment Manager: User entered '16 Oct 2022 00:01'	System	20 Nov 2020 07:49:24

**US3552412**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:53:07**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:49:24
Amendment Manager: User entered '20 Oct 2022 23:59'	System	20 Nov 2020 07:49:24

**US3552412**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:53:07**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:49:24
Amendment Manager: User entered 'Day 775'	System	20 Nov 2020 07:49:24

**US3552412**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:53:07**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:49:24
Amendment Manager: User entered '23 Oct 2022 00:01'	System	20 Nov 2020 07:49:24

**US3552412**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:53:07**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:49:24
Amendment Manager: User entered '27 Oct 2022 23:59'	System	20 Nov 2020 07:49:24

**US3552412**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:53:07**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:49:24
Amendment Manager: User entered 'Day 782'	System	20 Nov 2020 07:49:24

**US3552412**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:53:07**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:49:24
Amendment Manager: User entered '30 Oct 2022 00:01'	System	20 Nov 2020 07:49:24

**US3552412**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:53:07**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:49:24
Amendment Manager: User entered '03 Nov 2022 23:59'	System	20 Nov 2020 07:49:24

**US3552412**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:53:07**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:49:24
Amendment Manager: User entered 'Day 789'	System	20 Nov 2020 07:49:24

**US3552412**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:53:07**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:49:24
Amendment Manager: User entered '06 Nov 2022 00:01'	System	20 Nov 2020 07:49:24

**US3552412**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:53:07**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:49:24
Amendment Manager: User entered '10 Nov 2022 23:59'	System	20 Nov 2020 07:49:24

**US3552412**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:53:07**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:49:24
Amendment Manager: User entered 'Day 796'	System	20 Nov 2020 07:49:24

**US3552412**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:53:07**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:49:24
Amendment Manager: User entered '13 Nov 2022 00:01'	System	20 Nov 2020 07:49:24

**US3552412**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:53:07**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:49:24
Amendment Manager: User entered '17 Nov 2022 23:59'	System	20 Nov 2020 07:49:24

US3552412

**Folder: Cosmetic Injections and Dermal Fillers**

**Form: Cosmetic Injection\_ Dermal Filler eDiary (1)**

**Generated On: 11 Aug 2021 22:53:07**

Have you ever received facial cosmetic injections, such as Juvederm, Voluma, Radiesse, Restylane, Botox or other?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 11:36:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7f466cdad72abdb)', Time: '2021-03-01T06:19:13-06:00', User OID: 'PatientReportedOutcome (US3552412)', ODM File OID: 'b5b57927-297e-445c-a2cb-e70c13b83257'	System	01 Mar 2021 12:19:20
User entered 'No (N)'	System	01 Mar 2021 12:19:20

US3552412

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection\_ Dermal Filler eDiary (1)

Generated On: 11 Aug 2021 22:53:07

[Date & Time of Submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 11:36:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7f466cdad72abdb)', Time: '2021-03-01T06:19:16-06:00', User OID: 'PatientReportedOutcome (US3552412)', ODM File OID: 'b5b57927-297e-445c-a2cb-e70c13b83257'	System	01 Mar 2021 12:19:20
User entered '01 Mar 2021 06:19:16'	System	01 Mar 2021 12:19:20

US3552412

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:53:07

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 11:14:37
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 19:11:21
User entered 'No (N)'	Mikayla Frye (b) (4) (b) (4)	07 Jan 2021 21:34:04

US3552412

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:53:07

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 11:14:37
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:11:21
User entered empty.	(b) (4) Mikayla Frye (b) (4) (b) (4)	07 Jan 2021 21:34:04

US3552412

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:53:07

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 11:14:37
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 19:11:21
User entered empty.	Mikayla Frye (b) (4) (b) (4)	07 Jan 2021 21:34:04

US3552412

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:53:07

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 11:14:37
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 19:11:21
User entered empty.	Mikayla Frye (b) (4) (b) (4)	07 Jan 2021 21:34:04

US3552412

Folder: Safety Call Day 85 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:53:07

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 11:14:37
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:11:21
User entered 'Yes (Y)'	(b) (4) Mikayla Frye (b) (4) (b) (4)	07 Jan 2021 21:34:07

US3552412

Folder: Safety Call Day 85 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:53:07

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 11:14:37
User entered 'l'	System	07 Jan 2021 21:34:07

**US3552412**

**Folder: Safety Call Day 119 (1)**

**Form: Safety Call**

**Generated On: 11 Aug 2021 22:53:07**

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 12:01:44
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:11:21
User entered 'Yes (Y)'	(b) (4) Mikayla Frye (b) (4) (b) (4)	07 Jan 2021 21:34:17

US3552412

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:53:07

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 12:01:44
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:11:21
User entered '07 Jan 2021'	(b) (4) Mikayla Frye (b) (4) (b) (4)	07 Jan 2021 21:34:17

US3552412

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:53:07

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 12:01:44
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:11:21
User entered 'Contact Made (CONTACT MADE)'	(b) (4) Mikayla Frye (b) (4) (b) (4)	07 Jan 2021 21:34:17

US3552412

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:53:07

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 12:01:44
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:11:21
User entered empty.	(b) (4) Mikayla Frye (b) (4) (b) (4)	07 Jan 2021 21:34:17

US3552412

Folder: Safety Call Day 119 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:53:07

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 12:01:44
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:11:21
User entered 'Yes (Y)'	(b) (4) Stanley Dublin (b) (4) (b) (4)	05 Feb 2021 15:35:33

US3552412

Folder: Safety Call Day 119 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:53:07

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 12:01:44
User entered 'l'	System	05 Feb 2021 15:35:33

US3552412

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:53:07

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 12:01:44
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:11:21
User entered 'Yes (Y)'	(b) (4) Stanley Dublin (b) (4) (b) (4)	05 Feb 2021 15:35:49

US3552412

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:53:07

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 12:01:44
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:11:21
User entered '05 Feb 2021'	(b) (4) Stanley Dublin (b) (4) (b) (4)	05 Feb 2021 15:35:49

US3552412

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:53:07

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 12:01:44
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:11:21
User entered 'Contact Made (CONTACT MADE)'	(b) (4) Stanley Dublin (b) (4) (b) (4)	05 Feb 2021 15:35:49

US3552412

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:53:07

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 12:01:44
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:11:21
User entered empty.	(b) (4) Stanley Dublin (b) (4) (b) (4)	05 Feb 2021 15:35:49

US3552412

Folder: Safety Call Day 149 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:53:07

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 12:01:44
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 19:11:21
User entered 'Yes (Y)'	Cassandra Zehenny (b) (4) (b) (4)	11 Feb 2021 22:04:29

US3552412

Folder: Safety Call Day 149 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:53:07

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 12:01:44
User entered 'l'	System	11 Feb 2021 22:04:29

US3552412

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:53:07

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 12:01:44
User signature succeeded.	sharon frey (b) (4)	09 Mar 2021 17:03:11
User entered 'Yes (Y)'	(b) (4) Stanley Dublin (b) (4) (b) (4)	08 Mar 2021 15:24:39

US3552412

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:53:07

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 12:01:44
User signature succeeded.	sharon frey (b) (4)	09 Mar 2021 17:03:11
User entered '8 Mar 2021'	(b) (4) Stanley Dublin (b) (4) (b) (4)	08 Mar 2021 15:24:39

US3552412

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:53:07

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 12:01:44
User signature succeeded.	sharon frey (b) (4)	09 Mar 2021 17:03:11
User entered 'Contact Made (CONTACT MADE)'	(b) (4) Stanley Dublin (b) (4) (b) (4)	08 Mar 2021 15:24:39

US3552412

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:53:07

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 12:01:44
User signature succeeded.	sharon frey (b) (4)	09 Mar 2021 17:03:11
User entered empty.	(b) (4) Stanley Dublin (b) (4) (b) (4)	08 Mar 2021 15:24:39

US3552412

Folder: Safety Call Day 179 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:53:07

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 12:01:44
User signature succeeded.	sharon frey (b) (4)	09 Mar 2021 17:03:11
User entered 'Yes (Y)'	(b) (4) Stanley Dublin (b) (4) (b) (4)	08 Mar 2021 15:24:44

US3552412

Folder: Safety Call Day 179 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:53:07

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 12:01:44
User entered 'l'	System	08 Mar 2021 15:24:44

US3552412

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:53:07

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 12:01:44
User signature succeeded.	sharon frey (b) (4)	06 Apr 2021 15:14:13
User entered 'Yes (Y)'	(b) (4) Stanley Dublin (b) (4) (b) (4)	31 Mar 2021 12:10:58

US3552412

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:53:07

[Visit date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 12:01:44
User signature succeeded.	sharon frey (b) (4)	06 Apr 2021 15:14:13
User entered '30 Mar 2021'	(b) (4) Stanley Dublin (b) (4) (b) (4)	31 Mar 2021 12:10:58

US3552412

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:53:07

[Was visit performed at the participant's home or at the clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 12:01:44
User signature succeeded.	sharon frey (b) (4)	06 Apr 2021 15:14:13
User entered 'Clinic (Clinic)'	(b) (4) Stanley Doublin (b) (4) (b) (4)	31 Mar 2021 12:10:58

US3552412

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:53:07

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 12:01:44
User entered 'VISIT4'	System	31 Mar 2021 12:10:58

US3552412

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:53:07

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 12:01:44
User signature succeeded.	sharon frey (b) (4)	06 Apr 2021 15:14:13
User entered 'No (N)'	(b) (4) Stanley Dublin (b) (4) (b) (4)	31 Mar 2021 12:13:10

US3552412

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:53:07

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 12:01:44
User signature succeeded.	sharon frey (b) (4)	06 Apr 2021 15:14:13
User entered empty.	(b) (4) Stanley Dublin (b) (4) (b) (4)	31 Mar 2021 12:13:10

US3552412

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:53:07

Time of assessment (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 12:01:44
User signature succeeded.	sharon frey (b) (4)	06 Apr 2021 15:14:13
User entered empty.	(b) (4) Stanley Dublin (b) (4) (b) (4)	31 Mar 2021 12:13:10

US3552412

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:53:07

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 12:01:44
User entered empty.	System	31 Mar 2021 12:13:10

US3552412

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:53:07

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 12:01:44
User signature succeeded.	sharon frey (b) (4)	06 Apr 2021 15:14:13
User entered empty.	(b) (4) Stanley Dublin (b) (4) (b) (4)	31 Mar 2021 12:13:10

US3552412

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:53:07

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 12:01:44
User signature succeeded.	sharon frey (b) (4)	06 Apr 2021 15:14:13
User entered empty.	(b) (4) Stanley Dublin (b) (4) (b) (4)	31 Mar 2021 12:13:10

US3552412

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:53:07

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 12:01:44
User signature succeeded.	sharon frey (b) (4)	06 Apr 2021 15:14:13
User entered empty.	(b) (4) Stanley Dublin (b) (4) (b) (4)	31 Mar 2021 12:13:10

US3552412

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:53:07

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 12:01:44
User signature succeeded.	sharon frey (b) (4)	06 Apr 2021 15:14:13
User entered empty.	(b) (4) Stanley Dublin (b) (4) (b) (4)	31 Mar 2021 12:13:10

US3552412

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:53:07

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 12:01:44
User entered empty.	System	31 Mar 2021 12:13:10

US3552412

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:53:07

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 12:01:44
User signature succeeded.	sharon frey (b) (4)	06 Apr 2021 15:14:13
User entered empty.	(b) (4) Stanley Doublin (b) (4) (b) (4)	31 Mar 2021 12:13:10

US3552412

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:53:07

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 12:01:44
User entered empty.	System	31 Mar 2021 12:13:10

US3552412

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:53:07

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 12:01:44
User signature succeeded.	sharon frey (b) (4)	06 Apr 2021 15:14:13
User entered empty.	(b) (4) Stanley Dublin (b) (4) (b) (4)	31 Mar 2021 12:13:10

US3552412

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:53:07

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 12:01:44
User entered empty.	System	31 Mar 2021 12:13:10

US3552412

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:53:07

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 12:01:44
User signature succeeded.	sharon frey (b) (4)	06 Apr 2021 15:14:13
User entered empty.	(b) (4) Stanley Dublin (b) (4) (b) (4)	31 Mar 2021 12:13:10

US3552412

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:53:07

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 12:01:44
User entered empty.	System	31 Mar 2021 12:13:10

US3552412

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:53:07

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 12:01:44

US3552412

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:53:07

Weight (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 12:01:44

US3552412

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Generated On: 11 Aug 2021 22:53:07

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 12:01:44
User signature succeeded.	sharon frey (b) (4)	06 Apr 2021 15:14:13
User entered 'No (N)'	(b) (4) Stanley Dublin (b) (4) (b) (4)	31 Mar 2021 12:13:13

US3552412

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Generated On: 11 Aug 2021 22:53:07

Date of examination (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 12:01:44
User signature succeeded.	sharon frey (b) (4)	06 Apr 2021 15:14:13
User entered empty.	(b) (4) Stanley Dublin (b) (4) (b) (4)	31 Mar 2021 12:13:13

US3552412

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:53:07

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 12:01:44
User signature succeeded.	sharon frey (b) (4)	06 Apr 2021 15:14:13
User entered 'Yes (Y)'	(b) (4) Stanley Dublin (b) (4) (b) (4)	31 Mar 2021 12:13:23

US3552412

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:53:07

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 12:01:44
User signature succeeded.	sharon frey (b) (4)	06 Apr 2021 15:14:13
User entered '30 Mar 2021'	(b) (4) Stanley Dublin (b) (4) (b) (4)	31 Mar 2021 12:13:23

US3552412

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:53:07

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 12:01:44
User signature succeeded.	sharon frey (b) (4)	06 Apr 2021 15:14:13
User entered '15:45'	(b) (4) Stanley Dublin (b) (4) (b) (4)	31 Mar 2021 12:13:23

US3552412

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:53:07

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 12:01:44
User entered '30 Mar 2021 15:45'	System	31 Mar 2021 12:13:23

US3552412

Folder: Visit 4 Day 209 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:53:07

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 12:01:44
User signature succeeded.	sharon frey (b) (4)	06 Apr 2021 15:14:13
User entered 'Yes (Y)'	(b) (4) Stanley Dublin (b) (4) (b) (4)	31 Mar 2021 12:13:25

US3552412

Folder: Visit 4 Day 209 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:53:07

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 12:01:44
User entered 'I'	System	31 Mar 2021 12:13:25

US3552412

Folder: Covid-19 Assessment 15 Jan 2021

Form: COVID-19 Contact

Generated On: 11 Aug 2021 22:53:07

[Date of Contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:28:58
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 19:11:21
DataPoint Verified.	(b) (4), (b) (6)	01 Feb 2021 20:21:31
User entered '15 Jan 2021'	Heather Douds (b) (4) (b) (4)	15 Jan 2021 18:09:26

US3552412

Folder: Covid-19 Assessment 15 Jan 2021

Form: COVID-19 Contact

Generated On: 11 Aug 2021 22:53:07

[Time of Contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:28:58
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 19:11:21
DataPoint Verified.	(b) (4), (b) (6)	01 Feb 2021 20:21:31
User entered '07:10'	Heather Douds (b) (4) (b) (4)	15 Jan 2021 18:09:26

US3552412

Folder: Covid-19 Assessment 15 Jan 2021

Form: COVID-19 Contact

Generated On: 11 Aug 2021 22:53:07

[Date and Time of Contact \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:28:58
User entered '15 Jan 2021 07:10'	System	15 Jan 2021 18:09:26

US3552412

Folder: Covid-19 Assessment 15 Jan 2021

Form: COVID-19 Contact

Generated On: 11 Aug 2021 22:53:07

[Type of Contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:28:58
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 19:11:21
DataPoint Verified.	(b) (4), (b) (6)	01 Feb 2021 20:21:31
User entered 'Safety Call (Safety Call)'	Heather Douds (b) (4) (b) (4)	15 Jan 2021 18:09:26

US3552412

Folder: Covid-19 Assessment 15 Jan 2021

Form: COVID-19 Contact

Generated On: 11 Aug 2021 22:53:07

[Has the subject reported symptoms of SARS-COV-2?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:28:58
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:11:21
DataPoint Verified.	(b) (4)	01 Feb 2021 20:21:31
User entered 'Yes (Y)'	Heather Douds (b) (4)	15 Jan 2021 18:09:26
	(b) (4)	

US3552412

Folder: Covid-19 Assessment 15 Jan 2021

Form: Symptom Log (1)

Generated On: 11 Aug 2021 22:53:07

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:28:58
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 19:11:21
User entered 'Day 1 (Day 1)'	Heather Douds (b) (4) (b) (4)	15 Jan 2021 18:10:13

US3552412

Folder: Covid-19 Assessment 15 Jan 2021

Form: Symptom Log (1)

Generated On: 11 Aug 2021 22:53:07

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:28:58
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 19:11:21
User entered '12 Jan 2021'	Heather Douds (b) (4) (b) (4)	15 Jan 2021 18:10:13

US3552412

Folder: Covid-19 Assessment 15 Jan 2021

Form: Symptom Log (1)

Generated On: 11 Aug 2021 22:53:07

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:28:58
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:11:21
User entered '0'	(b) (4) Heather Douds (b) (4) (b) (4)	15 Jan 2021 18:10:13

US3552412

Folder: Covid-19 Assessment 15 Jan 2021

Form: Symptom Log (1)

Generated On: 11 Aug 2021 22:53:07

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:28:58
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 19:11:21
User entered missing code ND - Not Done.	Heather Douds (b) (4) (b) (4)	15 Jan 2021 18:10:13

US3552412

Folder: Covid-19 Assessment 15 Jan 2021

Form: Symptom Log (1)

Generated On: 11 Aug 2021 22:53:07

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:28:58
User entered '%'	System	15 Jan 2021 18:10:13

US3552412

Folder: Covid-19 Assessment 15 Jan 2021

Form: Symptom Log (1)

Generated On: 11 Aug 2021 22:53:07

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:28:58
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 19:11:21
User entered missing code ND - Not Done.	Heather Douds (b) (4) (b) (4)	15 Jan 2021 18:10:13

US3552412

Folder: Covid-19 Assessment 15 Jan 2021

Form: Symptom Log (1)

Generated On: 11 Aug 2021 22:53:07

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:28:58
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:11:21
User entered 'None (None)'	(b) (4) Heather Douds (b) (4)	15 Jan 2021 18:10:13

US3552412

Folder: Covid-19 Assessment 15 Jan 2021

Form: Symptom Log (1)

Generated On: 11 Aug 2021 22:53:07

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:28:58
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 19:11:21
User entered 'None (None)'	Heather Douds (b) (4) (b) (4)	15 Jan 2021 18:10:13

US3552412

Folder: Covid-19 Assessment 15 Jan 2021

Form: Symptom Log (1)

Generated On: 11 Aug 2021 22:53:07

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:28:58
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 19:11:21
User entered 'None (None)'	Heather Douds (b) (4) (b) (4)	15 Jan 2021 18:10:13

US3552412

Folder: Covid-19 Assessment 15 Jan 2021

Form: Symptom Log (1)

Generated On: 11 Aug 2021 22:53:07

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:28:58
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 19:11:21
User entered 'None (None)' reason for change: Data Entry Error	Heather Douds (b) (4) (b) (4)	15 Jan 2021 18:11:03
User entered 'Not Done (Not Done)'	Heather Douds (b) (4) (b) (4)	15 Jan 2021 18:10:13

US3552412

Folder: Covid-19 Assessment 15 Jan 2021

Form: Symptom Log (1)

Generated On: 11 Aug 2021 22:53:07

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:28:58
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 19:11:21
User entered 'None (None)'	Heather Douds (b) (4) (b) (4)	15 Jan 2021 18:10:13

US3552412

Folder: Covid-19 Assessment 15 Jan 2021

Form: Symptom Log (1)

Generated On: 11 Aug 2021 22:53:07

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:28:58
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 19:11:21
User entered 'None (None)'	Heather Douds (b) (4) (b) (4)	15 Jan 2021 18:10:13

US3552412

Folder: Covid-19 Assessment 15 Jan 2021

Form: Symptom Log (1)

Generated On: 11 Aug 2021 22:53:07

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:28:58
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 19:11:21
User entered 'None (None)'	Heather Douds (b) (4) (b) (4)	15 Jan 2021 18:10:13

US3552412

Folder: Covid-19 Assessment 15 Jan 2021

Form: Symptom Log (1)

Generated On: 11 Aug 2021 22:53:07

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:28:58
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 19:11:21
User entered 'None (None)'	Heather Douds (b) (4) (b) (4)	15 Jan 2021 18:10:13

US3552412

Folder: Covid-19 Assessment 15 Jan 2021

Form: Symptom Log (1)

Generated On: 11 Aug 2021 22:53:07

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:28:58
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 19:11:21
User entered 'None (None)' reason for change: Data Entry Error	Heather Douds (b) (4) (b) (4)	15 Jan 2021 18:10:55
User entered empty.	Heather Douds (b) (4) (b) (4)	15 Jan 2021 18:10:13

US3552412

Folder: Covid-19 Assessment 15 Jan 2021

Form: Symptom Log (1)

Generated On: 11 Aug 2021 22:53:07

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:28:58
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 19:11:21
User entered 'None (None)'	Heather Douds (b) (4) (b) (4)	15 Jan 2021 18:10:13

US3552412

Folder: Covid-19 Assessment 15 Jan 2021

Form: Symptom Log (1)

Generated On: 11 Aug 2021 22:53:07

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:28:58
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 19:11:21
User entered 'None (None)'	Heather Douds (b) (4) (b) (4)	15 Jan 2021 18:10:13

US3552412

Folder: Covid-19 Assessment 15 Jan 2021

Form: Symptom Log (1)

Generated On: 11 Aug 2021 22:53:07

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:28:58
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 19:11:21
User entered 'None (None)'	Heather Douds (b) (4) (b) (4)	15 Jan 2021 18:10:13

US3552412

Folder: Covid-19 Assessment 15 Jan 2021

Form: Symptom Log (1)

Generated On: 11 Aug 2021 22:53:07

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:28:58
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 19:11:21
User entered 'None (None)'	Heather Douds (b) (4) (b) (4)	15 Jan 2021 18:10:13

US3552412

Folder: Covid-19 Assessment 15 Jan 2021

Form: Symptom Log (1)

Generated On: 11 Aug 2021 22:53:07

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:28:58
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 19:11:21
User entered 'None (None)'	Heather Douds (b) (4) (b) (4)	15 Jan 2021 18:10:13

US3552412

Folder: Covid-19 Assessment 15 Jan 2021

Form: Symptom Log (1)

Generated On: 11 Aug 2021 22:53:07

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:28:58
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 19:11:21
User entered 'None (None)'	Heather Douds (b) (4) (b) (4)	15 Jan 2021 18:10:13

US3552412

Folder: Covid-19 Assessment 15 Jan 2021

Form: Symptom Log (1)

Generated On: 11 Aug 2021 22:53:07

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:28:58
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:11:21
User entered 'Mild (Mild)'	(b) (4) Heather Douds (b) (4)	15 Jan 2021 18:10:13

US3552412

Folder: Covid-19 Assessment 15 Jan 2021

Form: Symptom Log (2)

Generated On: 11 Aug 2021 22:53:07

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:28:58
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 19:11:21
User entered 'Day 2 (Day 2)'	Heather Douds (b) (4) (b) (4)	15 Jan 2021 18:10:55

US3552412

Folder: Covid-19 Assessment 15 Jan 2021

Form: Symptom Log (2)

Generated On: 11 Aug 2021 22:53:07

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:28:58
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 19:11:21
User entered '13 Jan 2021'	Heather Douds (b) (4) (b) (4)	15 Jan 2021 18:10:55

US3552412

Folder: Covid-19 Assessment 15 Jan 2021

Form: Symptom Log (2)

Generated On: 11 Aug 2021 22:53:07

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:28:58
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:11:21
User entered '0'	(b) (4) Heather Douds (b) (4) (b) (4)	15 Jan 2021 18:10:55

US3552412

Folder: Covid-19 Assessment 15 Jan 2021

Form: Symptom Log (2)

Generated On: 11 Aug 2021 22:53:07

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:28:58
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 19:11:21
User entered missing code ND - Not Done.	Heather Douds (b) (4) (b) (4)	15 Jan 2021 18:10:55

US3552412

Folder: Covid-19 Assessment 15 Jan 2021

Form: Symptom Log (2)

Generated On: 11 Aug 2021 22:53:07

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:28:58
User entered '%'	System	15 Jan 2021 18:10:55

US3552412

Folder: Covid-19 Assessment 15 Jan 2021

Form: Symptom Log (2)

Generated On: 11 Aug 2021 22:53:07

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:28:58
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:11:21
User entered missing code ND - Not Done.	(b) (4) Heather Douds (b) (4)	15 Jan 2021 18:10:55

US3552412

Folder: Covid-19 Assessment 15 Jan 2021

Form: Symptom Log (2)

Generated On: 11 Aug 2021 22:53:07

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:28:58
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 19:11:21
User entered 'None (None)'	Heather Douds (b) (4) (b) (4)	15 Jan 2021 18:10:55

US3552412

Folder: Covid-19 Assessment 15 Jan 2021

Form: Symptom Log (2)

Generated On: 11 Aug 2021 22:53:07

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:28:58
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 19:11:21
User entered 'None (None)'	Heather Douds (b) (4) (b) (4)	15 Jan 2021 18:10:55

US3552412

Folder: Covid-19 Assessment 15 Jan 2021

Form: Symptom Log (2)

Generated On: 11 Aug 2021 22:53:07

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:28:58
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 19:11:21
User entered 'None (None)'	Heather Douds (b) (4) (b) (4)	15 Jan 2021 18:10:55

US3552412

Folder: Covid-19 Assessment 15 Jan 2021

Form: Symptom Log (2)

Generated On: 11 Aug 2021 22:53:07

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:28:58
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 19:11:21
User entered 'None (None)'	Heather Douds (b) (4) (b) (4)	15 Jan 2021 18:10:55

US3552412

Folder: Covid-19 Assessment 15 Jan 2021

Form: Symptom Log (2)

Generated On: 11 Aug 2021 22:53:07

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:28:58
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 19:11:21
User entered 'None (None)'	Heather Douds (b) (4) (b) (4)	15 Jan 2021 18:10:55

US3552412

Folder: Covid-19 Assessment 15 Jan 2021

Form: Symptom Log (2)

Generated On: 11 Aug 2021 22:53:07

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:28:58
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 19:11:21
User entered 'None (None)'	Heather Douds (b) (4) (b) (4)	15 Jan 2021 18:10:55

US3552412

Folder: Covid-19 Assessment 15 Jan 2021

Form: Symptom Log (2)

Generated On: 11 Aug 2021 22:53:07

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:28:58
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 19:11:21
User entered 'None (None)'	Heather Douds (b) (4) (b) (4)	15 Jan 2021 18:10:55

US3552412

Folder: Covid-19 Assessment 15 Jan 2021

Form: Symptom Log (2)

Generated On: 11 Aug 2021 22:53:07

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:28:58
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 19:11:21
User entered 'None (None)'	Heather Douds (b) (4) (b) (4)	15 Jan 2021 18:10:55

US3552412

Folder: Covid-19 Assessment 15 Jan 2021

Form: Symptom Log (2)

Generated On: 11 Aug 2021 22:53:07

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:28:58
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 19:11:21
User entered 'None (None)'	Heather Douds (b) (4) (b) (4)	15 Jan 2021 18:10:55

US3552412

Folder: Covid-19 Assessment 15 Jan 2021

Form: Symptom Log (2)

Generated On: 11 Aug 2021 22:53:07

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:28:58
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 19:11:21
User entered 'None (None)'	Heather Douds (b) (4) (b) (4)	15 Jan 2021 18:10:55

US3552412

Folder: Covid-19 Assessment 15 Jan 2021

Form: Symptom Log (2)

Generated On: 11 Aug 2021 22:53:07

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:28:58
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 19:11:21
User entered 'None (None)'	Heather Douds (b) (4) (b) (4)	15 Jan 2021 18:10:55

US3552412

Folder: Covid-19 Assessment 15 Jan 2021

Form: Symptom Log (2)

Generated On: 11 Aug 2021 22:53:07

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:28:58
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 19:11:21
User entered 'None (None)'	Heather Douds (b) (4) (b) (4)	15 Jan 2021 18:10:55

US3552412

Folder: Covid-19 Assessment 15 Jan 2021

Form: Symptom Log (2)

Generated On: 11 Aug 2021 22:53:07

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:28:58
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 19:11:21
User entered 'None (None)'	Heather Douds (b) (4) (b) (4)	15 Jan 2021 18:10:55

US3552412

Folder: Covid-19 Assessment 15 Jan 2021

Form: Symptom Log (2)

