

US3142034 (Prod: Lynn Institute of The Rockies - ERN-PPDS)

Generated By: KC Joubran

Generated On: 11 Aug 2021 21:58:56

All time stamps listed in this document are displayed in GMT

US3142034

Form: Participant Creation

Data signed: (b) (4) 18 Apr 2021 19:03:28

Generated On: 11 Aug 2021 21:58:56

[Participant ID](#)

US3142034

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

US3142034

Folder: Screening

Form: Visit Date

Data signed: (b) (4) 18 Apr 2021 19:03:49

Generated On: 11 Aug 2021 21:58:56

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	31 JUL 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

US3142034

Folder: Screening

Form: Demographics

Data signed: (b) (4) 18 Apr 2021 19:03:48

Generated On: 11 Aug 2021 21:58:56

Date of Birth (MMM yyyy)	(b) (6) 1946
Age	74
Age Units	YEARS
Age (Derived)	74
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

US3142034

Folder: Screening

Form: Enrollment

Data signed: (b) (4) 18 Apr 2021 19:03:48

Generated On: 11 Aug 2021 21:58:56

Date of Informed Consent (*dd MMM yyyy*) 31 JUL 2020

Month and Year of Informed Consent (derived) JUL 2020

Year of Informed Consent (derived) 2020

Protocol Version

Amendment 1

Amendment 2

Amendment 3

Amendment 4

Amendment 5

Was participant enrolled in the study? Yes
No

If No, indicate reason for screen fail

Withdrew Consent

Inclusion/Exclusion

Cohort Full

Other

If reason for screen fail is Other, specify _____

Was this participant screened previously? Yes
No

If Yes, previous participant number _____

Enrollment Trigger 1

US3142034

Folder: Screening

Form: Inclusion/Exclusion Criteria Summary

Data signed: (b) (4) 18 Apr 2021 19:03:48

Generated On: 11 Aug 2021 21:58:56

Did the participant meet all eligibility criteria?

Yes

No

US3142034

Folder: Screening

Form: Medical History Summary

Data signed: (b) (4) 18 Apr 2021 19:03:49

Generated On: 11 Aug 2021 21:58:56

Were any significant conditions reported?

Yes

No

US3142034

Folder: Screening

Form: Medical History (1)

Data signed: (b) (4) 18 Apr 2021 19:03:48

Generated On: 11 Aug 2021 21:58:56

Condition	NEARSIGHTED BILATERAL
Start date (dd MMM yyyy)	UN UNK 1966
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 1966
Start Year (derived)	1966
Stop Month and Year (derived)	_____
Stop Year (derived)	_____

US3142034

Folder: Screening

Form: Medical History (2)

Data signed: (b) (4) 18 Apr 2021 19:03:48

Generated