Generated On: 11 Aug 2021 22:53:07

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:28:58
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 19:11:21
User entered 'None (None)'	Heather Douds (b) (4) (b) (4)	15 Jan 2021 18:10:55

US3552412

Folder: Covid-19 Assessment 15 Jan 2021

Form: Symptom Log (2)

Generated On: 11 Aug 2021 22:53:07

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:28:58
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 19:11:21
User entered 'None (None)'	Heather Douds (b) (4) (b) (4)	15 Jan 2021 18:10:55

US3552412

Folder: Covid-19 Assessment 15 Jan 2021

Form: Symptom Log (2)

Generated On: 11 Aug 2021 22:53:07

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:28:58
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 19:11:21
User entered 'Mild (Mild)'	Heather Douds (b) (4) (b) (4)	15 Jan 2021 18:10:55

US3552412

Folder: Covid-19 Assessment 15 Jan 2021

Form: Symptom Log (3)

Generated On: 11 Aug 2021 22:53:07

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:28:58
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 19:11:21
User entered 'Day 3 (Day 3)'	Heather Douds (b) (4) (b) (4)	15 Jan 2021 18:13:16

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Folder: Covid-19 Assessment 15 Jan 2021

Form: Symptom Log (3)

Generated On: 11 Aug 2021 22:53:07

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:28:58
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 19:11:21
User entered '14 Jan 2021'	Heather Douds (b) (4) (b) (4)	15 Jan 2021 18:13:16

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Folder: Covid-19 Assessment 15 Jan 2021

Form: Symptom Log (3)

Generated On: 11 Aug 2021 22:53:07

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:28:58
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:11:21
User entered '0'	(b) (4) Heather Douds (b) (4) (b) (4)	15 Jan 2021 18:13:16

US3552412

Folder: Covid-19 Assessment 15 Jan 2021

Form: Symptom Log (3)

Generated On: 11 Aug 2021 22:53:07

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:28:58
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 19:11:21
User entered missing code ND - Not Done.	Heather Douds (b) (4) (b) (4)	15 Jan 2021 18:13:16

US3552412

Folder: Covid-19 Assessment 15 Jan 2021

Form: Symptom Log (3)

Generated On: 11 Aug 2021 22:53:07

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:28:58
User entered '%'	System	15 Jan 2021 18:13:16

US3552412

Folder: Covid-19 Assessment 15 Jan 2021

Form: Symptom Log (3)

Generated On: 11 Aug 2021 22:53:07

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:28:58
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 19:11:21
User entered missing code ND - Not Done.	Heather Douds (b) (4) (b) (4)	15 Jan 2021 18:13:16

US3552412

Folder: Covid-19 Assessment 15 Jan 2021

Form: Symptom Log (3)

Generated On: 11 Aug 2021 22:53:07

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:28:58
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 19:11:21
User entered 'None (None)'	Heather Douds (b) (4) (b) (4)	15 Jan 2021 18:13:16

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Folder: Covid-19 Assessment 15 Jan 2021

Form: Symptom Log (3)

Generated On: 11 Aug 2021 22:53:07

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:28:58
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 19:11:21
User entered 'None (None)'	Heather Douds (b) (4) (b) (4)	15 Jan 2021 18:13:16

US3552412

Folder: Covid-19 Assessment 15 Jan 2021

Form: Symptom Log (3)

Generated On: 11 Aug 2021 22:53:07

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:28:58
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 19:11:21
User entered 'None (None)'	Heather Douds (b) (4) (b) (4)	15 Jan 2021 18:13:16

US3552412

Folder: Covid-19 Assessment 15 Jan 2021

Form: Symptom Log (3)

Generated On: 11 Aug 2021 22:53:07

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:28:58
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 19:11:21
User entered 'None (None)'	Heather Douds (b) (4) (b) (4)	15 Jan 2021 18:13:16

US3552412

Folder: Covid-19 Assessment 15 Jan 2021

Form: Symptom Log (3)

Generated On: 11 Aug 2021 22:53:07

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:28:58
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 19:11:21
User entered 'Mild (Mild)' reason for change: Data Entry Error	Heather Douds (b) (4) (b) (4)	15 Jan 2021 18:14:30
User entered 'None (None)'	Heather Douds (b) (4) (b) (4)	15 Jan 2021 18:13:16

US3552412

Folder: Covid-19 Assessment 15 Jan 2021

Form: Symptom Log (3)

Generated On: 11 Aug 2021 22:53:07

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:28:58
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 19:11:21
User entered 'None (None)'	Heather Douds (b) (4) (b) (4)	15 Jan 2021 18:13:16

US3552412

Folder: Covid-19 Assessment 15 Jan 2021

Form: Symptom Log (3)

Generated On: 11 Aug 2021 22:53:07

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:28:58
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 19:11:21
User entered 'None (None)'	Heather Douds (b) (4) (b) (4)	15 Jan 2021 18:13:16

US3552412

Folder: Covid-19 Assessment 15 Jan 2021

Form: Symptom Log (3)

Generated On: 11 Aug 2021 22:53:07

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:28:58
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 19:11:21
User entered 'Mild (Mild)'	Heather Douds (b) (4) (b) (4)	15 Jan 2021 18:13:16

US3552412

Folder: Covid-19 Assessment 15 Jan 2021

Form: Symptom Log (3)

Generated On: 11 Aug 2021 22:53:07

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:28:58
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 19:11:21
User entered 'None (None)'	Heather Douds (b) (4) (b) (4)	15 Jan 2021 18:13:16

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Folder: Covid-19 Assessment 15 Jan 2021

Form: Symptom Log (3)

Generated On: 11 Aug 2021 22:53:07

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:28:58
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 19:11:21
User entered 'None (None)'	Heather Douds (b) (4) (b) (4)	15 Jan 2021 18:13:16

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Folder: Covid-19 Assessment 15 Jan 2021

Form: Symptom Log (3)

Generated On: 11 Aug 2021 22:53:07

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:28:58
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 19:11:21
User entered 'Mild (Mild)' reason for change: Data Entry Error	Heather Douds (b) (4) (b) (4)	15 Jan 2021 18:14:30
User entered 'None (None)'	Heather Douds (b) (4) (b) (4)	15 Jan 2021 18:13:16

US3552412

Folder: Covid-19 Assessment 15 Jan 2021

Form: Symptom Log (3)

Generated On: 11 Aug 2021 22:53:07

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:28:58
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 19:11:21
User entered 'None (None)'	Heather Douds (b) (4) (b) (4)	15 Jan 2021 18:13:16

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Folder: Covid-19 Assessment 15 Jan 2021

Form: Symptom Log (3)

Generated On: 11 Aug 2021 22:53:07

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:28:58
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 19:11:21
User entered 'None (None)'	Heather Douds (b) (4) (b) (4)	15 Jan 2021 18:13:16

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Folder: Covid-19 Assessment 15 Jan 2021

Form: Symptom Log (3)

Generated On: 11 Aug 2021 22:53:07

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:28:58
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 19:11:21
User entered 'None (None)'	Heather Douds (b) (4) (b) (4)	15 Jan 2021 18:13:16

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Folder: Covid-19 Assessment 15 Jan 2021

Form: Symptom Log (3)

Generated On: 11 Aug 2021 22:53:07

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:28:58
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 19:11:21
User entered 'None (None)'	Heather Douds (b) (4) (b) (4)	15 Jan 2021 18:13:16

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Folder: Covid-19 Assessment 15 Jan 2021

Form: Symptom Log (3)

Generated On: 11 Aug 2021 22:53:07

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:28:58
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 19:11:21
User entered 'Mild (Mild)'	Heather Douds (b) (4) (b) (4)	15 Jan 2021 18:13:16

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Folder: Covid-19 Assessment 15 Jan 2021

Form: Symptom Log (4)

Generated On: 11 Aug 2021 22:53:07

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:28:58
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:11:21
User entered 'Day 4 (Day 4)'	(b) (4) Heather Douds (b) (4) (b) (4)	15 Jan 2021 18:14:30

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Folder: Covid-19 Assessment 15 Jan 2021

Form: Symptom Log (4)

Generated On: 11 Aug 2021 22:53:07

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:28:58
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 19:11:21
DataPoint Verified.	(b) (4), (b) (6)	01 Feb 2021 20:22:04
User entered '15 Jan 2021'	Heather Douds (b) (4) (b) (4)	15 Jan 2021 18:14:30

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Folder: Covid-19 Assessment 15 Jan 2021

Form: Symptom Log (4)

Generated On: 11 Aug 2021 22:53:07

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:28:58
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 19:11:21
DataPoint Verified.	(b) (4), (b) (6)	01 Feb 2021 20:22:04
User entered '0'	Heather Douds (b) (4) (b) (4)	15 Jan 2021 18:14:30

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Folder: Covid-19 Assessment 15 Jan 2021

Form: Symptom Log (4)

Generated On: 11 Aug 2021 22:53:07

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:28:58
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 19:11:21
DataPoint Verified.	(b) (4), (b) (6)	01 Feb 2021 20:22:04
User entered '95'	Heather Doubs (b) (4) (b) (4)	15 Jan 2021 18:14:30

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Folder: Covid-19 Assessment 15 Jan 2021

Form: Symptom Log (4)

Generated On: 11 Aug 2021 22:53:07

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:28:58
User entered '%'	System	15 Jan 2021 18:14:30

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Folder: Covid-19 Assessment 15 Jan 2021

Form: Symptom Log (4)

Generated On: 11 Aug 2021 22:53:07

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:28:58
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:11:21
DataPoint Verified.	(b) (4)	01 Feb 2021 20:22:04
User entered '96.5' F	(b) (4), (b) (6)	01 Feb 2021 20:22:04
	Heather Doubs (b) (4)	15 Jan 2021 18:14:30
	(b) (4)	

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Folder: Covid-19 Assessment 15 Jan 2021

Form: Symptom Log (4)

Generated On: 11 Aug 2021 22:53:07

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:28:58
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:11:21
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	01 Feb 2021 20:22:04
User entered 'None (None)'	Heather Douds (b) (4)	15 Jan 2021 18:14:30
	(b) (4)	

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Folder: Covid-19 Assessment 15 Jan 2021

Form: Symptom Log (4)

Generated On: 11 Aug 2021 22:53:07

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:28:58
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:11:21
DataPoint Verified.	(b) (4)	01 Feb 2021 20:22:04
User entered 'None (None)'	Heather Doubs (b) (4)	15 Jan 2021 18:14:30
	(b) (4)	

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Folder: Covid-19 Assessment 15 Jan 2021

Form: Symptom Log (4)

Generated On: 11 Aug 2021 22:53:07

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:28:58
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:11:21
DataPoint Verified.	(b) (4)	01 Feb 2021 20:22:04
User entered 'None (None)'	Heather Doubs (b) (4)	15 Jan 2021 18:14:30
	(b) (4)	

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Folder: Covid-19 Assessment 15 Jan 2021

Form: Symptom Log (4)

Generated On: 11 Aug 2021 22:53:07

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:28:58
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 19:11:21
DataPoint Verified.	(b) (4), (b) (6)	01 Feb 2021 20:22:04
User entered 'None (None)'	Heather Douds (b) (4) (b) (4)	15 Jan 2021 18:14:30

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Folder: Covid-19 Assessment 15 Jan 2021

Form: Symptom Log (4)

Generated On: 11 Aug 2021 22:53:07

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:28:58
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 19:11:21
DataPoint Verified.	(b) (4), (b) (6)	01 Feb 2021 20:22:04
User entered 'Mild (Mild)'	Heather Douds (b) (4) (b) (4)	15 Jan 2021 18:14:30

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Folder: Covid-19 Assessment 15 Jan 2021

Form: Symptom Log (4)

Generated On: 11 Aug 2021 22:53:07

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:28:58
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 19:11:21
DataPoint Verified.	(b) (4), (b) (6)	01 Feb 2021 20:22:04
User entered 'None (None)'	Heather Doubs (b) (4) (b) (4)	15 Jan 2021 18:14:30

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Folder: Covid-19 Assessment 15 Jan 2021

Form: Symptom Log (4)

Generated On: 11 Aug 2021 22:53:07

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:28:58
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:11:21
DataPoint Verified.	(b) (4)	01 Feb 2021 20:22:04
User entered 'None (None)'	(b) (4), (b) (6)	01 Feb 2021 20:22:04
	Heather Doubs (b) (4)	15 Jan 2021 18:14:30
	(b) (4)	

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Folder: Covid-19 Assessment 15 Jan 2021

Form: Symptom Log (4)

Generated On: 11 Aug 2021 22:53:07

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:28:58
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 19:11:21
DataPoint Verified.	(b) (4), (b) (6)	01 Feb 2021 20:22:04
User entered 'Mild (Mild)'	Heather Douds (b) (4) (b) (4)	15 Jan 2021 18:14:30

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Folder: Covid-19 Assessment 15 Jan 2021

Form: Symptom Log (4)

Generated On: 11 Aug 2021 22:53:07

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:28:58
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:11:21
DataPoint Verified.	(b) (4), (b) (6)	01 Feb 2021 20:22:04
User entered 'None (None)'	Heather Doubs (b) (4)	15 Jan 2021 18:14:30

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Folder: Covid-19 Assessment 15 Jan 2021

Form: Symptom Log (4)

Generated On: 11 Aug 2021 22:53:07

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:28:58
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 19:11:21
DataPoint Verified.	(b) (4), (b) (6)	01 Feb 2021 20:22:04
User entered 'None (None)'	Heather Doubs (b) (4) (b) (4)	15 Jan 2021 18:14:30

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Folder: Covid-19 Assessment 15 Jan 2021

Form: Symptom Log (4)

Generated On: 11 Aug 2021 22:53:07

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:28:58
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 19:11:21
DataPoint Verified.	(b) (4), (b) (6)	01 Feb 2021 20:22:04
User entered 'Mild (Mild)'	Heather Douds (b) (4) (b) (4)	15 Jan 2021 18:14:30

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Folder: Covid-19 Assessment 15 Jan 2021

Form: Symptom Log (4)

Generated On: 11 Aug 2021 22:53:07

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:28:58
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 19:11:21
DataPoint Verified.	(b) (4), (b) (6)	01 Feb 2021 20:22:04
User entered 'Mild (Mild)'	Heather Douds (b) (4) (b) (4)	15 Jan 2021 18:14:30

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Folder: Covid-19 Assessment 15 Jan 2021

Form: Symptom Log (4)

Generated On: 11 Aug 2021 22:53:07

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:28:58
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 19:11:21
DataPoint Verified.	(b) (4), (b) (6)	01 Feb 2021 20:22:04
User entered 'None (None)'	Heather Doubs (b) (4) (b) (4)	15 Jan 2021 18:14:30

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Folder: Covid-19 Assessment 15 Jan 2021

Form: Symptom Log (4)

Generated On: 11 Aug 2021 22:53:07

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:28:58
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:11:21
DataPoint Verified.	(b) (4)	01 Feb 2021 20:22:04
User entered 'None (None)'	Heather Doubs (b) (4)	15 Jan 2021 18:14:30
	(b) (4)	

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Folder: Covid-19 Assessment 15 Jan 2021

Form: Symptom Log (4)

Generated On: 11 Aug 2021 22:53:07

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:28:58
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 19:11:21
DataPoint Verified.	(b) (4), (b) (6)	01 Feb 2021 20:22:04
User entered 'None (None)'	Heather Doubs (b) (4) (b) (4)	15 Jan 2021 18:14:30

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Folder: Covid-19 Assessment 15 Jan 2021

Form: Symptom Log (4)

Generated On: 11 Aug 2021 22:53:07

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:28:58
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:11:21
DataPoint Verified.	(b) (4)	01 Feb 2021 20:22:04
User entered 'Mild (Mild)'	Heather Doubs (b) (4)	15 Jan 2021 18:14:30
	(b) (4)	

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Folder: Covid-19 Assessment 15 Jan 2021

Form: Symptom Log (5)

Generated On: 11 Aug 2021 22:53:07

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:28:58
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 19:11:21
User entered 'Day 5 (Day 5)'	Cassandra Zehenny (b) (4) (b) (4)	26 Jan 2021 22:42:13

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Folder: Covid-19 Assessment 15 Jan 2021

Form: Symptom Log (5)

Generated On: 11 Aug 2021 22:53:07

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:28:58
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 19:11:21
User entered '16 Jan 2021'	Cassandra Zehenny (b) (4) (b) (4)	26 Jan 2021 22:42:13

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Folder: Covid-19 Assessment 15 Jan 2021

Form: Symptom Log (5)

Generated On: 11 Aug 2021 22:53:07

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:28:58
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 19:11:21
User entered '0'	Cassandra Zehenny (b) (4) (b) (4)	26 Jan 2021 22:42:13

US3552412

Folder: Covid-19 Assessment 15 Jan 2021

Form: Symptom Log (5)

Generated On: 11 Aug 2021 22:53:07

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:28:58
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 19:11:21
User entered '97'	Cassandra Zehenny (b) (4) (b) (4)	26 Jan 2021 22:42:13

US3552412

Folder: Covid-19 Assessment 15 Jan 2021

Form: Symptom Log (5)

Generated On: 11 Aug 2021 22:53:07

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:28:58
User entered '%'	System	26 Jan 2021 22:42:13

US3552412

Folder: Covid-19 Assessment 15 Jan 2021

Form: Symptom Log (5)

Generated On: 11 Aug 2021 22:53:07

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:28:58
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 19:11:21
User entered '96.4' F	Cassandra Zehenny (b) (4) (b) (4)	26 Jan 2021 22:42:13

US3552412

Folder: Covid-19 Assessment 15 Jan 2021

Form: Symptom Log (5)

Generated On: 11 Aug 2021 22:53:07

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:28:58
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 19:11:21
User entered 'None (None)'	Cassandra Zehenny (b) (4) (b) (4)	26 Jan 2021 22:42:13

US3552412

Folder: Covid-19 Assessment 15 Jan 2021

Form: Symptom Log (5)

Generated On: 11 Aug 2021 22:53:07

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:28:58
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 19:11:21
User entered 'Mild (Mild)'	Cassandra Zehenny (b) (4) (b) (4)	26 Jan 2021 22:42:13

US3552412

Folder: Covid-19 Assessment 15 Jan 2021

Form: Symptom Log (5)

Generated On: 11 Aug 2021 22:53:07

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:28:58
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 19:11:21
User entered 'None (None)'	Cassandra Zehenny (b) (4) (b) (4)	26 Jan 2021 22:42:13

US3552412

Folder: Covid-19 Assessment 15 Jan 2021

Form: Symptom Log (5)

Generated On: 11 Aug 2021 22:53:07

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:28:58
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 19:11:21
User entered 'None (None)'	Cassandra Zehenny (b) (4) (b) (4)	26 Jan 2021 22:42:13

US3552412

Folder: Covid-19 Assessment 15 Jan 2021

Form: Symptom Log (5)

Generated On: 11 Aug 2021 22:53:07

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:28:58
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 19:11:21
User entered 'None (None)'	Cassandra Zehenny (b) (4) (b) (4)	26 Jan 2021 22:42:13

US3552412

Folder: Covid-19 Assessment 15 Jan 2021

Form: Symptom Log (5)

Generated On: 11 Aug 2021 22:53:07

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:28:58
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 19:11:21
User entered 'None (None)'	Cassandra Zehenny (b) (4) (b) (4)	26 Jan 2021 22:42:13

US3552412

Folder: Covid-19 Assessment 15 Jan 2021

Form: Symptom Log (5)

Generated On: 11 Aug 2021 22:53:07

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:28:58
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 19:11:21
User entered 'None (None)'	Cassandra Zehenny (b) (4) (b) (4)	26 Jan 2021 22:42:13

US3552412

Folder: Covid-19 Assessment 15 Jan 2021

Form: Symptom Log (5)

Generated On: 11 Aug 2021 22:53:07

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:28:58
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 19:11:21
User entered 'None (None)'	Cassandra Zehenny (b) (4) (b) (4)	26 Jan 2021 22:42:13

US3552412

Folder: Covid-19 Assessment 15 Jan 2021

Form: Symptom Log (5)

Generated On: 11 Aug 2021 22:53:07

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:28:58
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 19:11:21
User entered 'None (None)'	Cassandra Zehenny (b) (4) (b) (4)	26 Jan 2021 22:42:13

US3552412

Folder: Covid-19 Assessment 15 Jan 2021

Form: Symptom Log (5)

Generated On: 11 Aug 2021 22:53:07

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:28:58
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 19:11:21
User entered 'None (None)'	Cassandra Zehenny (b) (4) (b) (4)	26 Jan 2021 22:42:13

US3552412

Folder: Covid-19 Assessment 15 Jan 2021

Form: Symptom Log (5)

Generated On: 11 Aug 2021 22:53:07

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:28:58
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 19:11:21
User entered 'None (None)'	Cassandra Zehenny (b) (4) (b) (4)	26 Jan 2021 22:42:13

US3552412

Folder: Covid-19 Assessment 15 Jan 2021

Form: Symptom Log (5)

Generated On: 11 Aug 2021 22:53:07

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:28:58
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 19:11:21
User entered 'Mild (Mild)'	Cassandra Zehenny (b) (4) (b) (4)	26 Jan 2021 22:42:13

US3552412

Folder: Covid-19 Assessment 15 Jan 2021

Form: Symptom Log (5)

Generated On: 11 Aug 2021 22:53:07

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:28:58
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 19:11:21
User entered 'None (None)'	Cassandra Zehenny (b) (4) (b) (4)	26 Jan 2021 22:42:13

US3552412

Folder: Covid-19 Assessment 15 Jan 2021

Form: Symptom Log (5)

Generated On: 11 Aug 2021 22:53:07

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:28:58
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 19:11:21
User entered 'None (None)'	Cassandra Zehenny (b) (4) (b) (4)	26 Jan 2021 22:42:13

US3552412

Folder: Covid-19 Assessment 15 Jan 2021

Form: Symptom Log (5)

Generated On: 11 Aug 2021 22:53:07

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:28:58
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 19:11:21
User entered 'None (None)'	Cassandra Zehenny (b) (4) (b) (4)	26 Jan 2021 22:42:13

US3552412

Folder: Covid-19 Assessment 15 Jan 2021

Form: Symptom Log (5)

Generated On: 11 Aug 2021 22:53:07

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:28:58
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 19:11:21
User entered 'None (None)'	Cassandra Zehenny (b) (4) (b) (4)	26 Jan 2021 22:42:13

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Folder: Covid-19 Assessment 15 Jan 2021

Form: COVID Diagnostic Test

Generated On: 11 Aug 2021 22:53:07

[Date of Visit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:28:58
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 19:11:21
DataPoint Verified.	(b) (4), (b) (6)	01 Feb 2021 20:22:14
User entered '15 Jan 2021'	Cassandra Zehenny (b) (4) (b) (4)	26 Jan 2021 22:40:44

US3552412

Folder: Covid-19 Assessment 15 Jan 2021

Form: COVID Diagnostic Test

Generated On: 11 Aug 2021 22:53:07

[Was the Subject Tested For SARS-CoV-2 by RT-PCR?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:28:58
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:11:21
DataPoint Verified.	(b) (4), (b) (6)	01 Feb 2021 20:22:14
User entered 'Yes (Y)'	Cassandra Zehenny (b) (4)	26 Jan 2021 22:40:44

US3552412

Folder: Covid-19 Assessment 15 Jan 2021

Form: COVID Diagnostic Test

Generated On: 11 Aug 2021 22:53:07

[Did Subject Test Positive For SARS-CoV-2 by RT-PCR?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:28:58
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 19:11:21
DataPoint Verified.	(b) (4), (b) (6)	01 Feb 2021 20:22:14
User entered 'No (N)'	Cassandra Zehenny (b) (4) (b) (4)	26 Jan 2021 22:40:44

US3552412

Folder: Covid-19 Assessment 15 Jan 2021

Form: COVID Diagnostic Test

Generated On: 11 Aug 2021 22:53:07

[Date of Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:28:58
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 19:11:21
DataPoint Verified.	(b) (4), (b) (6)	01 Feb 2021 20:22:14
User entered '15 Jan 2021'	Cassandra Zehenny (b) (4) (b) (4)	26 Jan 2021 22:40:44

US3552412

Folder: Covid-19 Assessment 15 Jan 2021

Form: COVID Diagnostic Test

Generated On: 11 Aug 2021 22:53:07

[Type of Test Performed](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:28:58
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:11:21
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	01 Feb 2021 20:22:14
User entered 'Nasopharyngeal Swab (Nasopharyngeal Swab)'	Cassandra Zehenny (b) (4)	26 Jan 2021 22:40:44
	(b) (4)	

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Folder: Covid-19 Assessment 15 Jan 2021

Form: COVID Diagnostic Test

Generated On: 11 Aug 2021 22:53:07

[Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:28:58
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:11:21
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	01 Feb 2021 20:22:14
User entered empty.	Cassandra Zehenny (b) (4)	26 Jan 2021 22:40:44
	(b) (4)	

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Folder: Covid-19 Assessment 15 Jan 2021

Form: COVID Diagnostic Test

Generated On: 11 Aug 2021 22:53:07

[Was this diagnostic test performed at a lab other than the Study Central Lab?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:28:58
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 19:11:21
DataPoint Verified.	(b) (4), (b) (6)	01 Feb 2021 20:22:14
User entered 'No (N)'	Cassandra Zehenny (b) (4) (b) (4)	26 Jan 2021 22:40:44

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Folder: Covid-19 Assessment 15 Jan 2021

Form: COVID Diagnostic Test

Generated On: 11 Aug 2021 22:53:07

[Lab/ Institution Test Performed](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:28:58
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 19:11:21
DataPoint Verified.	(b) (4), (b) (6)	01 Feb 2021 20:22:14
User entered empty.	Cassandra Zehenny (b) (4) (b) (4)	26 Jan 2021 22:40:44

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Folder: Covid-19 Assessment 15 Jan 2021

Form: COVID Diagnostic Test

Generated On: 11 Aug 2021 22:53:07

[CLIA Certified?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:28:58
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 19:11:21
DataPoint Verified.	(b) (4), (b) (6)	01 Feb 2021 20:22:14
User entered empty.	Cassandra Zehenny (b) (4) (b) (4)	26 Jan 2021 22:40:44

US3552412

Folder: Covid-19 Assessment 15 Jan 2021

Form: COVID Diagnostic Test

Generated On: 11 Aug 2021 22:53:07

[COVID-19 Positive \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:28:58
User entered '0'	System	26 Jan 2021 22:40:44

US3552412

Folder: Covid-19 Assessment 15 Jan 2021

Form: COVID-19 Contact

Generated On: 11 Aug 2021 22:53:07

[Date of Contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:28:58
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:11:21
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	01 Feb 2021 20:22:23
User entered '15 Jan 2021'	Cassandra Zehenny (b) (4)	28 Jan 2021 15:10:08
	(b) (4)	

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Folder: Covid-19 Assessment 15 Jan 2021

Form: COVID-19 Contact

Generated On: 11 Aug 2021 22:53:07

[Time of Contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:28:58
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 19:11:21
DataPoint Verified.	(b) (4), (b) (6)	01 Feb 2021 20:22:23
User entered '07:10'	Cassandra Zehenny (b) (4) (b) (4)	28 Jan 2021 15:10:08

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Folder: Covid-19 Assessment 15 Jan 2021

Form: COVID-19 Contact

Generated On: 11 Aug 2021 22:53:07

[Date and Time of Contact \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:28:58
User entered '15 Jan 2021 07:10'	System	28 Jan 2021 15:10:08

US3552412

Folder: Covid-19 Assessment 15 Jan 2021

Form: COVID-19 Contact

Generated On: 11 Aug 2021 22:53:07

[Type of Contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:28:58
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 19:11:21
DataPoint Verified.	(b) (4), (b) (6)	01 Feb 2021 20:22:23
User entered 'Safety Call (Safety Call)'	Cassandra Zehenny (b) (4) (b) (4)	28 Jan 2021 15:10:08

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Folder: Covid-19 Assessment 15 Jan 2021

Form: COVID-19 Contact

Generated On: 11 Aug 2021 22:53:07

[Has the subject reported symptoms of SARS-COV-2?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:28:58
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:11:21
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	01 Feb 2021 20:22:23
User entered 'Yes (Y)'	Cassandra Zehenny (b) (4)	28 Jan 2021 15:10:08
	(b) (4)	

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Folder: Covid-19 Assessment 15 Jan 2021

Form: COVID Diagnostic Test

Generated On: 11 Aug 2021 22:53:07

[Date of Visit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:28:58
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 19:11:21
DataPoint Verified.	(b) (4), (b) (6)	01 Feb 2021 20:22:31
User entered '15 Jan 2021'	Cassandra Zehenny (b) (4) (b) (4)	28 Jan 2021 15:10:46

US3552412

Folder: Covid-19 Assessment 15 Jan 2021

Form: COVID Diagnostic Test

Generated On: 11 Aug 2021 22:53:07

[Was the Subject Tested For SARS-CoV-2 by RT-PCR?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:28:58
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:11:21
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	01 Feb 2021 20:22:31
User entered 'Yes (Y)'	Cassandra Zehenny (b) (4)	28 Jan 2021 15:10:46
	(b) (4)	

US3552412

Folder: Covid-19 Assessment 15 Jan 2021

Form: COVID Diagnostic Test

Generated On: 11 Aug 2021 22:53:07

[Did Subject Test Positive For SARS-CoV-2 by RT-PCR?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:28:58
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:11:21
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	01 Feb 2021 20:22:31
User entered 'No (N)'	Cassandra Zehenny (b) (4)	28 Jan 2021 15:10:46
	(b) (4)	

US3552412

Folder: Covid-19 Assessment 15 Jan 2021

Form: COVID Diagnostic Test

Generated On: 11 Aug 2021 22:53:07

[Date of Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:28:58
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:11:21
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	01 Feb 2021 20:22:31
User entered '15 Jan 2021'	Cassandra Zehenny (b) (4)	28 Jan 2021 15:10:46
	(b) (4)	

US3552412

Folder: Covid-19 Assessment 15 Jan 2021

Form: COVID Diagnostic Test

Generated On: 11 Aug 2021 22:53:07

[Type of Test Performed](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:28:58
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:11:21
DataPoint Verified.	(b) (4), (b) (6)	01 Feb 2021 20:22:31
User entered 'Nasopharyngeal Swab (Nasopharyngeal Swab)'	Cassandra Zehenny (b) (4)	28 Jan 2021 15:10:46

US3552412

Folder: Covid-19 Assessment 15 Jan 2021

Form: COVID Diagnostic Test

Generated On: 11 Aug 2021 22:53:07

[Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:28:58
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 19:11:21
DataPoint Verified.	(b) (4), (b) (6)	01 Feb 2021 20:22:31
User entered empty.	Cassandra Zehenny (b) (4) (b) (4)	28 Jan 2021 15:10:46

US3552412

Folder: Covid-19 Assessment 15 Jan 2021

Form: COVID Diagnostic Test

Generated On: 11 Aug 2021 22:53:07

[Was this diagnostic test performed at a lab other than the Study Central Lab?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:28:58
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 19:11:21
DataPoint Verified.	(b) (4), (b) (6)	01 Feb 2021 20:22:31
User entered 'Yes (Y)'	Cassandra Zehenny (b) (4) (b) (4)	28 Jan 2021 15:10:46

US3552412

Folder: Covid-19 Assessment 15 Jan 2021

Form: COVID Diagnostic Test

Generated On: 11 Aug 2021 22:53:07

[Lab/ Institution Test Performed](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:28:58
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 19:11:21
DataPoint Verified.	(b) (4), (b) (6)	01 Feb 2021 20:22:31
User entered 'Saint Louis University's Vaccine Development Center'	Cassandra Zehenny (b) (4) (b) (4)	28 Jan 2021 15:10:46

US3552412

Folder: Covid-19 Assessment 15 Jan 2021

Form: COVID Diagnostic Test

Generated On: 11 Aug 2021 22:53:07

[CLIA Certified?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:28:58
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:11:21
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	01 Feb 2021 20:22:31
User entered 'Yes (Y)'	Cassandra Zehenny (b) (4)	28 Jan 2021 15:10:46
	(b) (4)	

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Folder: Covid-19 Assessment 15 Jan 2021

Form: COVID Diagnostic Test

Generated On: 11 Aug 2021 22:53:07

[COVID-19 Positive \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:28:58
User entered '0'	System	28 Jan 2021 15:10:46

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Folder: Covid-19 Assessment 30 Nov 2020

Form: COVID-19 Contact

Generated On: 11 Aug 2021 22:53:07

[Date of Contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:28:58
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:11:21
DataPoint Verified.	(b) (4)	01 Feb 2021 20:26:46
User entered '30 Nov 2020'	(b) (4), (b) (6)	01 Feb 2021 20:26:46
	Stanley Doublin (b) (4)	03 Dec 2020 19:48:46
	(b) (4)	

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Folder: Covid-19 Assessment 30 Nov 2020

Form: COVID-19 Contact

Generated On: 11 Aug 2021 22:53:07

[Time of Contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:28:58
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:11:21
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	01 Feb 2021 20:26:46
User entered '07:56' reason for change: Data Entry Error	Cassandra Zehenny (b) (4)	03 Dec 2020 20:30:23
User entered '7:56'	(b) (4)	
	Stanley Doublin (b) (4)	03 Dec 2020 19:48:46
	(b) (4)	

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Folder: Covid-19 Assessment 30 Nov 2020

Form: COVID-19 Contact

Generated On: 11 Aug 2021 22:53:07

[Date and Time of Contact \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:28:58
User entered '30 Nov 2020 07:56'	System	03 Dec 2020 20:30:23
User entered '30 Nov 2020 7:56'	System	03 Dec 2020 19:48:46

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Folder: Covid-19 Assessment 30 Nov 2020

Form: COVID-19 Contact

Generated On: 11 Aug 2021 22:53:07

[Type of Contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:28:58
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 19:11:21
DataPoint Verified.	(b) (4), (b) (6)	01 Feb 2021 20:26:46
User entered 'Safety Call (Safety Call)'	Stanley Doublin (b) (4) (b) (4)	03 Dec 2020 19:48:46

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Form: COVID-19 Contact

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[Has the subject reported symptoms of SARS-COV-2?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:28:58
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:11:21
DataPoint Verified.	(b) (4)	01 Feb 2021 20:26:46
User entered 'Yes (Y)'	(b) (4), (b) (6)	01 Feb 2021 20:26:46
	Stanley Doublin (b) (4)	03 Dec 2020 19:48:46
	(b) (4)	

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Form: Symptom Log (1)

Generated On: 11 Aug 2021 22:53:07

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:28:58
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:11:21
User entered 'Day 1 (Day 1)'	(b) (4) Stanley Dublin (b) (4) (b) (4)	03 Dec 2020 19:50:15

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Form: Symptom Log (1)

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[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:28:58
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:11:21
User entered '27 Nov 2020'	(b) (4) Stanley Dublin (b) (4) (b) (4)	03 Dec 2020 19:50:15

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Form: Symptom Log (1)

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[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:28:58
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:11:21
User entered '0'	(b) (4) Stanley Dublin (b) (4) (b) (4)	03 Dec 2020 19:50:15

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Form: Symptom Log (1)

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[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:28:58
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:11:21
User entered missing code ND - Not Done.	(b) (4) Stanley Dublin (b) (4) (b) (4)	03 Dec 2020 19:50:15

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Folder: Covid-19 Assessment 30 Nov 2020

Form: Symptom Log (1)

Generated On: 11 Aug 2021 22:53:07

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:28:58
User entered '%'	System	03 Dec 2020 19:50:15

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Form: Symptom Log (1)

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[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:28:58
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:11:21
User entered missing code ND - Not Done.	(b) (4) Stanley Dublin (b) (4) (b) (4)	03 Dec 2020 19:50:15

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Folder: Covid-19 Assessment 30 Nov 2020

Form: Symptom Log (1)

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[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:28:58
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:11:21
User entered 'None (None)'	(b) (4) Stanley Dublin (b) (4) (b) (4)	03 Dec 2020 19:50:15

US3552412

Folder: Covid-19 Assessment 30 Nov 2020

Form: Symptom Log (1)

Generated On: 11 Aug 2021 22:53:07

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:28:58
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:11:21
User entered 'None (None)'	(b) (4) Stanley Dublin (b) (4) (b) (4)	03 Dec 2020 19:50:15

US3552412

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Form: Symptom Log (1)

Generated On: 11 Aug 2021 22:53:07

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:28:58
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:11:21
User entered 'None (None)'	(b) (4) Stanley Dublin (b) (4) (b) (4)	03 Dec 2020 19:50:15

US3552412

Folder: Covid-19 Assessment 30 Nov 2020

Form: Symptom Log (1)

Generated On: 11 Aug 2021 22:53:07

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:28:58
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:11:21
User entered 'None (None)'	(b) (4) Stanley Dublin (b) (4) (b) (4)	03 Dec 2020 19:50:15

US3552412

Folder: Covid-19 Assessment 30 Nov 2020

Form: Symptom Log (1)

Generated On: 11 Aug 2021 22:53:07

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:28:58
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:11:21
User entered 'None (None)'	(b) (4) Stanley Dublin (b) (4) (b) (4)	03 Dec 2020 19:50:15

US3552412

Folder: Covid-19 Assessment 30 Nov 2020

Form: Symptom Log (1)

Generated On: 11 Aug 2021 22:53:07

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:28:58
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:11:21
User entered 'None (None)'	(b) (4) Stanley Dublin (b) (4) (b) (4)	03 Dec 2020 19:50:15

US3552412

Folder: Covid-19 Assessment 30 Nov 2020

Form: Symptom Log (1)

Generated On: 11 Aug 2021 22:53:07

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:28:58
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:11:21
User entered 'None (None)'	(b) (4) Stanley Dublin (b) (4) (b) (4)	03 Dec 2020 19:50:15

US3552412

Folder: Covid-19 Assessment 30 Nov 2020

Form: Symptom Log (1)

Generated On: 11 Aug 2021 22:53:07

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:28:58
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:11:21
User entered 'None (None)'	(b) (4) Stanley Dublin (b) (4) (b) (4)	03 Dec 2020 19:50:15

US3552412

Folder: Covid-19 Assessment 30 Nov 2020

Form: Symptom Log (1)

Generated On: 11 Aug 2021 22:53:07

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:28:58
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:11:21
User entered 'None (None)'	(b) (4) Stanley Dublin (b) (4) (b) (4)	03 Dec 2020 19:50:15

US3552412

Folder: Covid-19 Assessment 30 Nov 2020

Form: Symptom Log (1)

Generated On: 11 Aug 2021 22:53:07

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:28:58
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:11:21
User entered 'None (None)'	(b) (4) Stanley Dublin (b) (4) (b) (4)	03 Dec 2020 19:50:15

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Folder: Covid-19 Assessment 30 Nov 2020

Form: Symptom Log (1)

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[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:28:58
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:11:21
User entered 'Moderate (Moderate)'	(b) (4) Stanley Dublin (b) (4) (b) (4)	03 Dec 2020 19:50:15

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Form: Symptom Log (1)

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[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:28:58
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:11:21
User entered 'Mild (Mild)'	(b) (4) Stanley Dublin (b) (4) (b) (4)	03 Dec 2020 19:50:15

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Form: Symptom Log (1)

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[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:28:58
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:11:21
User entered 'None (None)'	(b) (4) Stanley Dublin (b) (4) (b) (4)	03 Dec 2020 19:50:15

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Form: Symptom Log (1)

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[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:28:58
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:11:21
User entered 'None (None)'	(b) (4) Stanley Dublin (b) (4) (b) (4)	03 Dec 2020 19:50:15

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Form: Symptom Log (1)

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[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:28:58
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:11:21
User entered 'None (None)'	(b) (4) Stanley Dublin (b) (4) (b) (4)	03 Dec 2020 19:50:15

US3552412

Folder: Covid-19 Assessment 30 Nov 2020

Form: Symptom Log (1)

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[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:28:58
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:11:21
User entered 'Mild (Mild)'	(b) (4) Stanley Dublin (b) (4) (b) (4)	03 Dec 2020 19:50:15

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Folder: Covid-19 Assessment 30 Nov 2020

Form: Symptom Log (2)

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[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:28:58
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:11:21
User entered 'Day 2 (Day 2)'	(b) (4) Stanley Dublin (b) (4) (b) (4)	03 Dec 2020 19:50:57

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Form: Symptom Log (2)

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[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:28:58
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:11:21
User entered '28 Nov 2020'	(b) (4) Stanley Dublin (b) (4) (b) (4)	03 Dec 2020 19:50:57

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[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:28:58
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:11:21
User entered '0'	(b) (4) Stanley Dublin (b) (4) (b) (4)	03 Dec 2020 19:50:57

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Form: Symptom Log (2)

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[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:28:58
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:11:21
User entered missing code ND - Not Done.	(b) (4) Stanley Dublin (b) (4) (b) (4)	03 Dec 2020 19:50:57

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Form: Symptom Log (2)

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[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:28:58
User entered '%'	System	03 Dec 2020 19:50:57

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Form: Symptom Log (2)

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[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:28:58
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:11:21
User entered missing code ND - Not Done.	(b) (4) Stanley Dublin (b) (4) (b) (4)	03 Dec 2020 19:50:57

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Folder: Covid-19 Assessment 30 Nov 2020

Form: Symptom Log (2)

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[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:28:58
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:11:21
User entered 'None (None)'	(b) (4) Stanley Dublin (b) (4) (b) (4)	03 Dec 2020 19:50:57

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[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:28:58
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:11:21
User entered 'None (None)'	(b) (4) Stanley Dublin (b) (4) (b) (4)	03 Dec 2020 19:50:57

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Form: Symptom Log (2)

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[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:28:58
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:11:21
User entered 'None (None)'	(b) (4) Stanley Dublin (b) (4) (b) (4)	03 Dec 2020 19:50:57

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[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:28:58
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:11:21
User entered 'None (None)'	(b) (4) Stanley Dublin (b) (4) (b) (4)	03 Dec 2020 19:50:57

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[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:28:58
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:11:21
User entered 'None (None)'	(b) (4) Stanley Dublin (b) (4) (b) (4)	03 Dec 2020 19:50:57

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Form: Symptom Log (2)

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[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:28:58
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:11:21
User entered 'None (None)'	(b) (4) Stanley Dublin (b) (4) (b) (4)	03 Dec 2020 19:50:57

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[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:28:58
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:11:21
User entered 'None (None)'	(b) (4) Stanley Dublin (b) (4) (b) (4)	03 Dec 2020 19:50:57

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[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:28:58
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:11:21
User entered 'None (None)'	(b) (4) Stanley Dublin (b) (4) (b) (4)	03 Dec 2020 19:50:57

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Form: Symptom Log (2)

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[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:28:58
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:11:21
User entered 'None (None)'	(b) (4) Stanley Dublin (b) (4) (b) (4)	03 Dec 2020 19:50:57

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[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:28:58
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:11:21
User entered 'None (None)'	(b) (4) Stanley Dublin (b) (4) (b) (4)	03 Dec 2020 19:50:57

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Form: Symptom Log (2)

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[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:28:58
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:11:21
User entered 'Moderate (Moderate)'	(b) (4) Stanley Dublin (b) (4) (b) (4)	03 Dec 2020 19:50:57

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[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:28:58
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:11:21
User entered 'Mild (Mild)'	(b) (4) Stanley Dublin (b) (4) (b) (4)	03 Dec 2020 19:50:57

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[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:28:58
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:11:21
User entered 'None (None)'	(b) (4) Stanley Dublin (b) (4) (b) (4)	03 Dec 2020 19:50:57

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[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:28:58
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:11:21
User entered 'None (None)'	(b) (4) Stanley Dublin (b) (4) (b) (4)	03 Dec 2020 19:50:57

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[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:28:58
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:11:21
User entered 'None (None)'	(b) (4) Stanley Dublin (b) (4) (b) (4)	03 Dec 2020 19:50:57

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Form: Symptom Log (2)

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[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:28:58
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:11:21
User entered 'Mild (Mild)'	(b) (4) Stanley Dublin (b) (4) (b) (4)	03 Dec 2020 19:50:57

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Form: Symptom Log (3)

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[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:28:58
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:11:21
User entered 'Day 3 (Day 3)'	(b) (4) Stanley Dublin (b) (4) (b) (4)	03 Dec 2020 19:51:30

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Folder: Covid-19 Assessment 30 Nov 2020

Form: Symptom Log (3)

Generated On: 11 Aug 2021 22:53:07

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:28:58
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:11:21
User entered '29 Nov 2020'	(b) (4) Stanley Dublin (b) (4) (b) (4)	03 Dec 2020 19:51:30

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[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:28:58
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:11:21
User entered '0'	(b) (4) Stanley Dublin (b) (4) (b) (4)	03 Dec 2020 19:51:30

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Form: Symptom Log (3)

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[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:28:58
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:11:21
User entered missing code ND - Not Done.	(b) (4) Stanley Dublin (b) (4) (b) (4)	03 Dec 2020 19:51:30

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[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:28:58
User entered '%'	System	03 Dec 2020 19:51:30

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[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:28:58
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:11:21
User entered missing code ND - Not Done.	(b) (4) Stanley Dublin (b) (4) (b) (4)	03 Dec 2020 19:51:30

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[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:28:58
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:11:21
User entered 'None (None)'	(b) (4) Stanley Dublin (b) (4) (b) (4)	03 Dec 2020 19:51:30

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Form: Symptom Log (3)

Generated On: 11 Aug 2021 22:53:07

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:28:58
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:11:21
User entered 'None (None)'	(b) (4) Stanley Dublin (b) (4) (b) (4)	03 Dec 2020 19:51:30

US3552412

Folder: Covid-19 Assessment 30 Nov 2020

Form: Symptom Log (3)

Generated On: 11 Aug 2021 22:53:07

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:28:58
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:11:21
User entered 'None (None)'	(b) (4) Stanley Dublin (b) (4) (b) (4)	03 Dec 2020 19:51:30

US3552412

Folder: Covid-19 Assessment 30 Nov 2020

Form: Symptom Log (3)

Generated On: 11 Aug 2021 22:53:07

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:28:58
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:11:21
User entered 'None (None)'	(b) (4) Stanley Dublin (b) (4)	03 Dec 2020 19:51:30

US3552412

Folder: Covid-19 Assessment 30 Nov 2020

Form: Symptom Log (3)

Generated On: 11 Aug 2021 22:53:07

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:28:58
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:11:21
User entered 'None (None)'	(b) (4) Stanley Dublin (b) (4) (b) (4)	03 Dec 2020 19:51:30

US3552412

Folder: Covid-19 Assessment 30 Nov 2020

Form: Symptom Log (3)

Generated On: 11 Aug 2021 22:53:07

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:28:58
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:11:21
User entered 'None (None)'	(b) (4) Stanley Dublin (b) (4)	03 Dec 2020 19:51:30

US3552412

Folder: Covid-19 Assessment 30 Nov 2020

Form: Symptom Log (3)

Generated On: 11 Aug 2021 22:53:07

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:28:58
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:11:21
User entered 'None (None)'	(b) (4) Stanley Dublin (b) (4) (b) (4)	03 Dec 2020 19:51:30

US3552412

Folder: Covid-19 Assessment 30 Nov 2020

Form: Symptom Log (3)

Generated On: 11 Aug 2021 22:53:07

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:28:58
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:11:21
User entered 'None (None)'	(b) (4) Stanley Dublin (b) (4) (b) (4)	03 Dec 2020 19:51:30

US3552412

Folder: Covid-19 Assessment 30 Nov 2020

Form: Symptom Log (3)

Generated On: 11 Aug 2021 22:53:07

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:28:58
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:11:21
User entered 'None (None)'	(b) (4) Stanley Dublin (b) (4) (b) (4)	03 Dec 2020 19:51:30

US3552412

Folder: Covid-19 Assessment 30 Nov 2020

Form: Symptom Log (3)

Generated On: 11 Aug 2021 22:53:07

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:28:58
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:11:21
User entered 'None (None)'	(b) (4) Stanley Dublin (b) (4) (b) (4)	03 Dec 2020 19:51:30

US3552412

Folder: Covid-19 Assessment 30 Nov 2020

Form: Symptom Log (3)

Generated On: 11 Aug 2021 22:53:07

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:28:58
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:11:21
User entered 'Moderate (Moderate)'	(b) (4) Stanley Dublin (b) (4) (b) (4)	03 Dec 2020 19:51:30

US3552412

Folder: Covid-19 Assessment 30 Nov 2020

Form: Symptom Log (3)

Generated On: 11 Aug 2021 22:53:07

Runny Nose (Rhinorrhea)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:28:58
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:11:21
User entered 'Mild (Mild)'	(b) (4) Stanley Dublin (b) (4) (b) (4)	03 Dec 2020 19:51:30

US3552412

Folder: Covid-19 Assessment 30 Nov 2020

Form: Symptom Log (3)

Generated On: 11 Aug 2021 22:53:07

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:28:58
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:11:21
User entered 'None (None)'	(b) (4) Stanley Dublin (b) (4) (b) (4)	03 Dec 2020 19:51:30

US3552412

Folder: Covid-19 Assessment 30 Nov 2020

Form: Symptom Log (3)

Generated On: 11 Aug 2021 22:53:07

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:28:58
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:11:21
User entered 'None (None)'	(b) (4) Stanley Dublin (b) (4) (b) (4)	03 Dec 2020 19:51:30

US3552412

Folder: Covid-19 Assessment 30 Nov 2020

Form: Symptom Log (3)

Generated On: 11 Aug 2021 22:53:07

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:28:58
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:11:21
User entered 'None (None)'	(b) (4) Stanley Dublin (b) (4) (b) (4)	03 Dec 2020 19:51:30

US3552412

Folder: Covid-19 Assessment 30 Nov 2020

Form: Symptom Log (3)

Generated On: 11 Aug 2021 22:53:07

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:28:58
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:11:21
User entered 'Mild (Mild)'	(b) (4) Stanley Dublin (b) (4) (b) (4)	03 Dec 2020 19:51:30

US3552412

Folder: Covid-19 Assessment 30 Nov 2020

Form: Symptom Log (4)

Generated On: 11 Aug 2021 22:53:07

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:28:58
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:11:21
User entered 'Day 4 (Day 4)'	(b) (4) Stanley Dublin (b) (4) (b) (4)	03 Dec 2020 19:51:57

US3552412

Folder: Covid-19 Assessment 30 Nov 2020

Form: Symptom Log (4)

Generated On: 11 Aug 2021 22:53:07

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:28:58
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:11:21
User entered '30 Nov 2020'	(b) (4) Stanley Dublin (b) (4) (b) (4)	03 Dec 2020 19:51:57

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Folder: Covid-19 Assessment 30 Nov 2020

Form: Symptom Log (4)

Generated On: 11 Aug 2021 22:53:07

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:28:58
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:11:21
User entered '0'	(b) (4) Stanley Dublin (b) (4) (b) (4)	03 Dec 2020 19:51:57

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Folder: Covid-19 Assessment 30 Nov 2020

Form: Symptom Log (4)

Generated On: 11 Aug 2021 22:53:07

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:28:58
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:11:21
User entered missing code ND - Not Done.	(b) (4) Stanley Dublin (b) (4) (b) (4)	03 Dec 2020 19:51:57

US3552412

Folder: Covid-19 Assessment 30 Nov 2020

Form: Symptom Log (4)

Generated On: 11 Aug 2021 22:53:07

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:28:58
User entered '%'	System	03 Dec 2020 19:51:57

US3552412

Folder: Covid-19 Assessment 30 Nov 2020

Form: Symptom Log (4)

Generated On: 11 Aug 2021 22:53:07

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:28:58
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:11:21
User entered missing code ND - Not Done.	(b) (4) Stanley Dublin (b) (4) (b) (4)	03 Dec 2020 19:51:57

US3552412

Folder: Covid-19 Assessment 30 Nov 2020

Form: Symptom Log (4)

Generated On: 11 Aug 2021 22:53:07

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:28:58
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:11:21
User entered 'None (None)'	(b) (4) Stanley Dublin (b) (4) (b) (4)	03 Dec 2020 19:51:57

US3552412

Folder: Covid-19 Assessment 30 Nov 2020

Form: Symptom Log (4)

Generated On: 11 Aug 2021 22:53:07

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:28:58
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:11:21
User entered 'None (None)'	(b) (4) Stanley Dublin (b) (4) (b) (4)	03 Dec 2020 19:51:57

US3552412

Folder: Covid-19 Assessment 30 Nov 2020

Form: Symptom Log (4)

Generated On: 11 Aug 2021 22:53:07

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:28:58
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:11:21
User entered 'None (None)'	(b) (4) Stanley Dublin (b) (4) (b) (4)	03 Dec 2020 19:51:57

US3552412

Folder: Covid-19 Assessment 30 Nov 2020

Form: Symptom Log (4)

Generated On: 11 Aug 2021 22:53:07

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:28:58
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:11:21
User entered 'None (None)'	(b) (4) Stanley Dublin (b) (4) (b) (4)	03 Dec 2020 19:51:57

US3552412

Folder: Covid-19 Assessment 30 Nov 2020

Form: Symptom Log (4)

Generated On: 11 Aug 2021 22:53:07

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:28:58
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:11:21
User entered 'None (None)'	(b) (4) Stanley Dublin (b) (4) (b) (4)	03 Dec 2020 19:51:57

US3552412

Folder: Covid-19 Assessment 30 Nov 2020

Form: Symptom Log (4)

Generated On: 11 Aug 2021 22:53:07

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:28:58
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:11:21
User entered 'None (None)'	(b) (4) Stanley Dublin (b) (4) (b) (4)	03 Dec 2020 19:51:57

US3552412

Folder: Covid-19 Assessment 30 Nov 2020

Form: Symptom Log (4)

Generated On: 11 Aug 2021 22:53:07

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:28:58
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:11:21
User entered 'None (None)'	(b) (4) Stanley Dublin (b) (4) (b) (4)	03 Dec 2020 19:51:57

US3552412

Folder: Covid-19 Assessment 30 Nov 2020

Form: Symptom Log (4)

Generated On: 11 Aug 2021 22:53:07

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:28:58
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:11:21
User entered 'None (None)'	(b) (4) Stanley Dublin (b) (4) (b) (4)	03 Dec 2020 19:51:57

US3552412

Folder: Covid-19 Assessment 30 Nov 2020

Form: Symptom Log (4)

Generated On: 11 Aug 2021 22:53:07

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:28:58
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:11:21
User entered 'None (None)'	(b) (4) Stanley Dublin (b) (4) (b) (4)	03 Dec 2020 19:51:57

US3552412

Folder: Covid-19 Assessment 30 Nov 2020

Form: Symptom Log (4)

Generated On: 11 Aug 2021 22:53:07

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:28:58
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:11:21
User entered 'None (None)'	(b) (4) Stanley Dublin (b) (4) (b) (4)	03 Dec 2020 19:51:57

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Folder: Covid-19 Assessment 30 Nov 2020

Form: Symptom Log (4)

Generated On: 11 Aug 2021 22:53:07

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:28:58
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:11:21
User entered 'Mild (Mild)'	(b) (4) Stanley Doublin (b) (4) (b) (4)	03 Dec 2020 19:51:57

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Folder: Covid-19 Assessment 30 Nov 2020

Form: Symptom Log (4)

Generated On: 11 Aug 2021 22:53:07

Runny Nose (Rhinorrhea)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:28:58
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:11:21
User entered 'Mild (Mild)'	(b) (4) Stanley Dublin (b) (4) (b) (4)	03 Dec 2020 19:51:57

US3552412

Folder: Covid-19 Assessment 30 Nov 2020

Form: Symptom Log (4)

Generated On: 11 Aug 2021 22:53:07

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:28:58
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:11:21
User entered 'None (None)'	(b) (4) Stanley Dublin (b) (4) (b) (4)	03 Dec 2020 19:51:57

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Folder: Covid-19 Assessment 30 Nov 2020

Form: Symptom Log (4)

Generated On: 11 Aug 2021 22:53:07

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:28:58
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:11:21
User entered 'None (None)'	(b) (4) Stanley Dublin (b) (4) (b) (4)	03 Dec 2020 19:51:57

US3552412

Folder: Covid-19 Assessment 30 Nov 2020

Form: Symptom Log (4)

Generated On: 11 Aug 2021 22:53:07

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:28:58
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:11:21
User entered 'None (None)'	(b) (4) Stanley Dublin (b) (4) (b) (4)	03 Dec 2020 19:51:57

US3552412

Folder: Covid-19 Assessment 30 Nov 2020

Form: Symptom Log (4)

Generated On: 11 Aug 2021 22:53:07

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:28:58
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:11:21
User entered 'Mild (Mild)'	(b) (4) Stanley Dublin (b) (4) (b) (4)	03 Dec 2020 19:51:57

US3552412

Folder: Covid-19 Assessment 30 Nov 2020

Form: Symptom Log (5)

Generated On: 11 Aug 2021 22:53:07

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:28:58
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:11:21
User entered 'Day 5 (Day 5)'	(b) (4) Stanley Dublin (b) (4) (b) (4)	03 Dec 2020 19:52:30

US3552412

Folder: Covid-19 Assessment 30 Nov 2020

Form: Symptom Log (5)

Generated On: 11 Aug 2021 22:53:07

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:28:58
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:11:21
User entered '01 Dec 2020'	(b) (4) Stanley Dublin (b) (4) (b) (4)	03 Dec 2020 19:52:30

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Form: Symptom Log (5)

Generated On: 11 Aug 2021 22:53:07

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:28:58
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:11:21
User entered '0'	(b) (4) Stanley Dublin (b) (4) (b) (4)	03 Dec 2020 19:52:30

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Folder: Covid-19 Assessment 30 Nov 2020

Form: Symptom Log (5)

Generated On: 11 Aug 2021 22:53:07

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:28:58
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:11:21
User entered missing code ND - Not Done.	(b) (4) Stanley Dublin (b) (4) (b) (4)	03 Dec 2020 19:52:30

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Folder: Covid-19 Assessment 30 Nov 2020

Form: Symptom Log (5)

Generated On: 11 Aug 2021 22:53:07

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:28:58
User entered '%'	System	03 Dec 2020 19:52:30

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Folder: Covid-19 Assessment 30 Nov 2020

Form: Symptom Log (5)

Generated On: 11 Aug 2021 22:53:07

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:28:58
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:11:21
User entered missing code ND - Not Done.	(b) (4) Stanley Dublin (b) (4) (b) (4)	03 Dec 2020 19:52:30

US3552412

Folder: Covid-19 Assessment 30 Nov 2020

Form: Symptom Log (5)

Generated On: 11 Aug 2021 22:53:07

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:28:58
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:11:21
User entered 'None (None)'	(b) (4) Stanley Dublin (b) (4) (b) (4)	03 Dec 2020 19:52:30

US3552412

Folder: Covid-19 Assessment 30 Nov 2020

Form: Symptom Log (5)

Generated On: 11 Aug 2021 22:53:07

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:28:58
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:11:21
User entered 'None (None)'	(b) (4) Stanley Dublin (b) (4) (b) (4)	03 Dec 2020 19:52:30

US3552412

Folder: Covid-19 Assessment 30 Nov 2020

Form: Symptom Log (5)

Generated On: 11 Aug 2021 22:53:07

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:28:58
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:11:21
User entered 'None (None)'	(b) (4) Stanley Dublin (b) (4) (b) (4)	03 Dec 2020 19:52:30

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Folder: Covid-19 Assessment 30 Nov 2020

Form: Symptom Log (5)

Generated On: 11 Aug 2021 22:53:07

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:28:58
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:11:21
User entered 'None (None)'	(b) (4) Stanley Dublin (b) (4) (b) (4)	03 Dec 2020 19:52:30

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Folder: Covid-19 Assessment 30 Nov 2020

Form: Symptom Log (5)

Generated On: 11 Aug 2021 22:53:07

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:28:58
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:11:21
User entered 'None (None)'	(b) (4) Stanley Dublin (b) (4) (b) (4)	03 Dec 2020 19:52:30

US3552412

Folder: Covid-19 Assessment 30 Nov 2020

Form: Symptom Log (5)

Generated On: 11 Aug 2021 22:53:07

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:28:58
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:11:21
User entered 'None (None)'	(b) (4) Stanley Dublin (b) (4)	03 Dec 2020 19:52:30

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Folder: Covid-19 Assessment 30 Nov 2020

Form: Symptom Log (5)

Generated On: 11 Aug 2021 22:53:07

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:28:58
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:11:21
User entered 'None (None)'	(b) (4) Stanley Dublin (b) (4) (b) (4)	03 Dec 2020 19:52:30

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Folder: Covid-19 Assessment 30 Nov 2020

Form: Symptom Log (5)

Generated On: 11 Aug 2021 22:53:07

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:28:58
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:11:21
User entered 'None (None)'	(b) (4) Stanley Dublin (b) (4) (b) (4)	03 Dec 2020 19:52:30

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Folder: Covid-19 Assessment 30 Nov 2020

Form: Symptom Log (5)

Generated On: 11 Aug 2021 22:53:07

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:28:58
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:11:21
User entered 'None (None)'	(b) (4) Stanley Dublin (b) (4) (b) (4)	03 Dec 2020 19:52:30

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Folder: Covid-19 Assessment 30 Nov 2020

Form: Symptom Log (5)

Generated On: 11 Aug 2021 22:53:07

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:28:58
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:11:21
User entered 'None (None)'	(b) (4) Stanley Dublin (b) (4) (b) (4)	03 Dec 2020 19:52:30

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Folder: Covid-19 Assessment 30 Nov 2020

Form: Symptom Log (5)

Generated On: 11 Aug 2021 22:53:07

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:28:58
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:11:21
User entered 'Mild (Mild)'	(b) (4) Stanley Dublin (b) (4) (b) (4)	03 Dec 2020 19:52:30

US3552412

Folder: Covid-19 Assessment 30 Nov 2020

Form: Symptom Log (5)

Generated On: 11 Aug 2021 22:53:07

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:28:58
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:11:21
User entered 'Mild (Mild)'	(b) (4) Stanley Dublin (b) (4) (b) (4)	03 Dec 2020 19:52:30

US3552412

Folder: Covid-19 Assessment 30 Nov 2020

Form: Symptom Log (5)

Generated On: 11 Aug 2021 22:53:07

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:28:58
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:11:21
User entered 'None (None)'	(b) (4) Stanley Dublin (b) (4) (b) (4)	03 Dec 2020 19:52:30

US3552412

Folder: Covid-19 Assessment 30 Nov 2020

Form: Symptom Log (5)

Generated On: 11 Aug 2021 22:53:07

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:28:58
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:11:21
User entered 'None (None)'	(b) (4) Stanley Dublin (b) (4) (b) (4)	03 Dec 2020 19:52:30

US3552412

Folder: Covid-19 Assessment 30 Nov 2020

Form: Symptom Log (5)

Generated On: 11 Aug 2021 22:53:07

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:28:58
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:11:21
User entered 'None (None)'	(b) (4) Stanley Dublin (b) (4) (b) (4)	03 Dec 2020 19:52:30

US3552412

Folder: Covid-19 Assessment 30 Nov 2020

Form: Symptom Log (5)

Generated On: 11 Aug 2021 22:53:07

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:28:58
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:11:21
User entered 'Mild (Mild)'	(b) (4) Stanley Dublin (b) (4) (b) (4)	03 Dec 2020 19:52:30

US3552412

Folder: Covid-19 Assessment 30 Nov 2020

Form: Symptom Log (6)

Generated On: 11 Aug 2021 22:53:07

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:28:58
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:11:21
User entered 'Day 6 (Day 6)'	(b) (4) Stanley Dublin (b) (4) (b) (4)	03 Dec 2020 19:52:52

US3552412

Folder: Covid-19 Assessment 30 Nov 2020

Form: Symptom Log (6)

Generated On: 11 Aug 2021 22:53:07

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:28:58
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:11:21
User entered '02 Dec 2020' reason for change: Data Entry Error	(b) (4)	
	Stanley Dublin (b) (4)	03 Dec 2020 19:54:54
User entered '2 Dec 2020'	(b) (4)	
	Stanley Dublin (b) (4)	03 Dec 2020 19:52:52
	(b) (4)	

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Folder: Covid-19 Assessment 30 Nov 2020

Form: Symptom Log (6)

Generated On: 11 Aug 2021 22:53:07

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:28:58
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:11:21
User entered '0'	(b) (4) Stanley Dublin (b) (4) (b) (4)	03 Dec 2020 19:52:52

US3552412

Folder: Covid-19 Assessment 30 Nov 2020

Form: Symptom Log (6)

Generated On: 11 Aug 2021 22:53:07

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:28:58
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:11:21
User entered missing code ND - Not Done.	(b) (4) Stanley Dublin (b) (4) (b) (4)	03 Dec 2020 19:52:52

US3552412

Folder: Covid-19 Assessment 30 Nov 2020

Form: Symptom Log (6)

Generated On: 11 Aug 2021 22:53:07

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:28:58
User entered '%'	System	03 Dec 2020 19:52:52

US3552412

Folder: Covid-19 Assessment 30 Nov 2020

Form: Symptom Log (6)

Generated On: 11 Aug 2021 22:53:07

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:28:58
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:11:21
User entered missing code ND - Not Done.	(b) (4) Stanley Dublin (b) (4) (b) (4)	03 Dec 2020 19:52:52

US3552412

Folder: Covid-19 Assessment 30 Nov 2020

Form: Symptom Log (6)

Generated On: 11 Aug 2021 22:53:07

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:28:58
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:11:21
User entered 'None (None)'	(b) (4) Stanley Dublin (b) (4) (b) (4)	03 Dec 2020 19:52:52

US3552412

Folder: Covid-19 Assessment 30 Nov 2020

Form: Symptom Log (6)

Generated On: 11 Aug 2021 22:53:07

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:28:58
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:11:21
User entered 'None (None)'	(b) (4) Stanley Dublin (b) (4) (b) (4)	03 Dec 2020 19:52:52

US3552412

Folder: Covid-19 Assessment 30 Nov 2020

Form: Symptom Log (6)

Generated On: 11 Aug 2021 22:53:07

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:28:58
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:11:21
User entered 'None (None)'	(b) (4) Stanley Dublin (b) (4) (b) (4)	03 Dec 2020 19:52:52

US3552412

Folder: Covid-19 Assessment 30 Nov 2020

Form: Symptom Log (6)

Generated On: 11 Aug 2021 22:53:07

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:28:58
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:11:21
User entered 'None (None)'	(b) (4) Stanley Dublin (b) (4) (b) (4)	03 Dec 2020 19:52:52

US3552412

Folder: Covid-19 Assessment 30 Nov 2020

Form: Symptom Log (6)

Generated On: 11 Aug 2021 22:53:07

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:28:58
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:11:21
User entered 'None (None)'	(b) (4) Stanley Dublin (b) (4) (b) (4)	03 Dec 2020 19:52:52

US3552412

Folder: Covid-19 Assessment 30 Nov 2020

Form: Symptom Log (6)

Generated On: 11 Aug 2021 22:53:07

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:28:58
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:11:21
User entered 'None (None)'	(b) (4) Stanley Dublin (b) (4)	03 Dec 2020 19:52:52

US3552412

Folder: Covid-19 Assessment 30 Nov 2020

Form: Symptom Log (6)

Generated On: 11 Aug 2021 22:53:07

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:28:58
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:11:21
User entered 'None (None)'	(b) (4) Stanley Dublin (b) (4) (b) (4)	03 Dec 2020 19:52:52

US3552412

Folder: Covid-19 Assessment 30 Nov 2020

Form: Symptom Log (6)

Generated On: 11 Aug 2021 22:53:07

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:28:58
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:11:21
User entered 'None (None)'	(b) (4) Stanley Dublin (b) (4) (b) (4)	03 Dec 2020 19:52:52

US3552412

Folder: Covid-19 Assessment 30 Nov 2020

Form: Symptom Log (6)

Generated On: 11 Aug 2021 22:53:07

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:28:58
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:11:21
User entered 'None (None)'	(b) (4) Stanley Dublin (b) (4) (b) (4)	03 Dec 2020 19:52:52

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Folder: Covid-19 Assessment 30 Nov 2020

Form: Symptom Log (6)

Generated On: 11 Aug 2021 22:53:07

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:28:58
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:11:21
User entered 'None (None)'	(b) (4) Stanley Dublin (b) (4) (b) (4)	03 Dec 2020 19:52:52

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Folder: Covid-19 Assessment 30 Nov 2020

Form: Symptom Log (6)

Generated On: 11 Aug 2021 22:53:07

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:28:58
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:11:21
User entered 'Mild (Mild)'	(b) (4) Stanley Dublin (b) (4) (b) (4)	03 Dec 2020 19:52:52

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Folder: Covid-19 Assessment 30 Nov 2020

Form: Symptom Log (6)

Generated On: 11 Aug 2021 22:53:07

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:28:58
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:11:21
User entered 'Mild (Mild)'	(b) (4) Stanley Dublin (b) (4) (b) (4)	03 Dec 2020 19:52:52

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Form: Symptom Log (6)

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[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:28:58
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:11:21
User entered 'None (None)'	(b) (4) Stanley Dublin (b) (4) (b) (4)	03 Dec 2020 19:52:52

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Folder: Covid-19 Assessment 30 Nov 2020

Form: Symptom Log (6)

Generated On: 11 Aug 2021 22:53:07

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:28:58
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:11:21
User entered 'None (None)'	(b) (4) Stanley Dublin (b) (4) (b) (4)	03 Dec 2020 19:52:52

US3552412

Folder: Covid-19 Assessment 30 Nov 2020

Form: Symptom Log (6)

Generated On: 11 Aug 2021 22:53:07

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:28:58
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:11:21
User entered 'None (None)'	(b) (4) Stanley Dublin (b) (4) (b) (4)	03 Dec 2020 19:52:52

US3552412

Folder: Covid-19 Assessment 30 Nov 2020

Form: Symptom Log (6)

Generated On: 11 Aug 2021 22:53:07

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:28:58
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:11:21
User entered 'Mild (Mild)'	(b) (4) Stanley Doublin (b) (4) (b) (4)	03 Dec 2020 19:52:52

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Folder: Covid-19 Assessment 30 Nov 2020

Form: Symptom Log (7)

Generated On: 11 Aug 2021 22:53:07

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:28:58
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:11:21
User entered 'Day 7 (Day 7)'	(b) (4) Stanley Dublin (b) (4) (b) (4)	03 Dec 2020 19:54:41

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Folder: Covid-19 Assessment 30 Nov 2020

Form: Symptom Log (7)

Generated On: 11 Aug 2021 22:53:07

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:28:58
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:11:21
DataPoint Verified.	(b) (4)	01 Feb 2021 20:28:02
User entered '03 Dec 2020'	(b) (4), (b) (6)	01 Feb 2021 20:28:02
	Stanley Doublin (b) (4)	03 Dec 2020 19:54:41
	(b) (4)	

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Folder: Covid-19 Assessment 30 Nov 2020

Form: Symptom Log (7)

Generated On: 11 Aug 2021 22:53:07

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:28:58
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 19:11:21
DataPoint Verified.	(b) (4), (b) (6)	01 Feb 2021 20:28:02
User entered '0'	Stanley Dublin (b) (4) (b) (4)	03 Dec 2020 19:54:41

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Folder: Covid-19 Assessment 30 Nov 2020

Form: Symptom Log (7)

Generated On: 11 Aug 2021 22:53:07

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:28:58
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 19:11:21
DataPoint Verified.	(b) (4), (b) (6)	01 Feb 2021 20:28:02
User entered '99'	Stanley Doublin (b) (4) (b) (4)	03 Dec 2020 19:54:41

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Folder: Covid-19 Assessment 30 Nov 2020

Form: Symptom Log (7)

Generated On: 11 Aug 2021 22:53:07

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:28:58
User entered '%'	System	03 Dec 2020 19:54:41

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Folder: Covid-19 Assessment 30 Nov 2020

Form: Symptom Log (7)

Generated On: 11 Aug 2021 22:53:07

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:28:58
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 19:11:21
DataPoint Verified.	(b) (4), (b) (6)	01 Feb 2021 20:28:02
User entered '97.3' F	Stanley Doublin (b) (4) (b) (4)	03 Dec 2020 19:54:41

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Folder: Covid-19 Assessment 30 Nov 2020

Form: Symptom Log (7)

Generated On: 11 Aug 2021 22:53:07

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:28:58
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 19:11:21
DataPoint Verified.	(b) (4), (b) (6)	01 Feb 2021 20:28:02
User entered 'None (None)'	Stanley Dublin (b) (4) (b) (4)	03 Dec 2020 19:54:41

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Folder: Covid-19 Assessment 30 Nov 2020

Form: Symptom Log (7)

Generated On: 11 Aug 2021 22:53:07

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:28:58
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:11:21
DataPoint Verified.	(b) (4)	01 Feb 2021 20:28:02
User entered 'None (None)'	(b) (4), (b) (6)	01 Feb 2021 20:28:02
	Stanley Doublin (b) (4)	03 Dec 2020 19:54:41
	(b) (4)	

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Folder: Covid-19 Assessment 30 Nov 2020

Form: Symptom Log (7)

Generated On: 11 Aug 2021 22:53:07

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:28:58
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:11:21
DataPoint Verified.	(b) (4)	01 Feb 2021 20:28:02
User entered 'None (None)'	(b) (4), (b) (6)	01 Feb 2021 20:28:02
	Stanley Doublin (b) (4)	03 Dec 2020 19:54:41
	(b) (4)	

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Folder: Covid-19 Assessment 30 Nov 2020

Form: Symptom Log (7)

Generated On: 11 Aug 2021 22:53:07

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:28:58
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:11:21
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	01 Feb 2021 20:28:02
User entered 'None (None)'	Stanley Doublin (b) (4)	03 Dec 2020 19:54:41
	(b) (4)	

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Folder: Covid-19 Assessment 30 Nov 2020

Form: Symptom Log (7)

Generated On: 11 Aug 2021 22:53:07

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:28:58
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 19:11:21
DataPoint Verified.	(b) (4), (b) (6)	01 Feb 2021 20:28:02
User entered 'None (None)'	Stanley Doublin (b) (4) (b) (4)	03 Dec 2020 19:54:41

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Folder: Covid-19 Assessment 30 Nov 2020

Form: Symptom Log (7)

Generated On: 11 Aug 2021 22:53:07

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:28:58
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 19:11:21
DataPoint Verified.	(b) (4), (b) (6)	01 Feb 2021 20:28:02
User entered 'None (None)'	Stanley Doublin (b) (4) (b) (4)	03 Dec 2020 19:54:41

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Folder: Covid-19 Assessment 30 Nov 2020

Form: Symptom Log (7)

Generated On: 11 Aug 2021 22:53:07

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:28:58
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:11:21
DataPoint Verified.	(b) (4), (b) (6)	01 Feb 2021 20:28:02
User entered 'None (None)'	Stanley Doublin (b) (4)	03 Dec 2020 19:54:41

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Folder: Covid-19 Assessment 30 Nov 2020

Form: Symptom Log (7)

Generated On: 11 Aug 2021 22:53:07

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:28:58
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:11:21
DataPoint Verified.	(b) (4)	01 Feb 2021 20:28:02
User entered 'None (None)'	Stanley Doublin (b) (4)	03 Dec 2020 19:54:41
	(b) (4)	

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Folder: Covid-19 Assessment 30 Nov 2020

Form: Symptom Log (7)

Generated On: 11 Aug 2021 22:53:07

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:28:58
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:11:21
DataPoint Verified.	(b) (4)	01 Feb 2021 20:28:02
User entered 'None (None)'	(b) (4), (b) (6)	01 Feb 2021 20:28:02
	Stanley Doublin (b) (4)	03 Dec 2020 19:54:41
	(b) (4)	

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Form: Symptom Log (7)

Generated On: 11 Aug 2021 22:53:07

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:28:58
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:11:21
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	01 Feb 2021 20:28:02
User entered 'None (None)'	Stanley Dublin (b) (4)	03 Dec 2020 19:54:41
	(b) (4)	

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Form: Symptom Log (7)

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[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:28:58
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 19:11:21
DataPoint Verified.	(b) (4), (b) (6)	01 Feb 2021 20:28:02
User entered 'Mild (Mild)'	Stanley Doublin (b) (4) (b) (4)	03 Dec 2020 19:54:41

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Form: Symptom Log (7)

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[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:28:58
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:11:21
DataPoint Verified.	(b) (4)	01 Feb 2021 20:28:02
User entered 'Mild (Mild)'	Stanley Doublin (b) (4)	03 Dec 2020 19:54:41
	(b) (4)	

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[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:28:58
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:11:21
DataPoint Verified.	(b) (4)	01 Feb 2021 20:28:02
User entered 'None (None)'	(b) (4), (b) (6)	01 Feb 2021 20:28:02
	Stanley Doublin (b) (4)	03 Dec 2020 19:54:41
	(b) (4)	

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Form: Symptom Log (7)

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[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:28:58
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:11:21
DataPoint Verified.	(b) (4)	01 Feb 2021 20:28:02
User entered 'None (None)'	Stanley Doublin (b) (4)	03 Dec 2020 19:54:41
	(b) (4)	

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Form: Symptom Log (7)

Generated On: 11 Aug 2021 22:53:07

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:28:58
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 19:11:21
DataPoint Verified.	(b) (4), (b) (6)	01 Feb 2021 20:28:02
User entered 'None (None)'	Stanley Doublin (b) (4) (b) (4)	03 Dec 2020 19:54:41

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Folder: Covid-19 Assessment 30 Nov 2020

Form: Symptom Log (7)

Generated On: 11 Aug 2021 22:53:07

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:28:58
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:11:21
DataPoint Verified.	(b) (4)	01 Feb 2021 20:28:02
User entered 'None (None)'	(b) (4), (b) (6)	01 Feb 2021 20:28:02
	Stanley Doublin (b) (4)	03 Dec 2020 19:54:41
	(b) (4)	

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Folder: Covid-19 Assessment 30 Nov 2020

Form: Symptom Log (8)

Generated On: 11 Aug 2021 22:53:07

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:28:58
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:11:21
User entered 'Day 8 (Day 8)'	(b) (4) Mikayla Frye (b) (4) (b) (4)	04 Dec 2020 16:32:24

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Folder: Covid-19 Assessment 30 Nov 2020

Form: Symptom Log (8)

Generated On: 11 Aug 2021 22:53:07

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:28:58
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:11:21
User entered '04 Dec 2020'	(b) (4) Mikayla Frye (b) (4) (b) (4)	04 Dec 2020 16:32:24

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Folder: Covid-19 Assessment 30 Nov 2020

Form: Symptom Log (8)

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[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:28:58
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:11:21
User entered '0'	(b) (4) Mikayla Frye (b) (4) (b) (4)	04 Dec 2020 16:32:24

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Folder: Covid-19 Assessment 30 Nov 2020

Form: Symptom Log (8)

Generated On: 11 Aug 2021 22:53:07

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:28:58
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:11:21
User entered '99'	(b) (4) Mikayla Frye (b) (4) (b) (4)	04 Dec 2020 16:32:24

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Folder: Covid-19 Assessment 30 Nov 2020

Form: Symptom Log (8)

Generated On: 11 Aug 2021 22:53:07

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:28:58
User entered '%'	System	04 Dec 2020 16:32:24

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Folder: Covid-19 Assessment 30 Nov 2020

Form: Symptom Log (8)

Generated On: 11 Aug 2021 22:53:07

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:28:58
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:11:21
User entered '97.5' F	(b) (4) Mikayla Frye (b) (4) (b) (4)	04 Dec 2020 16:32:24

US3552412

Folder: Covid-19 Assessment 30 Nov 2020

Form: Symptom Log (8)

Generated On: 11 Aug 2021 22:53:07

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:28:58
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:11:21
User entered 'None (None)'	(b) (4) Mikayla Frye (b) (4) (b) (4)	04 Dec 2020 16:32:24

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Folder: Covid-19 Assessment 30 Nov 2020

Form: Symptom Log (8)

Generated On: 11 Aug 2021 22:53:07

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:28:58
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:11:21
User entered 'None (None)'	(b) (4) Mikayla Frye (b) (4) (b) (4)	04 Dec 2020 16:32:24

US3552412

Folder: Covid-19 Assessment 30 Nov 2020

Form: Symptom Log (8)

Generated On: 11 Aug 2021 22:53:07

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:28:58
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:11:21
User entered 'None (None)'	(b) (4) Mikayla Frye (b) (4) (b) (4)	04 Dec 2020 16:32:24

US3552412

Folder: Covid-19 Assessment 30 Nov 2020

Form: Symptom Log (8)

Generated On: 11 Aug 2021 22:53:07

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:28:58
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:11:21
User entered 'None (None)'	(b) (4) Mikayla Frye (b) (4) (b) (4)	04 Dec 2020 16:32:24

US3552412

Folder: Covid-19 Assessment 30 Nov 2020

Form: Symptom Log (8)

Generated On: 11 Aug 2021 22:53:07

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:28:58
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:11:21
User entered 'None (None)'	(b) (4) Mikayla Frye (b) (4) (b) (4)	04 Dec 2020 16:32:24

US3552412

Folder: Covid-19 Assessment 30 Nov 2020

Form: Symptom Log (8)

Generated On: 11 Aug 2021 22:53:07

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:28:58
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:11:21
User entered 'None (None)'	(b) (4) Mikayla Frye (b) (4) (b) (4)	04 Dec 2020 16:32:24

US3552412

Folder: Covid-19 Assessment 30 Nov 2020

Form: Symptom Log (8)

Generated On: 11 Aug 2021 22:53:07

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:28:58
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:11:21
User entered 'None (None)'	(b) (4) Mikayla Frye (b) (4) (b) (4)	04 Dec 2020 16:32:24

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Folder: Covid-19 Assessment 30 Nov 2020

Form: Symptom Log (8)

Generated On: 11 Aug 2021 22:53:07

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:28:58
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:11:21
User entered 'None (None)'	(b) (4) Mikayla Frye (b) (4) (b) (4)	04 Dec 2020 16:32:24

US3552412

Folder: Covid-19 Assessment 30 Nov 2020

Form: Symptom Log (8)

Generated On: 11 Aug 2021 22:53:07

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:28:58
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:11:21
User entered 'None (None)'	(b) (4) Mikayla Frye (b) (4) (b) (4)	04 Dec 2020 16:32:24

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Form: Symptom Log (8)

Generated On: 11 Aug 2021 22:53:07

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:28:58
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:11:21
User entered 'None (None)'	(b) (4) Mikayla Frye (b) (4) (b) (4)	04 Dec 2020 16:32:24

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Form: Symptom Log (8)

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[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:28:58
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:11:21
User entered 'Mild (Mild)'	(b) (4) Mikayla Frye (b) (4) (b) (4)	04 Dec 2020 16:32:24

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Folder: Covid-19 Assessment 30 Nov 2020

Form: Symptom Log (8)

Generated On: 11 Aug 2021 22:53:07

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:28:58
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:11:21
User entered 'None (None)'	(b) (4) Mikayla Frye (b) (4) (b) (4)	04 Dec 2020 16:32:24

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Folder: Covid-19 Assessment 30 Nov 2020

Form: Symptom Log (8)

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[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:28:58
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:11:21
User entered 'None (None)'	(b) (4) Mikayla Frye (b) (4) (b) (4)	04 Dec 2020 16:32:24

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Folder: Covid-19 Assessment 30 Nov 2020

Form: Symptom Log (8)

Generated On: 11 Aug 2021 22:53:07

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:28:58
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:11:21
User entered 'None (None)'	(b) (4) Mikayla Frye (b) (4) (b) (4)	04 Dec 2020 16:32:24

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Folder: Covid-19 Assessment 30 Nov 2020

Form: Symptom Log (8)

Generated On: 11 Aug 2021 22:53:07

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:28:58
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:11:21
User entered 'None (None)'	(b) (4) Mikayla Frye (b) (4) (b) (4)	04 Dec 2020 16:32:24

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Folder: Covid-19 Assessment 30 Nov 2020

Form: Symptom Log (8)

Generated On: 11 Aug 2021 22:53:07

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:28:58
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:11:21
User entered 'None (None)'	(b) (4) Mikayla Frye (b) (4) (b) (4)	04 Dec 2020 16:32:24

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Folder: Covid-19 Assessment 30 Nov 2020

Form: Symptom Log (9)

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[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:28:58
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:11:21
User entered 'Day 9 (Day 9)'	(b) (4) Stanley Dublin (b) (4) (b) (4)	07 Dec 2020 18:57:03

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Form: Symptom Log (9)

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[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:28:58
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 19:11:21
DataPoint Verified.	(b) (4), (b) (6)	01 Feb 2021 20:30:08
User entered '05 Dec 2020'	Stanley Doublin (b) (4) (b) (4)	07 Dec 2020 18:57:03

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Folder: Covid-19 Assessment 30 Nov 2020

Form: Symptom Log (9)

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[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:28:58
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:11:21
DataPoint Verified.	(b) (4)	01 Feb 2021 20:30:08
User entered '0'	Stanley Doublin (b) (4)	07 Dec 2020 18:57:03
	(b) (4)	

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Folder: Covid-19 Assessment 30 Nov 2020

Form: Symptom Log (9)

Generated On: 11 Aug 2021 22:53:07

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:28:58
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:11:21
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	01 Feb 2021 20:30:08
User entered '97'	Stanley Dublin (b) (4)	07 Dec 2020 18:57:03
	(b) (4)	

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Folder: Covid-19 Assessment 30 Nov 2020

Form: Symptom Log (9)

Generated On: 11 Aug 2021 22:53:07

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:28:58
User entered '%'	System	07 Dec 2020 18:57:03

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Folder: Covid-19 Assessment 30 Nov 2020

Form: Symptom Log (9)

Generated On: 11 Aug 2021 22:53:07

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:28:58
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:11:21
DataPoint Verified.	(b) (4)	01 Feb 2021 20:30:08
User entered '98.3' F	(b) (4), (b) (6)	01 Feb 2021 20:30:08
	Stanley Doublin (b) (4)	07 Dec 2020 18:57:03
	(b) (4)	

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Folder: Covid-19 Assessment 30 Nov 2020

Form: Symptom Log (9)

Generated On: 11 Aug 2021 22:53:07

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:28:58
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:11:21
DataPoint Verified.	(b) (4)	01 Feb 2021 20:30:08
User entered 'None (None)'	Stanley Doublin (b) (4)	07 Dec 2020 18:57:03
	(b) (4)	

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Form: Symptom Log (9)

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[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:28:58
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:11:21
DataPoint Verified.	(b) (4)	01 Feb 2021 20:30:08
User entered 'None (None)'	(b) (4), (b) (6)	01 Feb 2021 20:30:08
	Stanley Doublin (b) (4)	07 Dec 2020 18:57:03
	(b) (4)	

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Form: Symptom Log (9)

Generated On: 11 Aug 2021 22:53:07

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:28:58
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:11:21
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	01 Feb 2021 20:30:08
User entered 'None (None)'	Stanley Doublin (b) (4)	07 Dec 2020 18:57:03
	(b) (4)	

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Folder: Covid-19 Assessment 30 Nov 2020

Form: Symptom Log (9)

Generated On: 11 Aug 2021 22:53:07

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:28:58
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:11:21
DataPoint Verified.	(b) (4)	01 Feb 2021 20:30:08
User entered 'None (None)'	(b) (4), (b) (6)	01 Feb 2021 20:30:08
	Stanley Doublin (b) (4)	07 Dec 2020 18:57:03
	(b) (4)	

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Form: Symptom Log (9)

Generated On: 11 Aug 2021 22:53:07

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:28:58
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:11:21
DataPoint Verified.	(b) (4)	01 Feb 2021 20:30:08
User entered 'None (None)'	Stanley Doublin (b) (4)	07 Dec 2020 18:57:03
	(b) (4)	

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Folder: Covid-19 Assessment 30 Nov 2020

Form: Symptom Log (9)

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[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:28:58
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 19:11:21
DataPoint Verified.	(b) (4), (b) (6)	01 Feb 2021 20:30:08
User entered 'None (None)'	Stanley Doublin (b) (4) (b) (4)	07 Dec 2020 18:57:03

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Folder: Covid-19 Assessment 30 Nov 2020

Form: Symptom Log (9)

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[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:28:58
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:11:21
DataPoint Verified.	(b) (4)	01 Feb 2021 20:30:08
User entered 'None (None)'	Stanley Dublin (b) (4)	07 Dec 2020 18:57:03
	(b) (4)	

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Form: Symptom Log (9)

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[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:28:58
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:11:21
DataPoint Verified.	(b) (4)	01 Feb 2021 20:30:08
User entered 'None (None)'	(b) (4), (b) (6)	01 Feb 2021 20:30:08
	Stanley Doublin (b) (4)	07 Dec 2020 18:57:03
	(b) (4)	

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Form: Symptom Log (9)

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[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:28:58
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 19:11:21
DataPoint Verified.	(b) (4), (b) (6)	01 Feb 2021 20:30:08
User entered 'None (None)'	Stanley Dublin (b) (4) (b) (4)	07 Dec 2020 18:57:03

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Folder: Covid-19 Assessment 30 Nov 2020

Form: Symptom Log (9)

Generated On: 11 Aug 2021 22:53:07

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:28:58
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:11:21
DataPoint Verified.	(b) (4)	01 Feb 2021 20:30:08
User entered 'None (None)'	Stanley Dublin (b) (4)	07 Dec 2020 18:57:03
	(b) (4)	

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Folder: Covid-19 Assessment 30 Nov 2020

Form: Symptom Log (9)

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[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:28:58
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 19:11:21
DataPoint Verified.	(b) (4), (b) (6)	01 Feb 2021 20:30:08
User entered 'Mild (Mild)'	Stanley Doublin (b) (4) (b) (4)	07 Dec 2020 18:57:03

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Folder: Covid-19 Assessment 30 Nov 2020

Form: Symptom Log (9)

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[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:28:58
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 19:11:21
DataPoint Verified.	(b) (4), (b) (6)	01 Feb 2021 20:30:08
User entered 'None (None)'	Stanley Doublin (b) (4) (b) (4)	07 Dec 2020 18:57:03

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Form: Symptom Log (9)

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[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:28:58
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 19:11:21
DataPoint Verified.	(b) (4), (b) (6)	01 Feb 2021 20:30:08
User entered 'None (None)'	Stanley Doublin (b) (4) (b) (4)	07 Dec 2020 18:57:03

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Form: Symptom Log (9)

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[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:28:58
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 19:11:21
DataPoint Verified.	(b) (4), (b) (6)	01 Feb 2021 20:30:08
User entered 'None (None)'	Stanley Dublin (b) (4) (b) (4)	07 Dec 2020 18:57:03

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Form: Symptom Log (9)

Generated On: 11 Aug 2021 22:53:07

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:28:58
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 19:11:21
DataPoint Verified.	(b) (4), (b) (6)	01 Feb 2021 20:30:08
User entered 'None (None)'	Stanley Doublin (b) (4) (b) (4)	07 Dec 2020 18:57:03

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Form: Symptom Log (9)

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[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:28:58
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 19:11:21
DataPoint Verified.	(b) (4), (b) (6)	01 Feb 2021 20:30:08
User entered 'None (None)'	Stanley Doublin (b) (4) (b) (4)	07 Dec 2020 18:57:03

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Form: Symptom Log (10)

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[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:28:58
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:11:21
User entered 'Day 10 (Day 10)'	(b) (4) Stanley Dublin (b) (4) (b) (4)	07 Dec 2020 18:57:33

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Form: Symptom Log (10)

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[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:28:58
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:11:21
User entered '06 Dec 2020'	(b) (4) Stanley Dublin (b) (4) (b) (4)	07 Dec 2020 18:57:33

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Form: Symptom Log (10)

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[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:28:58
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:11:21
User entered '0'	(b) (4) Stanley Dublin (b) (4) (b) (4)	07 Dec 2020 18:57:33

US3552412

Folder: Covid-19 Assessment 30 Nov 2020

Form: Symptom Log (10)

Generated On: 11 Aug 2021 22:53:07

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:28:58
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:11:21
User entered '97'	(b) (4) Stanley Dublin (b) (4) (b) (4)	07 Dec 2020 18:57:33

US3552412

Folder: Covid-19 Assessment 30 Nov 2020

Form: Symptom Log (10)

Generated On: 11 Aug 2021 22:53:07

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:28:58
User entered '%'	System	07 Dec 2020 18:57:33

US3552412

Folder: Covid-19 Assessment 30 Nov 2020

Form: Symptom Log (10)

Generated On: 11 Aug 2021 22:53:07

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:28:58
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:11:21
User entered '98.5' F	(b) (4) Stanley Dublin (b) (4)	07 Dec 2020 18:57:33

US3552412

Folder: Covid-19 Assessment 30 Nov 2020

Form: Symptom Log (10)

Generated On: 11 Aug 2021 22:53:07

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:28:58
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:11:21
User entered 'None (None)'	(b) (4) Stanley Dublin (b) (4) (b) (4)	07 Dec 2020 18:57:33

US3552412

Folder: Covid-19 Assessment 30 Nov 2020

Form: Symptom Log (10)

Generated On: 11 Aug 2021 22:53:07

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:28:58
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:11:21
User entered 'None (None)'	(b) (4) Stanley Dublin (b) (4) (b) (4)	07 Dec 2020 18:57:33

US3552412

Folder: Covid-19 Assessment 30 Nov 2020

Form: Symptom Log (10)

Generated On: 11 Aug 2021 22:53:07

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:28:58
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:11:21
User entered 'None (None)'	(b) (4) Stanley Dublin (b) (4)	07 Dec 2020 18:57:33

US3552412

Folder: Covid-19 Assessment 30 Nov 2020

Form: Symptom Log (10)

Generated On: 11 Aug 2021 22:53:07

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:28:58
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:11:21
User entered 'None (None)'	(b) (4) Stanley Dublin (b) (4)	07 Dec 2020 18:57:33

US3552412

Folder: Covid-19 Assessment 30 Nov 2020

Form: Symptom Log (10)

Generated On: 11 Aug 2021 22:53:07

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:28:58
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:11:21
User entered 'None (None)'	(b) (4) Stanley Dublin (b) (4)	07 Dec 2020 18:57:33

US3552412

Folder: Covid-19 Assessment 30 Nov 2020

Form: Symptom Log (10)

Generated On: 11 Aug 2021 22:53:07

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:28:58
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:11:21
User entered 'None (None)'	(b) (4) Stanley Dublin (b) (4)	07 Dec 2020 18:57:33

US3552412

Folder: Covid-19 Assessment 30 Nov 2020

Form: Symptom Log (10)

Generated On: 11 Aug 2021 22:53:07

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:28:58
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:11:21
User entered 'None (None)'	(b) (4) Stanley Dublin (b) (4) (b) (4)	07 Dec 2020 18:57:33

US3552412

Folder: Covid-19 Assessment 30 Nov 2020

Form: Symptom Log (10)

Generated On: 11 Aug 2021 22:53:07

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:28:58
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:11:21
User entered 'None (None)'	(b) (4) Stanley Dublin (b) (4) (b) (4)	07 Dec 2020 18:57:33

US3552412

Folder: Covid-19 Assessment 30 Nov 2020

Form: Symptom Log (10)

Generated On: 11 Aug 2021 22:53:07

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:28:58
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:11:21
User entered 'None (None)'	(b) (4) Stanley Dublin (b) (4) (b) (4)	07 Dec 2020 18:57:33

US3552412

Folder: Covid-19 Assessment 30 Nov 2020

Form: Symptom Log (10)

Generated On: 11 Aug 2021 22:53:07

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:28:58
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:11:21
User entered 'None (None)'	(b) (4) Stanley Dublin (b) (4) (b) (4)	07 Dec 2020 18:57:33

US3552412

Folder: Covid-19 Assessment 30 Nov 2020

Form: Symptom Log (10)

Generated On: 11 Aug 2021 22:53:07

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:28:58
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:11:21
User entered 'Mild (Mild)'	(b) (4) Stanley Dublin (b) (4) (b) (4)	07 Dec 2020 18:57:33

US3552412

Folder: Covid-19 Assessment 30 Nov 2020

Form: Symptom Log (10)

Generated On: 11 Aug 2021 22:53:07

Runny Nose (Rhinorrhea)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:28:58
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:11:21
User entered 'None (None)'	(b) (4) Stanley Dublin (b) (4)	07 Dec 2020 18:57:33

US3552412

Folder: Covid-19 Assessment 30 Nov 2020

Form: Symptom Log (10)

Generated On: 11 Aug 2021 22:53:07

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:28:58
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:11:21
User entered 'None (None)'	(b) (4) Stanley Dublin (b) (4) (b) (4)	07 Dec 2020 18:57:33

US3552412

Folder: Covid-19 Assessment 30 Nov 2020

Form: Symptom Log (10)

Generated On: 11 Aug 2021 22:53:07

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:28:58
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:11:21
User entered 'None (None)'	(b) (4) Stanley Dublin (b) (4) (b) (4)	07 Dec 2020 18:57:33

US3552412

Folder: Covid-19 Assessment 30 Nov 2020

Form: Symptom Log (10)

Generated On: 11 Aug 2021 22:53:07

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:28:58
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:11:21
User entered 'None (None)'	(b) (4) Stanley Dublin (b) (4)	07 Dec 2020 18:57:33

US3552412

Folder: Covid-19 Assessment 30 Nov 2020

Form: Symptom Log (10)

Generated On: 11 Aug 2021 22:53:07

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:28:58
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:11:21
User entered 'None (None)'	(b) (4) Stanley Dublin (b) (4) (b) (4)	07 Dec 2020 18:57:33

US3552412

Folder: Covid-19 Assessment 30 Nov 2020

Form: Symptom Log (11)

Generated On: 11 Aug 2021 22:53:07

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:28:58
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:11:21
User entered 'Day 11 (Day 11)'	(b) (4) Stanley Dublin (b) (4) (b) (4)	07 Dec 2020 18:58:59

US3552412

Folder: Covid-19 Assessment 30 Nov 2020

Form: Symptom Log (11)

Generated On: 11 Aug 2021 22:53:07

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:28:58
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:11:21
User entered '07 Dec 2020'	(b) (4) Stanley Dublin (b) (4) (b) (4)	07 Dec 2020 18:58:59

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Folder: Covid-19 Assessment 30 Nov 2020

Form: Symptom Log (11)

Generated On: 11 Aug 2021 22:53:07

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:28:58
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:11:21
User entered '0'	(b) (4) Stanley Dublin (b) (4) (b) (4)	07 Dec 2020 18:58:59

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Folder: Covid-19 Assessment 30 Nov 2020

Form: Symptom Log (11)

Generated On: 11 Aug 2021 22:53:07

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:28:58
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:11:21
User entered '98'	(b) (4) Stanley Dublin (b) (4) (b) (4)	07 Dec 2020 18:58:59

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Folder: Covid-19 Assessment 30 Nov 2020

Form: Symptom Log (11)

Generated On: 11 Aug 2021 22:53:07

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:28:58
User entered '%'	System	07 Dec 2020 18:58:59

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Form: Symptom Log (11)

Generated On: 11 Aug 2021 22:53:07

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:28:58
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:11:21
User entered '98.5' F	(b) (4) Stanley Dublin (b) (4)	07 Dec 2020 18:58:59

US3552412

Folder: Covid-19 Assessment 30 Nov 2020

Form: Symptom Log (11)

Generated On: 11 Aug 2021 22:53:07

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:28:58
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:11:21
User entered 'None (None)'	(b) (4) Stanley Dublin (b) (4) (b) (4)	07 Dec 2020 18:58:59

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Folder: Covid-19 Assessment 30 Nov 2020

Form: Symptom Log (11)

Generated On: 11 Aug 2021 22:53:07

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:28:58
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:11:21
User entered 'None (None)'	(b) (4) Stanley Dublin (b) (4) (b) (4)	07 Dec 2020 18:58:59

US3552412

Folder: Covid-19 Assessment 30 Nov 2020

Form: Symptom Log (11)

Generated On: 11 Aug 2021 22:53:07

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:28:58
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:11:21
User entered 'None (None)'	(b) (4) Stanley Dublin (b) (4)	07 Dec 2020 18:58:59

US3552412

Folder: Covid-19 Assessment 30 Nov 2020

Form: Symptom Log (11)

Generated On: 11 Aug 2021 22:53:07

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:28:58
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:11:21
User entered 'None (None)'	(b) (4) Stanley Dublin (b) (4) (b) (4)	07 Dec 2020 18:58:59

US3552412

Folder: Covid-19 Assessment 30 Nov 2020

Form: Symptom Log (11)

Generated On: 11 Aug 2021 22:53:07

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:28:58
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:11:21
User entered 'None (None)'	(b) (4) Stanley Dublin (b) (4) (b) (4)	07 Dec 2020 18:58:59

US3552412

Folder: Covid-19 Assessment 30 Nov 2020

Form: Symptom Log (11)

Generated On: 11 Aug 2021 22:53:07

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:28:58
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:11:21
User entered 'None (None)'	(b) (4) Stanley Dublin (b) (4)	07 Dec 2020 18:58:59

US3552412

Folder: Covid-19 Assessment 30 Nov 2020

Form: Symptom Log (11)

Generated On: 11 Aug 2021 22:53:07

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:28:58
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:11:21
User entered 'None (None)'	(b) (4) Stanley Dublin (b) (4) (b) (4)	07 Dec 2020 18:58:59

US3552412

Folder: Covid-19 Assessment 30 Nov 2020

Form: Symptom Log (11)

Generated On: 11 Aug 2021 22:53:07

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:28:58
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:11:21
User entered 'None (None)'	(b) (4) Stanley Dublin (b) (4) (b) (4)	07 Dec 2020 18:58:59

US3552412

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Form: Symptom Log (11)

Generated On: 11 Aug 2021 22:53:07

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:28:58
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:11:21
User entered 'None (None)'	(b) (4) Stanley Dublin (b) (4) (b) (4)	07 Dec 2020 18:58:59

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Folder: Covid-19 Assessment 30 Nov 2020

Form: Symptom Log (11)

Generated On: 11 Aug 2021 22:53:07

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:28:58
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:11:21
User entered 'None (None)'	(b) (4) Stanley Dublin (b) (4) (b) (4)	07 Dec 2020 18:58:59

US3552412

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Form: Symptom Log (11)

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[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:28:58
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:11:21
User entered 'Mild (Mild)'	(b) (4) Stanley Dublin (b) (4) (b) (4)	07 Dec 2020 18:58:59

US3552412

Folder: Covid-19 Assessment 30 Nov 2020

Form: Symptom Log (11)

Generated On: 11 Aug 2021 22:53:07

Runny Nose (Rhinorrhea)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:28:58
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:11:21
User entered 'None (None)'	(b) (4) Stanley Dublin (b) (4) (b) (4)	07 Dec 2020 18:58:59

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[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:28:58
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:11:21
User entered 'None (None)'	(b) (4) Stanley Dublin (b) (4) (b) (4)	07 Dec 2020 18:58:59

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Folder: Covid-19 Assessment 30 Nov 2020

Form: Symptom Log (11)

Generated On: 11 Aug 2021 22:53:07

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:28:58
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:11:21
User entered 'None (None)'	(b) (4) Stanley Dublin (b) (4) (b) (4)	07 Dec 2020 18:58:59

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Folder: Covid-19 Assessment 30 Nov 2020

Form: Symptom Log (11)

Generated On: 11 Aug 2021 22:53:07

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:28:58
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:11:21
User entered 'None (None)'	(b) (4) Stanley Dublin (b) (4) (b) (4)	07 Dec 2020 18:58:59

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Folder: Covid-19 Assessment 30 Nov 2020

Form: Symptom Log (11)

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[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:28:58
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:11:21
User entered 'None (None)'	(b) (4) Stanley Dublin (b) (4) (b) (4)	07 Dec 2020 18:58:59

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Folder: Covid-19 Assessment 30 Nov 2020

Form: COVID Diagnostic Test

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[Date of Visit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:28:58
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:11:21
DataPoint Verified.	(b) (4), (b) (6)	01 Feb 2021 20:27:21
User entered '03 Dec 2020'	Cassandra Zehenny (b) (4)	03 Dec 2020 20:31:18

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Folder: Covid-19 Assessment 30 Nov 2020

Form: COVID Diagnostic Test

Generated On: 11 Aug 2021 22:53:07

[Was the Subject Tested For SARS-CoV-2 by RT-PCR?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:28:58
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:11:21
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	01 Feb 2021 20:27:21
User entered 'Yes (Y)'	Cassandra Zehenny (b) (4)	03 Dec 2020 20:31:18
	(b) (4)	

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[Did Subject Test Positive For SARS-CoV-2 by RT-PCR?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:28:58
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:11:21
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	01 Feb 2021 20:27:21
User entered 'No (N)'	Cassandra Zehenny (b) (4)	03 Dec 2020 20:31:18
	(b) (4)	

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[Date of Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:28:58
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:11:21
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	01 Feb 2021 20:27:21
User entered '03 Dec 2020'	Cassandra Zehenny (b) (4)	03 Dec 2020 20:31:18
	(b) (4)	

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[Type of Test Performed](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:28:58
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:11:21
DataPoint Verified.	(b) (4)	01 Feb 2021 20:27:21
User entered 'Nasopharyngeal Swab (Nasopharyngeal Swab)'	Cassandra Zehenny (b) (4)	03 Dec 2020 20:31:18

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Form: COVID Diagnostic Test

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[Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:28:58
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:11:21
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	01 Feb 2021 20:27:21
User entered empty.	Cassandra Zehenny (b) (4)	03 Dec 2020 20:31:18
	(b) (4)	

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Form: COVID Diagnostic Test

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[Was this diagnostic test performed at a lab other than the Study Central Lab?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:28:58
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:11:21
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	01 Feb 2021 20:27:21
User entered 'No (N)'	Cassandra Zehenny (b) (4)	03 Dec 2020 20:31:18
	(b) (4)	

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Form: COVID Diagnostic Test

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[Lab/ Institution Test Performed](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:28:58
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:11:21
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	01 Feb 2021 20:27:21
User entered empty.	Cassandra Zehenny (b) (4)	03 Dec 2020 20:31:18
	(b) (4)	

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[CLIA Certified?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:28:58
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:11:21
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	01 Feb 2021 20:27:21
User entered empty.	Cassandra Zehenny (b) (4)	03 Dec 2020 20:31:18
	(b) (4)	

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Form: COVID Diagnostic Test

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[COVID-19 Positive \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:28:58
User entered '0'	System	03 Dec 2020 20:31:18

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Folder: Covid-19 Assessment 30 Nov 2020

Form: Generate Next COVID-19 Assessment

Generated On: 11 Aug 2021 22:53:07

[Generate Next COVID-19 Assessment](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:28:58
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 19:11:21
User entered 'Yes (Y)'	Heather Douds (b) (4) (b) (4)	15 Jan 2021 18:05:48

US3552412

Folder: Illness Visit (1)

Form: Saliva Collection (1)

Generated On: 11 Aug 2021 22:53:07

[Visit](#)

Audit	User	Time (GMT)
User accepted default value 'Day 3 (Day 3)'	Cassandra Zehenny (b) (4)	15 Dec 2020 16:31:31

US3552412

Folder: Illness Visit (1)

Form: Saliva Collection (1)

Generated On: 11 Aug 2021 22:53:07

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:11:21
User entered 'Yes (Y)'	(b) (4) Cassandra Zehenny (b) (4) (b) (4)	15 Dec 2020 16:31:31

US3552412

Folder: Illness Visit (1)

Form: Saliva Collection (1)

Generated On: 11 Aug 2021 22:53:07

[Date of Collection](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:11:21
User entered '04 Dec 2020'	(b) (4) Cassandra Zehenny (b) (4) (b) (4)	15 Dec 2020 16:31:31

US3552412

Folder: Illness Visit (1)

Form: Saliva Collection (2)

Generated On: 11 Aug 2021 22:53:07

[Visit](#)

Audit	User	Time (GMT)
User accepted default value 'Day 5 (Day 5)'	Cassandra Zehenny (b) (4) (b) (4)	15 Dec 2020 16:31:31

US3552412

Folder: Illness Visit (1)

Form: Saliva Collection (2)

Generated On: 11 Aug 2021 22:53:07

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:11:21
User entered 'Yes (Y)'	(b) (4) Cassandra Zehenny (b) (4) (b) (4)	15 Dec 2020 16:31:31

US3552412

Folder: Illness Visit (1)

Form: Saliva Collection (2)

Generated On: 11 Aug 2021 22:53:07

[Date of Collection](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:11:21
User entered '07 Dec 2020'	(b) (4) Cassandra Zehenny (b) (4) (b) (4)	15 Dec 2020 16:31:31

US3552412

Folder: Illness Visit (1)

Form: Saliva Collection (3)

Generated On: 11 Aug 2021 22:53:07

[Visit](#)

Audit	User	Time (GMT)
User accepted default value 'Day 7 (Day 7)'	Cassandra Zehenny (b) (4)	15 Dec 2020 16:31:31

US3552412

Folder: Illness Visit (1)

Form: Saliva Collection (3)

Generated On: 11 Aug 2021 22:53:07

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:11:21
User entered 'NA (COVID-19 Negative) (NA)'	(b) (4) Cassandra Zehenny (b) (4) (b) (4)	15 Dec 2020 16:31:31

US3552412

Folder: Illness Visit (1)

Form: Saliva Collection (3)

Generated On: 11 Aug 2021 22:53:07

[Date of Collection](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:11:21
User entered empty.	(b) (4) Cassandra Zehenny (b) (4) (b) (4)	15 Dec 2020 16:31:31

US3552412

Folder: Illness Visit (1)

Form: Saliva Collection (4)

Generated On: 11 Aug 2021 22:53:07

[Visit](#)

Audit	User	Time (GMT)
User accepted default value 'Day 9 (Day 9)'	Cassandra Zehenny (b) (4) (b) (4)	15 Dec 2020 16:31:31

US3552412

Folder: Illness Visit (1)

Form: Saliva Collection (4)

Generated On: 11 Aug 2021 22:53:07

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:11:21
User entered 'NA (COVID-19 Negative) (NA)'	(b) (4) Cassandra Zehenny (b) (4) (b) (4)	15 Dec 2020 16:31:31

US3552412

Folder: Illness Visit (1)

Form: Saliva Collection (4)

Generated On: 11 Aug 2021 22:53:07

[Date of Collection](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:11:21
User entered empty.	(b) (4) Cassandra Zehenny (b) (4) (b) (4)	15 Dec 2020 16:31:31

US3552412

Folder: Illness Visit (1)

Form: Saliva Collection (5)

Generated On: 11 Aug 2021 22:53:07

[Visit](#)

Audit	User	Time (GMT)
User accepted default value 'Day 14 (Day 14)'	Cassandra Zehenny (b) (4) (b) (4)	15 Dec 2020 16:31:31

US3552412

Folder: Illness Visit (1)

Form: Saliva Collection (5)

Generated On: 11 Aug 2021 22:53:07

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:11:21
User entered 'NA (COVID-19 Negative) (NA)'	(b) (4) Cassandra Zehenny (b) (4) (b) (4)	15 Dec 2020 16:31:31

US3552412

Folder: Illness Visit (1)

Form: Saliva Collection (5)

Generated On: 11 Aug 2021 22:53:07

[Date of Collection](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:11:21
User entered empty.	(b) (4) Cassandra Zehenny (b) (4) (b) (4)	15 Dec 2020 16:31:31

US3552412

Folder: Illness Visit (1)

Form: Saliva Collection (6)

Generated On: 11 Aug 2021 22:53:07

[Visit](#)

Audit	User	Time (GMT)
User accepted default value 'Day 21 (Day 21)'	Cassandra Zehenny (b) (4) (b) (4)	15 Dec 2020 16:31:31

US3552412

Folder: Illness Visit (1)

Form: Saliva Collection (6)

Generated On: 11 Aug 2021 22:53:07

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:11:21
User entered 'NA (COVID-19 Negative) (NA)'	(b) (4) Cassandra Zehenny (b) (4) (b) (4)	15 Dec 2020 16:31:31

US3552412

Folder: Illness Visit (1)

Form: Saliva Collection (6)

Generated On: 11 Aug 2021 22:53:07

[Date of Collection](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:11:21
User entered empty.	(b) (4) Cassandra Zehenny (b) (4) (b) (4)	15 Dec 2020 16:31:31

US3552412

Folder: Illness Visit (1)

Form: Saliva Collection (7)

Generated On: 11 Aug 2021 22:53:07

[Visit](#)

Audit	User	Time (GMT)
User accepted default value 'Day 28 (Day 28)'	Cassandra Zehenny (b) (4) (b) (4)	15 Dec 2020 16:31:31

US3552412

Folder: Illness Visit (1)

Form: Saliva Collection (7)

Generated On: 11 Aug 2021 22:53:07

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:11:21
User entered 'NA (COVID-19 Negative) (NA)'	(b) (4) Cassandra Zehenny (b) (4) (b) (4)	15 Dec 2020 16:31:31

US3552412

Folder: Illness Visit (1)

Form: Saliva Collection (7)

Generated On: 11 Aug 2021 22:53:07

[Date of Collection](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:11:21
User entered empty.	(b) (4) Cassandra Zehenny (b) (4) (b) (4)	15 Dec 2020 16:31:31

US3552412

Folder: Illness Visit (2)

Form: Saliva Collection (1)

Generated On: 11 Aug 2021 22:53:07

[Visit](#)

Audit	User	Time (GMT)
User accepted default value 'Day 3 (Day 3)'	Cassandra Zehenny (b) (4) (b) (4)	26 Jan 2021 15:48:18

US3552412

Folder: Illness Visit (2)

Form: Saliva Collection (1)

Generated On: 11 Aug 2021 22:53:07

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:11:21
User entered 'NA (COVID-19 Negative) (NA)'	(b) (4) Cassandra Zehenny (b) (4) (b) (4)	26 Jan 2021 15:48:18

US3552412

Folder: Illness Visit (2)

Form: Saliva Collection (1)

Generated On: 11 Aug 2021 22:53:07

[Date of Collection](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:11:21
User entered empty.	(b) (4) Cassandra Zehenny (b) (4) (b) (4)	26 Jan 2021 15:48:18

US3552412

Folder: Illness Visit (2)

Form: Saliva Collection (2)

Generated On: 11 Aug 2021 22:53:07

[Visit](#)

Audit	User	Time (GMT)
User accepted default value 'Day 5 (Day 5)'	Cassandra Zehenny (b) (4) (b) (4)	26 Jan 2021 15:48:18

US3552412

Folder: Illness Visit (2)

Form: Saliva Collection (2)

Generated On: 11 Aug 2021 22:53:07

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:11:21
User entered 'NA (COVID-19 Negative) (NA)'	(b) (4) Cassandra Zehenny (b) (4) (b) (4)	26 Jan 2021 15:48:18

US3552412

Folder: Illness Visit (2)

Form: Saliva Collection (2)

Generated On: 11 Aug 2021 22:53:07

[Date of Collection](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:11:21
User entered empty.	(b) (4) Cassandra Zehenny (b) (4) (b) (4)	26 Jan 2021 15:48:18

US3552412

Folder: Illness Visit (2)

Form: Saliva Collection (3)

Generated On: 11 Aug 2021 22:53:07

[Visit](#)

Audit	User	Time (GMT)
User accepted default value 'Day 7 (Day 7)'	Cassandra Zehenny (b) (4) (b) (4)	26 Jan 2021 15:48:18

US3552412

Folder: Illness Visit (2)

Form: Saliva Collection (3)

Generated On: 11 Aug 2021 22:53:07

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:11:21
User entered 'NA (COVID-19 Negative) (NA)'	(b) (4) Cassandra Zehenny (b) (4) (b) (4)	26 Jan 2021 15:48:18

US3552412

Folder: Illness Visit (2)

Form: Saliva Collection (3)

Generated On: 11 Aug 2021 22:53:07

[Date of Collection](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:11:21
User entered empty.	(b) (4) Cassandra Zehenny (b) (4) (b) (4)	26 Jan 2021 15:48:18

US3552412

Folder: Illness Visit (2)

Form: Saliva Collection (4)

Generated On: 11 Aug 2021 22:53:07

[Visit](#)

Audit	User	Time (GMT)
User accepted default value 'Day 9 (Day 9)'	Cassandra Zehenny (b) (4) (b) (4)	26 Jan 2021 15:48:18

US3552412

Folder: Illness Visit (2)

Form: Saliva Collection (4)

Generated On: 11 Aug 2021 22:53:07

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:11:21
User entered 'NA (COVID-19 Negative) (NA)'	(b) (4) Cassandra Zehenny (b) (4) (b) (4)	26 Jan 2021 15:48:18

US3552412

Folder: Illness Visit (2)

Form: Saliva Collection (4)

Generated On: 11 Aug 2021 22:53:07

[Date of Collection](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:11:21
User entered empty.	(b) (4) Cassandra Zehenny (b) (4) (b) (4)	26 Jan 2021 15:48:18

US3552412

Folder: Illness Visit (2)

Form: Saliva Collection (5)

Generated On: 11 Aug 2021 22:53:07

[Visit](#)

Audit	User	Time (GMT)
User accepted default value 'Day 14 (Day 14)'	Cassandra Zehenny (b) (4) (b) (4)	26 Jan 2021 15:48:18

US3552412

Folder: Illness Visit (2)

Form: Saliva Collection (5)

Generated On: 11 Aug 2021 22:53:07

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:11:21
User entered 'NA (COVID-19 Negative) (NA)'	(b) (4) Cassandra Zehenny (b) (4) (b) (4)	26 Jan 2021 15:48:18

US3552412

Folder: Illness Visit (2)

Form: Saliva Collection (5)

Generated On: 11 Aug 2021 22:53:07

[Date of Collection](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:11:21
User entered empty.	(b) (4) Cassandra Zehenny (b) (4) (b) (4)	26 Jan 2021 15:48:18

US3552412

Folder: Illness Visit (2)

Form: Saliva Collection (6)

Generated On: 11 Aug 2021 22:53:07

[Visit](#)

Audit	User	Time (GMT)
User accepted default value 'Day 21 (Day 21)'	Cassandra Zehenny (b) (4) (b) (4)	26 Jan 2021 15:48:18

US3552412

Folder: Illness Visit (2)

Form: Saliva Collection (6)

Generated On: 11 Aug 2021 22:53:07

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:11:21
User entered 'NA (COVID-19 Negative) (NA)'	(b) (4) Cassandra Zehenny (b) (4) (b) (4)	26 Jan 2021 15:48:18

US3552412

Folder: Illness Visit (2)

Form: Saliva Collection (6)

Generated On: 11 Aug 2021 22:53:07

[Date of Collection](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:11:21
User entered empty.	(b) (4) Cassandra Zehenny (b) (4) (b) (4)	26 Jan 2021 15:48:18

US3552412

Folder: Illness Visit (2)

Form: Saliva Collection (7)

Generated On: 11 Aug 2021 22:53:07

[Visit](#)

Audit	User	Time (GMT)
User accepted default value 'Day 28 (Day 28)'	Cassandra Zehenny (b) (4) (b) (4)	26 Jan 2021 15:48:18

US3552412

Folder: Illness Visit (2)

Form: Saliva Collection (7)

Generated On: 11 Aug 2021 22:53:07

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:11:21
User entered 'NA (COVID-19 Negative) (NA)'	(b) (4) Cassandra Zehenny (b) (4) (b) (4)	26 Jan 2021 15:48:18

US3552412

Folder: Illness Visit (2)

Form: Saliva Collection (7)

Generated On: 11 Aug 2021 22:53:07

[Date of Collection](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:11:21
User entered empty.	(b) (4) Cassandra Zehenny (b) (4) (b) (4)	26 Jan 2021 15:48:18

US3552412

Folder: Illness Visit Day 1 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:53:07

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 18:53:31
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 19:11:21
DataPoint Verified.	(b) (4), (b) (6)	01 Feb 2021 20:25:04
User entered 'Yes (Y)'	Stanley Doublin (b) (4) (b) (4)	03 Dec 2020 19:44:25

US3552412

Folder: Illness Visit Day 1 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:53:07

Visit date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 18:53:31
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 19:11:21
DataPoint Verified.	(b) (4), (b) (6)	01 Feb 2021 20:25:04
User closed query 'Per GCL Lab Reconciliation: Saliva: Sample dated 04DEC2020 and 07DEC2020 is reported under Illness Visit in PPD Central lab, however the sample details are missing in EDC. Please review if the sample has been collected for illness visit and update the details in Saliva collection log under appropriate visit, thank you.' (Site from DM).	(b) (4)	16 Dec 2020 11:48:31
Query 'Per GCL Lab Reconciliation: Saliva: Sample dated 04DEC2020 and 07DEC2020 is reported under Illness Visit in PPD Central lab, however the sample details are missing in EDC. Please review if the sample has been collected for illness visit and update the details in Saliva collection log under appropriate visit, thank you.' answered with 'updated' (Site from DM).	Cassandra Zehenny (b) (4) (b) (4)	15 Dec 2020 16:31:11
User opened query 'Per GCL Lab Reconciliation: Saliva: Sample dated 04DEC2020 and 07DEC2020 is reported under Illness Visit in PPD Central lab, however the sample details are missing in EDC. Please review if the sample has been collected for illness visit and update the details in Saliva collection log under appropriate visit, thank you.' (Site from DM).	(b) (4), (b) (6)	15 Dec 2020 10:43:02
User entered '03 Dec 2020'	Stanley Dublin (b) (4) (b) (4)	03 Dec 2020 19:44:25

US3552412

Folder: Illness Visit Day 1 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:53:07

[Was visit performed at the participant's home or at the clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 18:53:31
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 19:11:21
DataPoint Verified.	(b) (4), (b) (6)	01 Feb 2021 20:25:04
User entered 'Clinic (Clinic)'	Stanley Doublin (b) (4) (b) (4)	03 Dec 2020 19:44:25

US3552412

Folder: Illness Visit Day 1 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:53:07

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 18:53:31
User entered 'SICKD1'	System	03 Dec 2020 19:44:25

US3552412

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:53:07

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 18:53:31
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 19:11:21
DataPoint Verified.	(b) (4), (b) (6)	01 Feb 2021 20:26:13
User entered 'Yes (Y)'	Stanley Doublin (b) (4) (b) (4)	03 Dec 2020 19:45:43

US3552412

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:53:07

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 18:53:31
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 19:11:21
DataPoint Verified.	(b) (4), (b) (6)	01 Feb 2021 20:26:13
User entered '03 Dec 2020'	Stanley Doublin (b) (4) (b) (4)	03 Dec 2020 19:45:43

US3552412

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:53:07

Time of assessment (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 18:53:31
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 19:11:21
DataPoint Verified.	(b) (4), (b) (6)	01 Feb 2021 20:26:13
User entered '09:40'	Stanley Doublin (b) (4) (b) (4)	03 Dec 2020 19:45:43

US3552412

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:53:07

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 18:53:31
User entered '03 Dec 2020 09:40'	System	03 Dec 2020 19:45:43

US3552412

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:53:07

[Height \(xxx.x\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 18:53:31
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 19:11:21
DataPoint Verified.	(b) (4), (b) (6)	01 Feb 2021 20:26:13
User entered '65' in	Stanley Dublin (b) (4) (b) (4)	03 Dec 2020 19:45:43
DataPoint set to visible.	System	03 Dec 2020 19:44:25

US3552412

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:53:07

Weight (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 18:53:31
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:11:21
DataPoint Verified.	(b) (4)	01 Feb 2021 20:26:13
User entered '101' lb	(b) (4), (b) (6)	01 Feb 2021 20:26:13
DataPoint set to visible.	Stanley Doublin (b) (4)	03 Dec 2020 19:45:43
	(b) (4)	03 Dec 2020 19:44:25
	System	03 Dec 2020 19:44:25

US3552412

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:53:07

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 18:53:31
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 19:11:21
DataPoint Verified.	(b) (4), (b) (6)	01 Feb 2021 20:26:13
User entered '97.3' F	Stanley Doublin (b) (4) (b) (4)	03 Dec 2020 19:45:43

US3552412

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:53:07

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 18:53:31
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 19:11:21
DataPoint Verified.	(b) (4), (b) (6)	01 Feb 2021 20:26:13
User entered 'Oral (Oral)'	Stanley Doublin (b) (4) (b) (4)	03 Dec 2020 19:45:43

US3552412

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:53:07

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 18:53:31
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 19:11:21
DataPoint Verified.	(b) (4), (b) (6)	01 Feb 2021 20:26:13
User entered empty.	Stanley Doublin (b) (4) (b) (4)	03 Dec 2020 19:45:43

US3552412

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:53:07

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 18:53:31
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 19:11:21
DataPoint Verified.	(b) (4), (b) (6)	01 Feb 2021 20:26:13
User entered '85'	Stanley Doublin (b) (4) (b) (4)	03 Dec 2020 19:45:43

US3552412

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:53:07

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 18:53:31
User entered 'bpm'	System	03 Dec 2020 19:45:43

US3552412

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:53:07

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 18:53:31
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 19:11:21
DataPoint Verified.	(b) (4), (b) (6)	01 Feb 2021 20:26:13
User entered '14'	Stanley Doublin (b) (4) (b) (4)	03 Dec 2020 19:45:43

US3552412

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:53:07

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 18:53:31
User entered 'breaths/min'	System	03 Dec 2020 19:45:43

US3552412

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:53:07

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 18:53:31
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 19:11:21
DataPoint Verified.	(b) (4), (b) (6)	01 Feb 2021 20:26:13
User entered '100'	Stanley Doublin (b) (4) (b) (4)	03 Dec 2020 19:45:43

US3552412

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:53:07

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 18:53:31
User entered 'mmHg'	System	03 Dec 2020 19:45:43

US3552412

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:53:07

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 18:53:31
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 19:11:21
DataPoint Verified.	(b) (4), (b) (6)	01 Feb 2021 20:26:13
User entered '70'	Stanley Dublin (b) (4) (b) (4)	03 Dec 2020 19:45:43

US3552412

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:53:07

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 18:53:31
User entered 'mmHg'	System	03 Dec 2020 19:45:43

US3552412

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:53:07

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 18:53:31

US3552412

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:53:07

Weight (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 18:53:31

US3552412

Folder: Illness Visit Day 1 (1)

Form: Physical Examination

Generated On: 11 Aug 2021 22:53:07

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 18:53:31
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:11:21
DataPoint Verified.	(b) (4)	01 Feb 2021 20:26:22
User entered 'Yes (Y)'	(b) (4), (b) (6)	01 Feb 2021 20:26:22
	Stanley Doublin (b) (4)	03 Dec 2020 19:45:58
	(b) (4)	

US3552412

Folder: Illness Visit Day 1 (1)

Form: Physical Examination

Generated On: 11 Aug 2021 22:53:07

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 18:53:31
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 19:11:21
DataPoint Verified.	(b) (4), (b) (6)	01 Feb 2021 20:26:22
User entered '03 Dec 2020'	Stanley Doublin (b) (4) (b) (4)	03 Dec 2020 19:45:58

US3552412

Folder: Illness Visit Day 1 (1)

Form: Blood Sample Collection for Immunologic Assessment of SARS-CoV-2 Infection

Generated On: 11 Aug 2021 22:53:07

[Was Blood Sample Taken for Immunologic Assessment of SARS\\_COV-2 Infection?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 18:53:31
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 19:11:21
DataPoint Verified.	(b) (4), (b) (6)	01 Feb 2021 20:26:27
User entered 'Yes (Y)'	Cassandra Zehenny (b) (4) (b) (4)	03 Dec 2020 20:30:10

US3552412

Folder: Illness Visit Day 1 (1)

Form: Blood Sample Collection for Immunologic Assessment of SARS-CoV-2 Infection

Generated On: 11 Aug 2021 22:53:07

[Date of Collection](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 18:53:31
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:11:21
DataPoint Verified.	(b) (4)	01 Feb 2021 20:26:27
User entered '03 Dec 2020'	Cassandra Zehenny (b) (4)	03 Dec 2020 20:30:10
	(b) (4)	

US3552412

Folder: Illness Visit Day 1 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:53:07

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 18:53:31
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 19:11:21
DataPoint Verified.	(b) (4), (b) (6)	01 Feb 2021 20:16:07
User entered 'Yes (Y)'	Heather Douds (b) (4) (b) (4)	15 Jan 2021 18:04:26

US3552412

Folder: Illness Visit Day 1 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:53:07

Visit date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 18:53:31
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 19:11:21
DataPoint Verified.	(b) (4), (b) (6)	01 Feb 2021 20:16:07
User entered '15 Jan 2021'	Heather Douds (b) (4) (b) (4)	15 Jan 2021 18:04:26

US3552412

Folder: Illness Visit Day 1 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:53:07

[Was visit performed at the participant's home or at the clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 18:53:31
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:11:21
DataPoint Verified.	(b) (4)	01 Feb 2021 20:16:07
User entered 'Home (Home)'	Heather Doubs (b) (4)	15 Jan 2021 18:04:26
	(b) (4)	

US3552412

Folder: Illness Visit Day 1 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:53:07

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 18:53:31
User entered 'SICKD1'	System	15 Jan 2021 18:04:26

US3552412

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:53:07

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 18:53:31
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 19:11:21
DataPoint Verified.	(b) (4), (b) (6)	01 Feb 2021 20:17:26
User entered 'Yes (Y)'	Heather Douds (b) (4) (b) (4)	15 Jan 2021 18:05:05

US3552412

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:53:07

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 18:53:31
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 19:11:21
DataPoint Verified.	(b) (4), (b) (6)	01 Feb 2021 20:17:26
User entered '15 Jan 2021'	Heather Douds (b) (4) (b) (4)	15 Jan 2021 18:05:05

US3552412

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:53:07

Time of assessment (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 18:53:31
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:11:21
DataPoint Verified.	(b) (4), (b) (6)	01 Feb 2021 20:17:26
User entered '10:58'	Heather Douds (b) (4)	15 Jan 2021 18:05:05

US3552412

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:53:07

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 18:53:31
User entered '15 Jan 2021 10:58'	System	15 Jan 2021 18:05:05

US3552412

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:53:07

[Height \(xxx.x\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 18:53:31
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 19:11:21
DataPoint Verified.	(b) (4), (b) (6)	01 Feb 2021 20:17:26
User entered missing code ND - Not Done.	Heather Douds (b) (4) (b) (4)	15 Jan 2021 18:05:05
DataPoint set to visible.	System	15 Jan 2021 18:04:26

US3552412

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:53:07

Weight (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 18:53:31
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 19:11:21
DataPoint Verified.	(b) (4), (b) (6)	01 Feb 2021 20:17:26
User entered missing code ND - Not Done.	Heather Douds (b) (4) (b) (4)	15 Jan 2021 18:05:05
DataPoint set to visible.	System	15 Jan 2021 18:04:26

US3552412

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:53:07

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 18:53:31
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 19:11:21
DataPoint Verified.	(b) (4), (b) (6)	01 Feb 2021 20:17:26
User closed query 'Temperature reported is out of range < 36C (96.8 F) per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' (Site from System).		20 Jan 2021 04:21:15
Query 'Temperature reported is out of range < 36C (96.8 F) per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' answered with 'NCS' (Site from System).	Cassandra Zehenny (b) (4) (b) (4)	19 Jan 2021 19:19:57
User opened query 'Temperature reported is out of range < 36C (96.8 F) per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' (Site from System).	System	15 Jan 2021 18:05:05
User entered '96.5' F	Heather Douds (b) (4) (b) (4)	15 Jan 2021 18:05:05

US3552412

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:53:07

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 18:53:31
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 19:11:21
DataPoint Verified.	(b) (4), (b) (6)	01 Feb 2021 20:17:26
User entered 'Oral (Oral)'	Heather Douds (b) (4) (b) (4)	15 Jan 2021 18:05:05

US3552412

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:53:07

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 18:53:31
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 19:11:21
DataPoint Verified.	(b) (4), (b) (6)	01 Feb 2021 20:17:26
User entered empty.	Heather Douds (b) (4) (b) (4)	15 Jan 2021 18:05:05

US3552412

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:53:07

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 18:53:31
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 19:11:21
DataPoint Verified.	(b) (4), (b) (6)	01 Feb 2021 20:17:26
User entered '67'	Heather Douds (b) (4) (b) (4)	15 Jan 2021 18:05:05

US3552412

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:53:07

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 18:53:31
User entered 'bpm'	System	15 Jan 2021 18:05:05

US3552412

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:53:07

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 18:53:31
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 19:11:21
DataPoint Verified.	(b) (4), (b) (6)	01 Feb 2021 20:17:26
User entered '18'	Heather Douds (b) (4) (b) (4)	15 Jan 2021 18:05:05

US3552412

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:53:07

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 18:53:31
User entered 'breaths/min'	System	15 Jan 2021 18:05:05

US3552412

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:53:07

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 18:53:31
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 19:11:21
DataPoint Verified.	(b) (4), (b) (6)	01 Feb 2021 20:17:26
User closed query 'Per CDM: Systolic blood pressure is out of range per protocol. Please indicate if CS or NCS and report as AE, if appropriate ' (Site from DM).		21 Jan 2021 06:00:41
Query 'Per CDM: Systolic blood pressure is out of range per protocol. Please indicate if CS or NCS and report as AE, if appropriate ' answered with 'NCS' (Site from DM).	Cassandra Zehenny (b) (4) (b) (4)	20 Jan 2021 15:31:15
User opened query 'Per CDM: Systolic blood pressure is out of range per protocol. Please indicate if CS or NCS and report as AE, if appropriate ' (Site from DM).	(b) (4), (b) (6)	20 Jan 2021 04:23:40
User entered '80'	Heather Douds (b) (4) (b) (4)	15 Jan 2021 18:05:05

US3552412

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:53:07

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 18:53:31
User entered 'mmHg'	System	15 Jan 2021 18:05:05

US3552412

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:53:07

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 18:53:31
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:11:21
DataPoint Verified.	(b) (4)	01 Feb 2021 20:17:26
User closed query 'Diastolic Blood Pressure reported is out of range < 60 or > 110 per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' (Site from System).	(b) (4), (b) (6)	20 Jan 2021 04:22:03
Query 'Diastolic Blood Pressure reported is out of range < 60 or > 110 per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' answered with 'NCS' (Site from System).	Cassandra Zehenny (b) (4)	19 Jan 2021 19:20:03
User opened query 'Diastolic Blood Pressure reported System is out of range < 60 or > 110 per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' (Site from System).		15 Jan 2021 18:05:05
User entered '42'	Heather Douds (b) (4)	15 Jan 2021 18:05:05

US3552412

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:53:07

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 18:53:31
User entered 'mmHg'	System	15 Jan 2021 18:05:05

US3552412

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:53:07

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 18:53:31

US3552412

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:53:07

Weight (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 18:53:31

US3552412

Folder: Illness Visit Day 1 (1)

Form: Physical Examination

Generated On: 11 Aug 2021 22:53:07

Was the physical examination performed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 18:53:31
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 19:11:21
DataPoint Verified.	(b) (4), (b) (6)	09 Feb 2021 19:24:10
User closed query 'Per source, PE not performed - home visit . Please reconcile. ' (Site from CRA).		09 Feb 2021 19:24:06
Query 'Per source, PE not performed - home visit . Please reconcile. ' answered with 'updated, thank you!' (Site from CRA).	Cassandra Zehenny (b) (4) (b) (4)	02 Feb 2021 22:50:39
User entered 'No (N)' reason for change: Data Entry Error	Cassandra Zehenny (b) (4) (b) (4)	02 Feb 2021 22:50:29
User opened query 'Per source, PE not performed - home visit . Please reconcile. ' (Site from CRA).	(b) (4), (b) (6)	01 Feb 2021 20:18:56
User entered 'Yes (Y)'	Heather Douds (b) (4) (b) (4)	15 Jan 2021 18:05:23

US3552412

Folder: Illness Visit Day 1 (1)

Form: Physical Examination

Generated On: 11 Aug 2021 22:53:07

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 18:53:31
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 19:11:21
DataPoint Verified.	(b) (4), (b) (6)	09 Feb 2021 19:24:12
DataPoint Un-verified.	Cassandra Zehenny (b) (4) (b) (4)	02 Feb 2021 22:50:29
User entered empty; reason for change Data Entry Error	Cassandra Zehenny (b) (4) (b) (4)	02 Feb 2021 22:50:29
DataPoint Verified.	(b) (4), (b) (6)	01 Feb 2021 20:18:59
User entered '15 Jan 2021'	Heather Douds (b) (4) (b) (4)	15 Jan 2021 18:05:23

US3552412

Folder: Illness Visit Day 1 (1)

Form: Blood Sample Collection for Immunologic Assessment of SARS-CoV-2 Infection

Generated On: 11 Aug 2021 22:53:07

[Was Blood Sample Taken for Immunologic Assessment of SARS\\_COV-2 Infection?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 18:53:31
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 19:11:21
DataPoint Verified.	(b) (4), (b) (6)	01 Feb 2021 20:21:08
User entered 'Yes (Y)'	Heather Douds (b) (4) (b) (4)	15 Jan 2021 18:05:35

US3552412

Folder: Illness Visit Day 1 (1)

Form: Blood Sample Collection for Immunologic Assessment of SARS-CoV-2 Infection

Generated On: 11 Aug 2021 22:53:07

[Date of Collection](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 18:53:31
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 19:11:21
User closed query 'Per Lab Recon: SARS-COV2: Sample dated 15 JAN 2021, is still missing in PPD GCL records. Please review if the sample has been shipped, if yes, then please provide the Accession number, Tracking number, shipping date in response, as this helps to track the sample with the details provided. Please also confirm if the site had scan in barcodes through Preclarus, so that the data reflects in PPD GCL records. Thank you.' (Site from DM). Query 'Per Lab Recon: SARS-COV2: Sample dated 15 JAN 2021, is still missing in PPD GCL records. Please review if the sample has been shipped, if yes, then please provide the Accession number, Tracking number, shipping date in response, as this helps to track the sample with the details provided. Please also confirm if the site had scan in barcodes through Preclarus, so that the data reflects in PPD GCL records. Thank you.' answered with '1F60IGN' (Site from DM).	(b) (4), (b) (6)	15 Feb 2021 18:23:01
DataPoint Verified.	Cassandra Zehenny (b) (4) (b) (4)	03 Feb 2021 22:26:38
User opened query 'Per Lab Recon: SARS-COV2: Sample dated 15 JAN 2021, is still missing in PPD GCL records. Please review if the sample has been shipped, if yes, then please provide the Accession number, Tracking number, shipping date in response, as this helps to track the sample with the details provided. Please also confirm if the site had scan in barcodes through Preclarus, so that the data reflects in PPD GCL records. Thank you.' (Site from DM). User entered '15 Jan 2021'	(b) (4), (b) (6)	01 Feb 2021 20:21:10
		29 Jan 2021 12:31:01
	Heather Douds (b) (4) (b) (4)	15 Jan 2021 18:05:35

US3552412

Folder: Participant Decision Visit / OL-D1 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:53:07

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:04:38
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:11:21
User entered 'Yes (Y)'	(b) (4) Stanley Dublin (b) (4) (b) (4)	13 Jan 2021 14:23:25

US3552412

Folder: Participant Decision Visit / OL-D1 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:53:07

[Visit date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:04:38
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:11:21
User entered '12 Jan 2021'	(b) (4) Stanley Dublin (b) (4) (b) (4)	13 Jan 2021 14:23:25

US3552412

Folder: Participant Decision Visit / OL-D1 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:53:07

[Was visit performed at the participant's home or at the clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:04:38
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:11:21
User entered 'Clinic (Clinic)'	(b) (4) Stanley Doublin (b) (4) (b) (4)	13 Jan 2021 14:23:25

US3552412

Folder: Participant Decision Visit / OL-D1 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:53:07

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:04:38
User entered 'UNBLND_DECIDE'	System	13 Jan 2021 14:23:25

US3552412

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 11 Aug 2021 22:53:07

Date of updated informed consent (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:04:38
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:11:21
User entered '12 Jan 2021'	(b) (4) Stanley Dublin (b) (4) (b) (4)	13 Jan 2021 14:23:39

US3552412

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 11 Aug 2021 22:53:07

[N/A - Subject Unblinded under Amendment 5 and Discontinued from Study](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:04:38
User signature succeeded.	sharon frey (b) (4)	23 Mar 2021 15:40:44
User entered '0' WR# 5295537	(b) (4)	10 Mar 2021 16:55:28
Amendment Manager inserted this DataPoint.	System	06 Mar 2021 19:15:04

US3552412

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 11 Aug 2021 22:53:07

[Was the participant unblinded?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:04:38
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:11:21
User entered 'Yes (Y)'	(b) (4) Stanley Dublin (b) (4) (b) (4)	13 Jan 2021 14:23:39

US3552412

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 11 Aug 2021 22:53:07

[Under what version of the Protocol was the Participant unblinded?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:04:38
User signature succeeded.	sharon frey (b) (4)	23 Mar 2021 15:40:44
User entered 'AMENDMENT 6 OR LATER (AMENDMENT 6 OR LATER)' WR# 5295537	(b) (4) System	10 Mar 2021 16:55:28
Amendment Manager inserted this DataPoint.	System	06 Mar 2021 19:15:04

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Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 11 Aug 2021 22:53:07

Date of unblinding (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:04:38
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:11:21
User entered '12 Jan 2021'	(b) (4) Stanley Dublin (b) (4) (b) (4)	13 Jan 2021 14:23:39

US3552412

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 11 Aug 2021 22:53:07

[Participant randomization assignment](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:04:38
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:11:21
User entered 'mRNA-1273 (mRNA-1273)'	(b) (4) Stanley Doublin (b) (4)	13 Jan 2021 14:23:39

US3552412

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 11 Aug 2021 22:53:07

[Actual Dose 1](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:04:38
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:11:21
Amendment Manager: User entered 'mRNA-1273 (mRNA-1273)'	(b) (4)	20 Jan 2021 14:49:45
User entered 'mRNA-1273 (mRNA-1273)'	Stanley Dublin (b) (4)	13 Jan 2021 14:23:39
	(b) (4)	

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Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 11 Aug 2021 22:53:07

[Actual Dose 2](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:04:38
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:11:21
Amendment Manager: User entered 'mRNA-1273 (mRNA-1273)'	(b) (4)	20 Jan 2021 14:49:45
User entered 'mRNA-1273 (mRNA-1273)'	Stanley Dublin (b) (4)	13 Jan 2021 14:23:39
	(b) (4)	

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Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 11 Aug 2021 22:53:07

[Will participant receive mRNA-1273?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:04:38
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:11:21
User entered 'No (N)'	(b) (4) Stanley Doublin (b) (4) (b) (4)	13 Jan 2021 14:23:39

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Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 11 Aug 2021 22:53:07

[Placebo Only Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:04:38
User entered empty.	System	13 Jan 2021 14:23:39

**US3552412**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Unblinding**

**Generated On: 11 Aug 2021 22:53:07**

[Continuing with mRNA-1273](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:04:38
User entered empty.	System	13 Jan 2021 14:23:39

US3552412

Folder: Participant Decision Visit / OL-D1 (1)

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:53:07

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:04:38
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:11:21
User entered 'Yes (Y)'	(b) (4) Stanley Dublin (b) (4)	13 Jan 2021 14:23:49

US3552412

Folder: Participant Decision Visit / OL-D1 (1)

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:53:07

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:04:38
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:11:21
User entered '12 Jan 2021'	(b) (4) Stanley Dublin (b) (4) (b) (4)	13 Jan 2021 14:23:49

US3552412

Folder: Participant Decision Visit / OL-D1 (1)

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:53:07

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:04:38
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:11:21
User entered '14:59'	(b) (4) Stanley Dublin (b) (4) (b) (4)	13 Jan 2021 14:23:49

US3552412

Folder: Participant Decision Visit / OL-D1 (1)

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:53:07

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:04:38
User entered '12 Jan 2021 14:59'	System	13 Jan 2021 14:23:49

US3552412

Folder: Participant Decision Visit / OL-D1 (1)

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 11 Aug 2021 22:53:07

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:04:38
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:11:21
User entered 'Yes (Y)'	(b) (4) Stanley Dublin (b) (4) (b) (4)	13 Jan 2021 14:24:00

US3552412

Folder: Participant Decision Visit / OL-D1 (1)

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 11 Aug 2021 22:53:07

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:04:38
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:11:21
User entered '12 Jan 2021'	(b) (4) Stanley Dublin (b) (4) (b) (4)	13 Jan 2021 14:24:00

US3552412

Folder: Participant Decision Visit / OL-D1 (1)

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 11 Aug 2021 22:53:07

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:04:38
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:11:21
User entered '15:03'	(b) (4) Stanley Dublin (b) (4) (b) (4)	13 Jan 2021 14:24:00

**US3552412**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Central Laboratory - Nasopharyngeal Swab (Single)**

**Generated On: 11 Aug 2021 22:53:07**

[Collection Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:04:38
User entered '12 Jan 2021 15:03'	System	13 Jan 2021 14:24:00

US3552412

Folder: Adverse Events

Form: Adverse Events Summary

Generated On: 11 Aug 2021 22:53:07

[Did the participant experience any adverse events?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:38:39
User closed query 'Per DM CLR: Per Safety Follow Up Diary Day 71, 'Any changes since last questionnaire or contact with study clinic?'; and 'Have you contacted a healthcare provider since last questionnaire or study contact?' = YES, however, there is no corresponding AE recorded for this information in the AE eCRF page within this timeframe. Please confirm and update if a Medically-attended AE should be recorded, otherwise provide clarification. ' (Site from DM).		30 Mar 2021 12:38:17
Query 'Per DM CLR: Per Safety Follow Up Diary Day 71, 'Any changes since last questionnaire or contact with study clinic?'; and 'Have you contacted a healthcare provider since last questionnaire or study contact?' = YES, however, there is no corresponding AE recorded for this information in the AE eCRF page within this timeframe. Please confirm and update if a Medically-attended AE should be recorded, otherwise provide clarification. ' answered with 'reported exposure to COVID, no AE to report' (Site from DM).	Cassandra Zehenny (b) (4) (b) (4)	29 Mar 2021 16:27:15
User opened query 'Per DM CLR: Per Safety Follow Up Diary Day 71, 'Any changes since last questionnaire or contact with study clinic?'; and 'Have you contacted a healthcare provider since last questionnaire or study contact?' = YES, however, there is no corresponding AE recorded for this information in the AE eCRF page within this timeframe. Please confirm and update if a Medically-attended AE should be recorded, otherwise provide clarification. ' (Site from DM).	(b) (4), (b) (6)	27 Mar 2021 06:40:31
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 19:11:21
User entered 'Yes (Y)'	Mikayla Frye (b) (4) (b) (4)	04 Dec 2020 16:33:10

US3552412

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:53:07

[Adverse event](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:11:21
User coded data point as SOC: Infections and infestations, HLGT: Viral infectious disorders, HLT: Rhinoviral infections, PT: Rhinovirus infection, LLT: Rhinovirus infection - version MedDRA\\23.0.	(b) (4) Coder Import (b) (4)	04 Dec 2020 16:36:02
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	04 Dec 2020 16:36:02
Data point term sent to Coder	System	04 Dec 2020 16:35:13
User entered 'rhino/enterovirus'	Mikayla Frye (b) (4) (b) (4)	04 Dec 2020 16:34:12

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:53:07

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:11:21
User entered 'Yes (Y)'	(b) (4) Mikayla Frye (b) (4) (b) (4)	04 Dec 2020 16:34:12

US3552412

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:53:07

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:11:21
User entered 'No (N)'	(b) (4) Mikayla Frye (b) (4) (b) (4)	04 Dec 2020 16:34:12

US3552412

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:53:07

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:11:21
User entered 'No (N)'	(b) (4) Mikayla Frye (b) (4) (b) (4)	04 Dec 2020 16:34:12

US3552412

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:53:07

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:11:21
User entered '27 Nov 2020'	(b) (4) Mikayla Frye (b) (4) (b) (4)	04 Dec 2020 16:34:12

US3552412

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:53:07

Start time (00:00-23:59)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:11:21
User entered empty.	(b) (4) Mikayla Frye (b) (4) (b) (4)	04 Dec 2020 16:34:12

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:53:07

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	04 Dec 2020 16:34:12

US3552412

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:53:07

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:11:21
User entered 'No (N)' reason for change: Data Entry Error	(b) (4) Stanley Doublin (b) (4)	08 Dec 2020 14:29:01
User entered 'Yes (Y)'	(b) (4) Mikayla Frye (b) (4)	04 Dec 2020 16:34:12

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:53:07

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:11:21
User closed query 'Outcome is not Recovered/Resolved, Recovered/Resolved with sequelae or Fatal, but End Date is provided. Please correct.' (Site from System).	(b) (4) System	08 Dec 2020 14:29:09
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	08 Dec 2020 14:29:09
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	08 Dec 2020 14:29:01
User entered '08 Dec 2020' reason for change: Data Entry Error	Stanley Doublin (b) (4)	08 Dec 2020 14:29:01
User entered empty.	(b) (4) Mikayla Frye (b) (4) (b) (4)	04 Dec 2020 16:34:12

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:53:07

End time (00:00-23:59)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:11:21
User entered empty.	(b) (4) Mikayla Frye (b) (4) (b) (4)	04 Dec 2020 16:34:12

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**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 11 Aug 2021 22:53:07**

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	04 Dec 2020 16:34:12

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:53:07

[Severity](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:11:21
User entered 'Grade 1/Mild (Grade 1/Mild)'	(b) (4) Mikayla Frye (b) (4) (b) (4)	04 Dec 2020 16:34:12

US3552412

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:53:07

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:11:21
User entered 'No (N)'	(b) (4) Mikayla Frye (b) (4) (b) (4)	04 Dec 2020 16:34:12

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:53:07

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:11:21
User entered '0'	(b) (4) Mikayla Frye (b) (4) (b) (4)	04 Dec 2020 16:34:12

US3552412

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:53:07

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:11:21
User entered '0'	(b) (4) Mikayla Frye (b) (4) (b) (4)	04 Dec 2020 16:34:12

US3552412

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:53:07

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:11:21
User entered '0'	(b) (4) Mikayla Frye (b) (4) (b) (4)	04 Dec 2020 16:34:12

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:53:07

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:11:21
User entered empty.	(b) (4) Mikayla Frye (b) (4) (b) (4)	04 Dec 2020 16:34:12

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:53:07

Hospital Discharge Date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:11:21
User entered empty.	(b) (4) Mikayla Frye (b) (4) (b) (4)	04 Dec 2020 16:34:12

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:53:07

[Admitted to ICU?](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:11:21
User entered empty.	(b) (4) Mikayla Frye (b) (4) (b) (4)	04 Dec 2020 16:34:12

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:53:07

[Number of Days in ICU](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:11:21
User entered empty.	(b) (4) Mikayla Frye (b) (4) (b) (4)	04 Dec 2020 16:34:12

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:53:07

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:11:21
User entered '0'	(b) (4) Mikayla Frye (b) (4) (b) (4)	04 Dec 2020 16:34:12

US3552412

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:53:07

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:11:21
User entered '0'	(b) (4) Mikayla Frye (b) (4) (b) (4)	04 Dec 2020 16:34:12

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:53:07

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:11:21
User entered '0'	(b) (4) Mikayla Frye (b) (4) (b) (4)	04 Dec 2020 16:34:12

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:53:07

[Relationship to investigational product](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:11:21
User entered 'Not Related (NOT RELATED)'	(b) (4) Mikayla Frye (b) (4) (b) (4)	04 Dec 2020 16:34:12

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:53:07

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:11:21
User entered 'Not Related (NOT RELATED)'	(b) (4) Mikayla Frye (b) (4) (b) (4)	04 Dec 2020 16:34:12

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:53:07

[Action taken with investigational product](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:11:21
User entered 'Not Applicable (NOT APPLICABLE)'	(b) (4) Mikayla Frye (b) (4) (b) (4)	04 Dec 2020 16:34:12

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:53:07

None

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:11:21
User entered 'I'	(b) (4) Mikayla Frye (b) (4) (b) (4)	04 Dec 2020 16:34:12

US3552412

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:53:07

[Concomitant Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:11:21
User entered '0'	(b) (4) Mikayla Frye (b) (4) (b) (4)	04 Dec 2020 16:34:12

US3552412

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:53:07

[Concomitant Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:11:21
User entered '0'	(b) (4) Mikayla Frye (b) (4) (b) (4)	04 Dec 2020 16:34:12

US3552412

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:53:07

[Outcome](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:11:21
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)' reason for change: Data Entry Error	(b) (4) Stanley Doublin (b) (4)	08 Dec 2020 14:29:09
User entered 'Recovering/Resolving (RECOVERING/RESOLVING)'	Mikayla Frye (b) (4)	04 Dec 2020 16:34:12

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:53:07

If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:11:21
User entered empty.	(b) (4) Mikayla Frye (b) (4) (b) (4)	04 Dec 2020 16:34:12

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:53:07

[Narrative](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:11:21
User entered empty.	(b) (4) Mikayla Frye (b) (4) (b) (4)	04 Dec 2020 16:34:12

US3552412

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:53:07

Serious Adverse Event Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
User entered '0'	System	04 Dec 2020 16:34:12

US3552412

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:53:07

Medically Attended AE Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
User entered 'I'	System	04 Dec 2020 16:34:12

US3552412

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 22:53:07

[AEID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:50:51

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 22:53:07

[Adverse event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:50:51
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:11:21
User coded data point as SOC: Infections and infestations, HLGT: Viral infectious disorders, HLT: Rhinoviral infections, PT: Rhinovirus infection, LLT: Rhinovirus infection - version MedDRA\\23.0.	Coder Import (b) (4)	22 Jan 2021 18:56:03
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4)	22 Jan 2021 18:56:03
Data point term sent to Coder	System	20 Jan 2021 14:47:11
User entered 'rhino / enterovirus'	Mikayla Frye (b) (4)	20 Jan 2021 14:46:10

US3552412

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 22:53:07

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:50:51
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:11:21
User entered 'Yes (Y)'	(b) (4) Mikayla Frye (b) (4) (b) (4)	20 Jan 2021 14:46:10

US3552412

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 22:53:07

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:50:51
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:11:21
User entered 'No (N)'	(b) (4) Mikayla Frye (b) (4) (b) (4)	20 Jan 2021 14:46:10

US3552412

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 22:53:07

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:50:51
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:11:21
User entered 'No (N)'	(b) (4) Mikayla Frye (b) (4) (b) (4)	20 Jan 2021 14:46:10

US3552412

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 22:53:07

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:50:51
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:11:21
User entered '15 Jan 2021'	(b) (4) Mikayla Frye (b) (4) (b) (4)	20 Jan 2021 14:46:10

US3552412

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 22:53:07

Start time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:50:51
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:11:21
User entered empty.	(b) (4) Mikayla Frye (b) (4) (b) (4)	20 Jan 2021 14:46:10

US3552412

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 22:53:07

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:50:51
User entered empty.	System	20 Jan 2021 14:46:10

US3552412

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 22:53:07

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:50:51
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:11:21
User entered 'No (N)' reason for change: Data Entry Error	(b) (4)	
	Stanley Dublin (b) (4)	05 Feb 2021 15:36:26
User entered 'Yes (Y)'	(b) (4)	
	Mikayla Frye (b) (4)	20 Jan 2021 14:46:10
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 22:53:07

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:50:51
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:11:21
User entered '25 Jan 2021' reason for change: Data Entry Error	(b) (4)	
	Stanley Dublin (b) (4)	05 Feb 2021 15:36:26
User entered empty.	(b) (4)	
	Mikayla Frye (b) (4)	20 Jan 2021 14:46:10
	(b) (4)	

US3552412

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 22:53:07

[End time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:50:51
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:11:21
User entered empty.	(b) (4) Mikayla Frye (b) (4) (b) (4)	20 Jan 2021 14:46:10

US3552412

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 22:53:07

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:50:51
User entered empty.	System	20 Jan 2021 14:46:10

US3552412

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 22:53:07

[Severity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:50:51
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:11:21
User entered 'Grade 1/Mild (Grade 1/Mild)'	(b) (4) Mikayla Frye (b) (4) (b) (4)	20 Jan 2021 14:46:10

US3552412

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 22:53:07

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:50:51
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:11:21
User entered 'No (N)'	(b) (4) Mikayla Frye (b) (4) (b) (4)	20 Jan 2021 14:46:10

US3552412

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 22:53:07

[Death](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:50:51
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:11:21
User entered '0'	(b) (4) Mikayla Frye (b) (4) (b) (4)	20 Jan 2021 14:46:10

US3552412

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 22:53:07

[Life threatening](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:50:51
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:11:21
User entered '0'	(b) (4) Mikayla Frye (b) (4) (b) (4)	20 Jan 2021 14:46:10

US3552412

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 22:53:07

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:50:51
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:11:21
User entered '0'	(b) (4) Mikayla Frye (b) (4) (b) (4)	20 Jan 2021 14:46:10

US3552412

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 22:53:07

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:50:51
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:11:21
User entered empty.	(b) (4) Mikayla Frye (b) (4) (b) (4)	20 Jan 2021 14:46:10

US3552412

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 22:53:07

Hospital Discharge Date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:50:51
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:11:21
User entered empty.	(b) (4) Mikayla Frye (b) (4) (b) (4)	20 Jan 2021 14:46:10

US3552412

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 22:53:07

[Admitted to ICU?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:50:51
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:11:21
User entered empty.	(b) (4) Mikayla Frye (b) (4) (b) (4)	20 Jan 2021 14:46:10

US3552412

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 22:53:07

[Number of Days in ICU](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:50:51
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:11:21
User entered empty.	(b) (4) Mikayla Frye (b) (4) (b) (4)	20 Jan 2021 14:46:10

US3552412

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 22:53:07

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:50:51
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:11:21
User entered '0'	(b) (4) Mikayla Frye (b) (4) (b) (4)	20 Jan 2021 14:46:10

US3552412

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 22:53:07

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:50:51
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:11:21
User entered '0'	(b) (4) Mikayla Frye (b) (4) (b) (4)	20 Jan 2021 14:46:10

US3552412

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 22:53:07

[Other medically important event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:50:51
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:11:21
User entered '0'	(b) (4) Mikayla Frye (b) (4) (b) (4)	20 Jan 2021 14:46:10

US3552412

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 22:53:07

[Relationship to investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:50:51
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:11:21
User entered 'Not Related (NOT RELATED)'	(b) (4) Mikayla Frye (b) (4) (b) (4)	20 Jan 2021 14:46:10

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 22:53:07

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:50:51
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:11:21
User entered 'Not Related (NOT RELATED)'	(b) (4) Mikayla Frye (b) (4) (b) (4)	20 Jan 2021 14:46:10

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 22:53:07

[Action taken with investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:50:51
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:11:21
User entered 'Not Applicable (NOT APPLICABLE)'	(b) (4) Mikayla Frye (b) (4) (b) (4)	20 Jan 2021 14:46:10

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 22:53:07

None

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:50:51
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:11:21
User closed query 'Other action taken is missing. Please check at least one action from the options provided.' (Site from System).	(b) (4) System	20 Jan 2021 14:46:17
User entered '1' reason for change: Data Entry Error	Mikayla Frye (b) (4)	20 Jan 2021 14:46:17
User opened query 'Other action taken is missing. Please check at least one action from the options provided.' (Site from System).	(b) (4) System	20 Jan 2021 14:46:10
User entered '0'	Mikayla Frye (b) (4) (b) (4)	20 Jan 2021 14:46:10

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 22:53:07

[Concomitant Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:50:51
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:11:21
User entered '0'	(b) (4) Mikayla Frye (b) (4) (b) (4)	20 Jan 2021 14:46:10

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 22:53:07

[Concomitant Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:50:51
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:11:21
User entered '0'	(b) (4) Mikayla Frye (b) (4) (b) (4)	20 Jan 2021 14:46:10

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 22:53:07

[Outcome](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:50:51
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:11:21
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)' reason for change:	(b) (4)	
Data Entry Error	Stanley Dublin (b) (4)	05 Feb 2021 15:36:26
User entered 'Recovering/Resolving (RECOVERING/RESOLVING)'	(b) (4)	
	Mikayla Frye (b) (4)	20 Jan 2021 14:46:10
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 22:53:07

If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:50:51
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:11:21
User entered empty.	(b) (4) Mikayla Frye (b) (4) (b) (4)	20 Jan 2021 14:46:10

US3552412

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 22:53:07

[Narrative](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:50:51
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:11:21
User entered empty.	(b) (4) Mikayla Frye (b) (4) (b) (4)	20 Jan 2021 14:46:10

US3552412

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 22:53:07

Serious Adverse Event Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:50:51
User entered '0'	System	20 Jan 2021 14:46:10

US3552412

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 22:53:07

Medically Attended AE Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:50:51
User entered 'l'	System	20 Jan 2021 14:46:10

US3552412

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 22:53:07

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:50:51

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**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination Summary**

**Generated On: 11 Aug 2021 22:53:07**

[Were any prior/concomitant medications and/or vaccinations taken?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:38:39
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 19:11:21
User entered 'Yes (Y)'	Stanley Dublin (b) (4) (b) (4)	12 Sep 2020 19:10:28

US3552412

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 22:53:07

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:11:21
User coded data point as ATC: MUSCULO-SKELETAL SYSTEM, ATC: ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, ATC: ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, NON-STEROIDS, ATC: PROPIONIC ACID DERIVATIVES, PRODUCT: IBUPROFEN - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4)	12 Sep 2020 19:12:33
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	12 Sep 2020 19:12:33
Data point term sent to Coder	System	12 Sep 2020 19:11:36
User entered 'ibuprofen'	Stanley Doublin (b) (4)	12 Sep 2020 19:11:01

US3552412

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 11 Aug 2021 22:53:07**

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:11:21
User entered 'No (N)'	(b) (4) Stanley Doublin (b) (4) (b) (4)	12 Sep 2020 19:11:01

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**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 11 Aug 2021 22:53:07**

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:11:21
User entered 'headache'	(b) (4) Stanley Doublin (b) (4) (b) (4)	12 Sep 2020 19:11:01

US3552412

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 11 Aug 2021 22:53:07**

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:11:21
User entered '400'	(b) (4) Stanley Doublin (b) (4) (b) (4)	12 Sep 2020 19:11:01

US3552412

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 22:53:07

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:11:21
User entered 'mg (mg)'	(b) (4) Stanley Doublin (b) (4) (b) (4)	12 Sep 2020 19:11:01

US3552412

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 11 Aug 2021 22:53:07**

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:11:21
User entered empty.	(b) (4) Stanley Doublin (b) (4) (b) (4)	12 Sep 2020 19:11:01

US3552412

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 11 Aug 2021 22:53:07**

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:11:21
User entered 'as needed (PRN)'	(b) (4) Stanley Doublin (b) (4) (b) (4)	12 Sep 2020 19:11:01

US3552412

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 11 Aug 2021 22:53:07**

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:11:21
User entered empty.	(b) (4) Stanley Doublin (b) (4) (b) (4)	12 Sep 2020 19:11:01

US3552412

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 11 Aug 2021 22:53:07**

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:11:21
User entered 'Oral (ORAL)'	(b) (4) Stanley Doublin (b) (4) (b) (4)	12 Sep 2020 19:11:01

US3552412

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 11 Aug 2021 22:53:07**

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:11:21
User entered empty.	(b) (4) Stanley Doublin (b) (4) (b) (4)	12 Sep 2020 19:11:01

US3552412

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 11 Aug 2021 22:53:07**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:11:21
User entered 'un UNK 2000'	(b) (4) Stanley Doublin (b) (4) (b) (4)	12 Sep 2020 19:11:01

US3552412

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 11 Aug 2021 22:53:07**

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:11:21
User entered '0'	(b) (4) Stanley Doublin (b) (4) (b) (4)	12 Sep 2020 19:11:01

US3552412

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 11 Aug 2021 22:53:07**

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:11:21
User entered 'Yes (Y)'	(b) (4) Stanley Doublin (b) (4) (b) (4)	12 Sep 2020 19:11:01

US3552412

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 11 Aug 2021 22:53:07**

*If not Ongoing, End date (dd MMM yyyy)*

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:11:21
User entered empty.	(b) (4) Stanley Doublin (b) (4) (b) (4)	12 Sep 2020 19:11:01

US3552412

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 11 Aug 2021 22:53:07**

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:11:21
User entered 'No (N)'	(b) (4) Stanley Doublin (b) (4) (b) (4)	12 Sep 2020 19:11:01

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**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 11 Aug 2021 22:53:07**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	12 Sep 2020 19:11:01

US3552412

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 11 Aug 2021 22:53:07**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	12 Sep 2020 19:11:01

US3552412

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 11 Aug 2021 22:53:07**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	12 Sep 2020 19:11:01

US3552412

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 22:53:07

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:28:14
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:11:21
User coded data point as ATC: GENITO URINARY SYSTEM AND SEX HORMONES, ATC: OTHER GYNECOLOGICALS, ATC: CONTRACEPTIVES FOR TOPICAL USE, ATC: INTRAUTERINE CONTRACEPTIVES, PRODUCT: LEVONORGESTREL, PRODUCTSYNONYM: MIRENA - version WHODrug-Global-B3\202003.	(b) (4)	
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\202003.	Coder Import (b) (4)	12 Sep 2020 19:14:38
Data point term sent to Coder User entered 'mirena IUD'	(b) (4)	
	System	12 Sep 2020 19:13:40
	Stanley Doublin (b) (4)	12 Sep 2020 19:13:07
	(b) (4)	

US3552412

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 22:53:07

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:28:14
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:11:21
User entered 'Yes (Y)'	(b) (4) Stanley Dublin (b) (4)	12 Sep 2020 19:13:07

US3552412

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 22:53:07

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:28:14
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:11:21
User entered 'contraception'	(b) (4) Stanley Dublin (b) (4) (b) (4)	12 Sep 2020 19:13:07

US3552412

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 22:53:07

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:28:14
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:11:21
User entered '52'	(b) (4) Stanley Dublin (b) (4)	12 Sep 2020 19:13:07

US3552412

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 22:53:07

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:28:14
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:11:21
User entered 'mg (mg)'	(b) (4) Stanley Dublin (b) (4) (b) (4)	12 Sep 2020 19:13:07

US3552412

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 22:53:07

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:28:14
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:11:21
User entered empty.	(b) (4) Stanley Dublin (b) (4)	12 Sep 2020 19:13:07

US3552412

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 22:53:07

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:28:14
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:11:21
User entered 'once daily (QD)'	(b) (4) Stanley Dublin (b) (4)	12 Sep 2020 19:13:07

US3552412

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 22:53:07

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:28:14
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:11:21
User entered empty.	(b) (4) Stanley Dublin (b) (4) (b) (4)	12 Sep 2020 19:13:07

US3552412

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 11 Aug 2021 22:53:07**

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:28:14
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:11:21
User entered 'Other (OTHER)'	(b) (4) Stanley Dublin (b) (4) (b) (4)	12 Sep 2020 19:13:07

US3552412

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 22:53:07

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:28:14
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:11:21
User entered 'intrauterine'	(b) (4) Stanley Dublin (b) (4) (b) (4)	12 Sep 2020 19:13:07

US3552412

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 22:53:07

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:28:14
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:11:21
User entered '07 Oct 2019'	(b) (4) Stanley Dublin (b) (4)	12 Sep 2020 19:13:07

US3552412

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 22:53:07

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:28:14
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:11:21
User entered '0'	(b) (4) Stanley Dublin (b) (4) (b) (4)	12 Sep 2020 19:13:07

US3552412

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 22:53:07

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:28:14
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:11:21
User entered 'No (N)' reason for change: New Information	Mikayla Frye (b) (4)	07 Jan 2021 21:34:54
User entered 'Yes (Y)'	Stanley Dublin (b) (4)	12 Sep 2020 19:13:07

US3552412

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 22:53:07

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:28:14
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:11:21
User entered '06 Jan 2021' reason for change: New Information	Mikayla Frye (b) (4)	07 Jan 2021 21:34:54
User entered empty.	Stanley Dublin (b) (4)	12 Sep 2020 19:13:07

US3552412

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 22:53:07

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:28:14
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:11:21
User entered 'No (N)'	(b) (4) Stanley Dublin (b) (4) (b) (4)	12 Sep 2020 19:13:07

US3552412

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 11 Aug 2021 22:53:07**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:28:14
User entered 'I'	System	12 Sep 2020 19:13:07

US3552412

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 11 Aug 2021 22:53:07**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:28:14
User entered '1'	System	12 Sep 2020 19:13:07

US3552412

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 11 Aug 2021 22:53:07**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:28:14
User entered '804 (804)'	System	12 Sep 2020 19:13:07

US3552412

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 11 Aug 2021 22:53:07

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:11:21
User coded data point as ATC: DERMATOLOGICALS, ATC: ANTI-ACNE PREPARATIONS, ATC: ANTI-ACNE PREPARATIONS FOR TOPICAL USE, ATC: RETINOIDS FOR TOPICAL USE IN ACNE, PRODUCT: ADAPALENE, PRODUCTSYNONYM: DIFFERIN - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4)	09 Oct 2020 15:55:34
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	09 Oct 2020 15:55:34
Data point term sent to Coder	System	09 Oct 2020 15:27:48
User entered 'differin .1%'	Stanley Doublin (b) (4) (b) (4)	09 Oct 2020 15:27:28

US3552412

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 11 Aug 2021 22:53:07**

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:11:21
User entered 'No (N)'	(b) (4) Stanley Doublin (b) (4) (b) (4)	09 Oct 2020 15:27:28

US3552412

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 11 Aug 2021 22:53:07**

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:11:21
User entered 'acne'	(b) (4) Stanley Doublin (b) (4) (b) (4)	09 Oct 2020 15:27:28

US3552412

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 11 Aug 2021 22:53:07**

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:11:21
User entered 'I'	(b) (4) Stanley Doublin (b) (4) (b) (4)	09 Oct 2020 15:27:28

US3552412

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 11 Aug 2021 22:53:07**

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:11:21
User entered 'Other (OTHER)'	(b) (4) Stanley Doublin (b) (4) (b) (4)	09 Oct 2020 15:27:28

US3552412

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 11 Aug 2021 22:53:07**

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:11:21
User entered 'application'	(b) (4) Stanley Doublin (b) (4) (b) (4)	09 Oct 2020 15:27:28

US3552412

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 11 Aug 2021 22:53:07**

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:11:21
User entered 'once daily (QD)'	(b) (4) Stanley Doublin (b) (4) (b) (4)	09 Oct 2020 15:27:28

US3552412

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 11 Aug 2021 22:53:07**

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:11:21
User entered empty.	(b) (4) Stanley Doublin (b) (4) (b) (4)	09 Oct 2020 15:27:28

US3552412

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 11 Aug 2021 22:53:07**

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:11:21
User entered 'Topical (TOPICAL)'	(b) (4) Stanley Doublin (b) (4) (b) (4)	09 Oct 2020 15:27:28

US3552412

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 11 Aug 2021 22:53:07**

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:11:21
User entered empty.	(b) (4) Stanley Doublin (b) (4) (b) (4)	09 Oct 2020 15:27:28

US3552412

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 11 Aug 2021 22:53:07

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:11:21
User entered '02 Oct 2020' reason for change: Data Entry Error	(b) (4) Heather Douds (b) (4)	09 Nov 2020 21:00:16
User entered '2 Oct 2020'	(b) (4) Stanley Doublin (b) (4)	09 Oct 2020 15:27:28

US3552412

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 11 Aug 2021 22:53:07**

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:11:21
User entered '0'	(b) (4) Stanley Doublin (b) (4) (b) (4)	09 Oct 2020 15:27:28

US3552412

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 11 Aug 2021 22:53:07**

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:11:21
User entered 'Yes (Y)'	(b) (4) Stanley Doublin (b) (4) (b) (4)	09 Oct 2020 15:27:28

US3552412

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 11 Aug 2021 22:53:07**

*If not Ongoing, End date (dd MMM yyyy)*

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:11:21
User entered empty.	(b) (4) Stanley Doublin (b) (4) (b) (4)	09 Oct 2020 15:27:28

US3552412

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 11 Aug 2021 22:53:07

Was this medication taken for solicited event?

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:11:21
User closed query 'Per DM CLR: Note, Was this medication taken for solicited event?' = Yes. However, recorded indication is not a solicited event per protocol. Review and update entry as appropriate. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	05 Nov 2020 04:40:44
Query 'Per DM CLR: Note, Was this medication taken for solicited event?' = Yes. However, recorded indication is not a solicited event per protocol. Review and update entry as appropriate. ' answered with 'updated' (Site from DM).	Cassandra Zehenny (b) (4) (b) (4)	03 Nov 2020 17:40:32
User entered 'No (N)' reason for change: Data Entry Error	Cassandra Zehenny (b) (4) (b) (4)	03 Nov 2020 17:40:28
User opened query 'Per DM CLR: Note, Was this medication taken for solicited event?' = Yes. However, recorded indication is not a solicited event per protocol. Review and update entry as appropriate. ' (Site from DM).	(b) (4), (b) (6)	03 Nov 2020 14:48:50
User entered 'Yes (Y)'	Stanley Doublin (b) (4) (b) (4)	09 Oct 2020 15:27:28

US3552412

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 11 Aug 2021 22:53:07**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered 'l'	System	09 Oct 2020 15:27:28

US3552412

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 11 Aug 2021 22:53:07**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered 'I'	System	09 Oct 2020 15:27:28

US3552412

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 11 Aug 2021 22:53:07**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	09 Oct 2020 15:27:28

US3552412

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 11 Aug 2021 22:53:07

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:27:22
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:11:21
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: OTHER ANALGESICS AND ANTIPYRETICS, ATC: ANILIDES, PRODUCT: PARACETAMOL, PRODUCTSYNONYM: TYLENOL - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4)	12 Oct 2020 16:39:18
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	12 Oct 2020 16:39:18
Data point term sent to Coder	System	12 Oct 2020 16:38:53
User entered 'Tylenol'	Cassandra Zehenny (b) (4)	12 Oct 2020 16:37:54

US3552412

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 11 Aug 2021 22:53:07

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:27:22
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:11:21
User entered 'No (N)'	(b) (4) Cassandra Zehenny (b) (4)	12 Oct 2020 16:37:54

US3552412

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 11 Aug 2021 22:53:07

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:27:22
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:11:21
User closed query 'Per DM CLR: Please note that there is no AE that matches this Con Med indication during this timeframe. If the BODY ACHES 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 BODY ACHES did not meet the AE reporting criteria. ' (Site from DM).	(b) (4), (b) (6)	02 Dec 2020 05:22:41
Query 'Per DM CLR: Please note that there is no AE that matches this Con Med indication during this timeframe. If the BODY ACHES 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 BODY ACHES did not meet the AE reporting criteria. ' answered with 'This occurred within the 7 day post-vaccination diary period, therefore considered an AR, not an AE. Thank you.' (Site from DM).	Cassandra Zehenny (b) (4)	30 Nov 2020 20:33:43

US3552412

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 11 Aug 2021 22:53:07

[Indication](#)

Audit	User	Time (GMT)
User opened query 'Per DM CLR: Please note that there is no AE that matches this Con Med indication during this timeframe. If the BODY ACHES 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 BODY ACHES did not meet the AE reporting criteria. ' (Site from DM). User entered 'Body aches'	(b) (4), (b) (6) Cassandra Zehenny (b) (4)	26 Nov 2020 07:51:21 12 Oct 2020 16:37:54

US3552412

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 11 Aug 2021 22:53:07

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:27:22
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:11:21
User entered '1000'	(b) (4) Cassandra Zehenny (b) (4)	12 Oct 2020 16:37:54

US3552412

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 11 Aug 2021 22:53:07

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:27:22
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:11:21
User entered 'mg (mg)'	(b) (4) Cassandra Zehenny (b) (4)	12 Oct 2020 16:37:54

US3552412

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 11 Aug 2021 22:53:07**

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:27:22
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:11:21
User entered empty.	(b) (4) Cassandra Zehenny (b) (4)	12 Oct 2020 16:37:54

US3552412

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 11 Aug 2021 22:53:07

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:27:22
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:11:21
User entered 'as needed (PRN)'	(b) (4) Cassandra Zehenny (b) (4)	12 Oct 2020 16:37:54

US3552412

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 11 Aug 2021 22:53:07

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:27:22
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:11:21
User entered empty.	(b) (4) Cassandra Zehenny (b) (4)	12 Oct 2020 16:37:54

US3552412

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 11 Aug 2021 22:53:07

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:27:22
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:11:21
User entered 'Oral (ORAL)'	(b) (4) Cassandra Zehenny (b) (4)	12 Oct 2020 16:37:54

US3552412

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 11 Aug 2021 22:53:07

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:27:22
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:11:21
User entered empty.	(b) (4) Cassandra Zehenny (b) (4)	12 Oct 2020 16:37:54

US3552412

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 11 Aug 2021 22:53:07**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:27:22
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:11:21
User entered '09 Oct 2020' reason for change: Data Entry Error	(b) (4)	
	Heather Douds (b) (4)	09 Nov 2020 21:00:26
User entered '9 Oct 2020'	(b) (4)	
	Cassandra Zehenny (b) (4)	12 Oct 2020 16:37:54
	(b) (4)	

US3552412

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 11 Aug 2021 22:53:07

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:27:22
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:11:21
User entered '0'	(b) (4) Cassandra Zehenny (b) (4)	12 Oct 2020 16:37:54

US3552412

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 11 Aug 2021 22:53:07

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:27:22
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:11:21
User entered 'No (N)'	(b) (4) Cassandra Zehenny (b) (4)	12 Oct 2020 16:37:54

US3552412

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 11 Aug 2021 22:53:07

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:27:22
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:11:21
User entered '09 Oct 2020' reason for change: Data Entry Error	(b) (4)	
	Heather Douds (b) (4)	09 Nov 2020 21:00:26
User entered '9 Oct 2020'	(b) (4)	
	Cassandra Zehenny (b) (4)	12 Oct 2020 16:37:54
	(b) (4)	

US3552412

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 11 Aug 2021 22:53:07

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:27:22
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:11:21
User entered 'Yes (Y)'	(b) (4) Cassandra Zehenny (b) (4)	12 Oct 2020 16:37:54

US3552412

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 11 Aug 2021 22:53:07**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:27:22
User entered empty.	System	12 Oct 2020 16:37:54

US3552412

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 11 Aug 2021 22:53:07**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:27:22
User entered empty.	System	12 Oct 2020 16:37:54

US3552412

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 11 Aug 2021 22:53:07**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:27:22
User entered empty.	System	12 Oct 2020 16:37:54

US3552412

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 11 Aug 2021 22:53:07

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:27:24
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:11:21
User coded data point as ATC: MUSCULO-SKELETAL SYSTEM, ATC: ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, ATC: ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, NON-STEROIDS, ATC: PROPIONIC ACID DERIVATIVES, PRODUCT: IBUPROFEN - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	12 Oct 2020 16:39:19
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	12 Oct 2020 16:39:19
Data point term sent to Coder	System	12 Oct 2020 16:38:55
User entered 'ibuprofen'	Cassandra Zehenny (b) (4)	12 Oct 2020 16:38:23

US3552412

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 11 Aug 2021 22:53:07

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:27:24
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:11:21
User entered 'No (N)'	(b) (4) Cassandra Zehenny (b) (4)	12 Oct 2020 16:38:23

US3552412

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 11 Aug 2021 22:53:07

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:27:24
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:11:21
User closed query 'Per DM CLR: Please note that there is no AE that matches this Con Med indication during this timeframe. If the BODY ACHES 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 BODY ACHES did not meet the AE reporting criteria. ' (Site from DM).	(b) (4), (b) (6)	02 Dec 2020 05:23:21
Query 'Per DM CLR: Please note that there is no AE that matches this Con Med indication during this timeframe. If the BODY ACHES 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 BODY ACHES did not meet the AE reporting criteria. ' answered with 'This occurred within the 7 day post-vaccination diary period, therefore considered an AR, not an AE. Thank you.' (Site from DM).	Cassandra Zehenny (b) (4)	30 Nov 2020 20:33:49



US3552412

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 11 Aug 2021 22:53:07

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:27:24
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:11:21
User entered '400'	(b) (4) Cassandra Zehenny (b) (4)	12 Oct 2020 16:38:23

US3552412

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 11 Aug 2021 22:53:07

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:27:24
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:11:21
User entered 'mg (mg)'	(b) (4) Cassandra Zehenny (b) (4)	12 Oct 2020 16:38:23

US3552412

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 11 Aug 2021 22:53:07

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:27:24
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:11:21
User entered empty.	(b) (4) Cassandra Zehenny (b) (4)	12 Oct 2020 16:38:23

US3552412

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 11 Aug 2021 22:53:07

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:27:24
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:11:21
User entered 'as needed (PRN)'	(b) (4) Cassandra Zehenny (b) (4)	12 Oct 2020 16:38:23

US3552412

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 11 Aug 2021 22:53:07

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:27:24
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:11:21
User entered empty.	(b) (4) Cassandra Zehenny (b) (4)	12 Oct 2020 16:38:23

US3552412

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 11 Aug 2021 22:53:07

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:27:24
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:11:21
User entered 'Oral (ORAL)'	(b) (4) Cassandra Zehenny (b) (4)	12 Oct 2020 16:38:23

US3552412

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 11 Aug 2021 22:53:07

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:27:24
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:11:21
User entered empty.	(b) (4) Cassandra Zehenny (b) (4)	12 Oct 2020 16:38:23

US3552412

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 11 Aug 2021 22:53:07

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:27:24
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:11:21
User entered '10 Oct 2020'	(b) (4) Cassandra Zehenny (b) (4)	12 Oct 2020 16:38:23

US3552412

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 11 Aug 2021 22:53:07

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:27:24
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:11:21
User entered '0'	(b) (4) Cassandra Zehenny (b) (4)	12 Oct 2020 16:38:23

US3552412

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 11 Aug 2021 22:53:07

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:27:24
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:11:21
User entered 'No (N)'	(b) (4) Cassandra Zehenny (b) (4)	12 Oct 2020 16:38:23

US3552412

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 11 Aug 2021 22:53:07

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:27:24
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:11:21
User entered '10 Oct 2020'	(b) (4) Cassandra Zehenny (b) (4)	12 Oct 2020 16:38:23

US3552412

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 11 Aug 2021 22:53:07

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:27:24
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:11:21
User entered 'Yes (Y)'	(b) (4) Cassandra Zehenny (b) (4)	12 Oct 2020 16:38:23

US3552412

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 11 Aug 2021 22:53:07**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:27:24
User entered empty.	System	12 Oct 2020 16:38:23

US3552412

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 11 Aug 2021 22:53:07**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:27:24
User entered empty.	System	12 Oct 2020 16:38:23

US3552412

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 11 Aug 2021 22:53:07**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:27:24
User entered empty.	System	12 Oct 2020 16:38:23

US3552412

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 11 Aug 2021 22:53:07

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:27:27
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:11:21
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: OTHER ANALGESICS AND ANTIPYRETICS, ATC: ANILIDES, PRODUCT: PARACETAMOL, PRODUCTSYNONYM: TYLENOL - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4)	17 Oct 2020 04:00:13
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	17 Oct 2020 04:00:13
Data point term sent to Coder	System	16 Oct 2020 17:43:55
User entered 'tylenol'	Stanley Doublin (b) (4)	16 Oct 2020 17:43:45

US3552412

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 11 Aug 2021 22:53:07

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:27:27
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:11:21
User entered 'No (N)'	(b) (4) Stanley Dublin (b) (4) (b) (4)	16 Oct 2020 17:43:45

US3552412

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 11 Aug 2021 22:53:07

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:27:27
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:11:21
User closed query 'Per DM CLR: Please review if this medication was added because the patient's medical history condition worsened. If yes, please review if an AE of Worsening MIGRAINE should be recorded, and update con med indication or provide clarification. ' (Site from DM).	(b) (4), (b) (6)	02 Dec 2020 05:31:04
Query 'Per DM CLR: Please review if this medication was added because the patient's medical history condition worsened. If yes, please review if an AE of Worsening MIGRAINE should be recorded, and update con med indication or provide clarification. ' answered with 'typical migraine, not worsened' (Site from DM).	Cassandra Zehenny (b) (4)	30 Nov 2020 20:34:09
User opened query 'Per DM CLR: Please review if this medication was added because the patient's medical history condition worsened. If yes, please review if an AE of Worsening MIGRAINE should be recorded, and update con med indication or provide clarification. ' (Site from DM).	(b) (4), (b) (6)	26 Nov 2020 07:52:35
User entered 'migraine'	Stanley Dublin (b) (4)	16 Oct 2020 17:43:45

US3552412

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 11 Aug 2021 22:53:07

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:27:27
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:11:21
User entered '650'	(b) (4) Stanley Dublin (b) (4) (b) (4)	16 Oct 2020 17:43:45

US3552412

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 11 Aug 2021 22:53:07

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:27:27
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:11:21
User entered 'mg (mg)'	(b) (4) Stanley Dublin (b) (4)	16 Oct 2020 17:43:45

US3552412

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 11 Aug 2021 22:53:07**

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:27:27
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:11:21
User entered empty.	(b) (4) Stanley Dublin (b) (4) (b) (4)	16 Oct 2020 17:43:45

US3552412

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 11 Aug 2021 22:53:07

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:27:27
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:11:21
User entered 'once (ONCE)'	(b) (4) Stanley Dublin (b) (4) (b) (4)	16 Oct 2020 17:43:45

US3552412

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 11 Aug 2021 22:53:07

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:27:27
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:11:21
User entered empty.	(b) (4) Stanley Dublin (b) (4) (b) (4)	16 Oct 2020 17:43:45

US3552412

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 11 Aug 2021 22:53:07

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:27:27
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:11:21
User entered 'Oral (ORAL)'	(b) (4) Stanley Dublin (b) (4)	16 Oct 2020 17:43:45

US3552412

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 11 Aug 2021 22:53:07**

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:27:27
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:11:21
User entered empty.	(b) (4) Stanley Dublin (b) (4) (b) (4)	16 Oct 2020 17:43:45

US3552412

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 11 Aug 2021 22:53:07

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:27:27
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:11:21
User entered '15 Oct 2020'	(b) (4) Stanley Dublin (b) (4) (b) (4)	16 Oct 2020 17:43:45

US3552412

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 11 Aug 2021 22:53:07

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:27:27
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:11:21
User entered '0'	(b) (4) Stanley Dublin (b) (4) (b) (4)	16 Oct 2020 17:43:45

US3552412

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 11 Aug 2021 22:53:07

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:27:27
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:11:21
User entered 'No (N)'	(b) (4) Stanley Dublin (b) (4) (b) (4)	16 Oct 2020 17:43:45

US3552412

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 11 Aug 2021 22:53:07

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:27:27
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:11:21
User entered '15 Oct 2020'	(b) (4) Stanley Dublin (b) (4) (b) (4)	16 Oct 2020 17:43:45

US3552412

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 11 Aug 2021 22:53:07

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:27:27
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:11:21
User entered 'No (N)'	(b) (4) Stanley Dublin (b) (4) (b) (4)	16 Oct 2020 17:43:45

US3552412

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 11 Aug 2021 22:53:07**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:27:27
User entered empty.	System	16 Oct 2020 17:43:45

US3552412

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 11 Aug 2021 22:53:07**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:27:27
User entered empty.	System	16 Oct 2020 17:43:45

US3552412

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 11 Aug 2021 22:53:07**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:27:27
User entered empty.	System	16 Oct 2020 17:43:45

US3552412

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 11 Aug 2021 22:53:07

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:27:29
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:11:21
User coded data point as ATC: MUSCULO-SKELETAL SYSTEM, ATC: ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, ATC: ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, NON-STEROIDS, ATC: PROPIONIC ACID DERIVATIVES, PRODUCT: NAPROXEN - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	17 Oct 2020 04:00:25
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	17 Oct 2020 04:00:25
Data point term sent to Coder	System	16 Oct 2020 17:44:56
User entered 'naproxen'	Stanley Dublin (b) (4)	16 Oct 2020 17:44:20

US3552412

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 11 Aug 2021 22:53:07

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:27:29
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:11:21
User entered 'No (N)'	(b) (4) Stanley Dublin (b) (4) (b) (4)	16 Oct 2020 17:44:20

US3552412

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 11 Aug 2021 22:53:07

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:27:29
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:11:21
User entered 'migraine'	(b) (4) Stanley Dublin (b) (4) (b) (4)	16 Oct 2020 17:44:20

US3552412

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 11 Aug 2021 22:53:07

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:27:29
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:11:21
User entered '250'	(b) (4) Stanley Dublin (b) (4) (b) (4)	16 Oct 2020 17:44:20

US3552412

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 11 Aug 2021 22:53:07

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:27:29
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:11:21
User entered 'mg (mg)'	(b) (4) Stanley Dublin (b) (4) (b) (4)	16 Oct 2020 17:44:20

US3552412

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 11 Aug 2021 22:53:07

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:27:29
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:11:21
User entered empty.	(b) (4) Stanley Dublin (b) (4) (b) (4)	16 Oct 2020 17:44:20

US3552412

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 11 Aug 2021 22:53:07

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:27:29
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:11:21
User entered 'once (ONCE)'	(b) (4) Stanley Dublin (b) (4) (b) (4)	16 Oct 2020 17:44:20

US3552412

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 11 Aug 2021 22:53:07

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:27:29
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:11:21
User entered empty.	(b) (4) Stanley Dublin (b) (4) (b) (4)	16 Oct 2020 17:44:20

US3552412

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 11 Aug 2021 22:53:07

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:27:29
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:11:21
User entered 'Oral (ORAL)'	(b) (4) Stanley Dublin (b) (4)	16 Oct 2020 17:44:20

US3552412

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 11 Aug 2021 22:53:07

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:27:29
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:11:21
User entered empty.	(b) (4) Stanley Dublin (b) (4) (b) (4)	16 Oct 2020 17:44:20

US3552412

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 11 Aug 2021 22:53:07

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:27:29
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:11:21
User entered '15 Oct 2020'	(b) (4) Stanley Dublin (b) (4) (b) (4)	16 Oct 2020 17:44:20

US3552412

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 11 Aug 2021 22:53:07

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:27:29
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:11:21
User entered '0'	(b) (4) Stanley Dublin (b) (4) (b) (4)	16 Oct 2020 17:44:20

US3552412

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 11 Aug 2021 22:53:07

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:27:29
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:11:21
User entered 'No (N)'	(b) (4) Stanley Dublin (b) (4) (b) (4)	16 Oct 2020 17:44:20

US3552412

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 11 Aug 2021 22:53:07

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:27:29
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:11:21
User entered '15 Oct 2020'	(b) (4) Stanley Dublin (b) (4) (b) (4)	16 Oct 2020 17:44:20

US3552412

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 11 Aug 2021 22:53:07

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:27:29
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:11:21
User entered 'No (N)'	(b) (4) Stanley Dublin (b) (4) (b) (4)	16 Oct 2020 17:44:20

US3552412

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 11 Aug 2021 22:53:07**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:27:29
User entered empty.	System	16 Oct 2020 17:44:20

US3552412

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 11 Aug 2021 22:53:07**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:27:29
User entered empty.	System	16 Oct 2020 17:44:20

US3552412

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 11 Aug 2021 22:53:07**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:27:29
User entered empty.	System	16 Oct 2020 17:44:20

US3552412

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 11 Aug 2021 22:53:07

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:27:49
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:11:21
User coded data point as ATC: ANTIINFECTIVES FOR SYSTEMIC USE, ATC: VACCINES, ATC: VIRAL VACCINES, ATC: INFLUENZA VACCINES, PRODUCT: INFLUENZA VACCINE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	05 Feb 2021 15:44:43
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	05 Feb 2021 15:44:43
Data point term sent to Coder	System	05 Feb 2021 15:43:30
Coding entries removed.	Stanley Doublin (b) (4)	05 Feb 2021 15:42:36
User coded data point as ATC: ANTIINFECTIVES FOR SYSTEMIC USE, ATC: VACCINES, ATC: VIRAL VACCINES, ATC: INFLUENZA VACCINES, PRODUCT: INFLUENZA VACCINE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	30 Oct 2020 15:52:56
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	30 Oct 2020 15:52:56
Data point term sent to Coder	System	30 Oct 2020 15:52:14
User entered 'influenza vaccine'	Stanley Doublin (b) (4)	30 Oct 2020 15:52:04

US3552412

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 11 Aug 2021 22:53:07

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:27:49
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:11:21
User entered 'Yes (Y)'	(b) (4) Stanley Dublin (b) (4)	30 Oct 2020 15:52:04

US3552412

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 11 Aug 2021 22:53:07

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:27:49
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:11:21
User entered 'influenza PROPHYLAXIS' reason for change: Data Entry Error	(b) (4)	05 Feb 2021 15:42:36
User entered 'prophylaxis'	Stanley Dublin (b) (4)	30 Oct 2020 15:52:04
	(b) (4)	

US3552412

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 11 Aug 2021 22:53:07

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:27:49
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:11:21
User entered 'l'	(b) (4) Stanley Dublin (b) (4) (b) (4)	30 Oct 2020 15:52:04

US3552412

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 11 Aug 2021 22:53:07

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:27:49
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:11:21
User entered 'Other (OTHER)'	(b) (4) Stanley Dublin (b) (4) (b) (4)	30 Oct 2020 15:52:04

US3552412

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 11 Aug 2021 22:53:07

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:27:49
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:11:21
User entered 'injection'	(b) (4) Stanley Dublin (b) (4) (b) (4)	30 Oct 2020 15:52:04

US3552412

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 11 Aug 2021 22:53:07

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:27:49
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:11:21
User entered 'once (ONCE)'	(b) (4) Stanley Dublin (b) (4)	30 Oct 2020 15:52:04

US3552412

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 11 Aug 2021 22:53:07

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:27:49
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:11:21
User entered empty.	(b) (4) Stanley Dublin (b) (4) (b) (4)	30 Oct 2020 15:52:04

US3552412

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 11 Aug 2021 22:53:07

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:27:49
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:11:21
User entered 'Intramuscular (INTRAMUSCULAR)'	(b) (4) Stanley Dublin (b) (4) (b) (4)	30 Oct 2020 15:52:04

US3552412

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 11 Aug 2021 22:53:07

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:27:49
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:11:21
User entered empty.	(b) (4) Stanley Dublin (b) (4) (b) (4)	30 Oct 2020 15:52:04

US3552412

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 11 Aug 2021 22:53:07

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:27:49
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:11:21
User entered '27 Oct 2020'	(b) (4) Stanley Dublin (b) (4) (b) (4)	30 Oct 2020 15:52:04

US3552412

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 11 Aug 2021 22:53:07

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:27:49
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:11:21
User entered '0'	(b) (4) Stanley Dublin (b) (4) (b) (4)	30 Oct 2020 15:52:04

US3552412

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 11 Aug 2021 22:53:07

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:27:49
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:11:21
User entered 'No (N)'	(b) (4) Stanley Dublin (b) (4) (b) (4)	30 Oct 2020 15:52:04

US3552412

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 11 Aug 2021 22:53:07

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:27:49
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:11:21
User entered '27 Oct 2020'	(b) (4) Stanley Dublin (b) (4) (b) (4)	30 Oct 2020 15:52:04

US3552412

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 11 Aug 2021 22:53:07

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:27:49
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:11:21
User entered 'No (N)'	(b) (4) Stanley Dublin (b) (4) (b) (4)	30 Oct 2020 15:52:04

US3552412

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (8)**

**Generated On: 11 Aug 2021 22:53:07**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:27:49
User entered empty.	System	30 Oct 2020 15:52:04

US3552412

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (8)**

**Generated On: 11 Aug 2021 22:53:07**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:27:49
User entered empty.	System	30 Oct 2020 15:52:04

US3552412

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (8)**

**Generated On: 11 Aug 2021 22:53:07**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:27:49
User entered empty.	System	30 Oct 2020 15:52:04

US3552412

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 11 Aug 2021 22:53:07

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:11:21
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: VITAMINS, ATC: OTHER VITAMIN PRODUCTS, COMBINATIONS, ATC: COMBINATIONS OF VITAMINS, PRODUCT: VITAMINS NOS, PRODUCTSYNONYM: MULTIVITAMIN [VITAMINS NOS] - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4)	08 Jan 2021 16:02:40
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	08 Jan 2021 16:02:40
Data point term sent to Coder	System	07 Jan 2021 21:36:46
User entered 'prenatal vitamin'	Mikayla Frye (b) (4) (b) (4)	07 Jan 2021 21:35:52

US3552412

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (9)**

**Generated On: 11 Aug 2021 22:53:07**

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:11:21
User entered 'Yes (Y)'	(b) (4) Mikayla Frye (b) (4) (b) (4)	07 Jan 2021 21:35:52

US3552412

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (9)**

**Generated On: 11 Aug 2021 22:53:07**

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:11:21
User entered 'health promotion'	(b) (4) Mikayla Frye (b) (4) (b) (4)	07 Jan 2021 21:35:52

US3552412

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (9)**

**Generated On: 11 Aug 2021 22:53:07**

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:11:21
User entered 'l'	(b) (4) Mikayla Frye (b) (4) (b) (4)	07 Jan 2021 21:35:52

US3552412

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (9)**

**Generated On: 11 Aug 2021 22:53:07**

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:11:21
User entered 'tablet (TABLET)'	(b) (4) Mikayla Frye (b) (4) (b) (4)	07 Jan 2021 21:35:52

US3552412

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (9)**

**Generated On: 11 Aug 2021 22:53:07**

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:11:21
User entered empty.	(b) (4) Mikayla Frye (b) (4) (b) (4)	07 Jan 2021 21:35:52

US3552412

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (9)**

**Generated On: 11 Aug 2021 22:53:07**

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:11:21
User entered 'once daily (QD)'	(b) (4) Mikayla Frye (b) (4) (b) (4)	07 Jan 2021 21:35:52

US3552412

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (9)**

**Generated On: 11 Aug 2021 22:53:07**

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:11:21
User entered empty.	(b) (4) Mikayla Frye (b) (4) (b) (4)	07 Jan 2021 21:35:52

US3552412

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (9)**

**Generated On: 11 Aug 2021 22:53:07**

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:11:21
User entered 'Oral (ORAL)'	(b) (4) Mikayla Frye (b) (4) (b) (4)	07 Jan 2021 21:35:52

US3552412

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (9)**

**Generated On: 11 Aug 2021 22:53:07**

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:11:21
User entered empty.	(b) (4) Mikayla Frye (b) (4) (b) (4)	07 Jan 2021 21:35:52

US3552412

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 11 Aug 2021 22:53:07

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:11:21
User entered '07 Jan 2021'	(b) (4) Mikayla Frye (b) (4) (b) (4)	07 Jan 2021 21:35:52

US3552412

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (9)**

**Generated On: 11 Aug 2021 22:53:07**

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:11:21
User entered '0'	(b) (4) Mikayla Frye (b) (4) (b) (4)	07 Jan 2021 21:35:52

US3552412

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (9)**

**Generated On: 11 Aug 2021 22:53:07**

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:11:21
User entered 'Yes (Y)'	(b) (4) Mikayla Frye (b) (4) (b) (4)	07 Jan 2021 21:35:52

US3552412

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (9)**

**Generated On: 11 Aug 2021 22:53:07**

*If not Ongoing, End date (dd MMM yyyy)*

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:11:21
User entered empty.	(b) (4) Mikayla Frye (b) (4) (b) (4)	07 Jan 2021 21:35:52

US3552412

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (9)**

**Generated On: 11 Aug 2021 22:53:07**

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:11:21
User entered 'No (N)'	(b) (4) Mikayla Frye (b) (4) (b) (4)	07 Jan 2021 21:35:52

US3552412

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (9)**

**Generated On: 11 Aug 2021 22:53:07**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered 'l'	System	07 Jan 2021 21:35:52

US3552412

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (9)**

**Generated On: 11 Aug 2021 22:53:07**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered 'I'	System	07 Jan 2021 21:35:52

US3552412

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (9)**

**Generated On: 11 Aug 2021 22:53:07**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	07 Jan 2021 21:35:52

US3552412

**Folder: Concomitant Procedures (1)**

**Form: Concomitant Procedures Summary**

**Generated On: 11 Aug 2021 22:53:07**

[Were any concomitant procedures performed?](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	09 Mar 2021 17:03:11
User entered 'No (N)'	(b) (4) Joan Siegner (b) (4)	02 Mar 2021 15:35:34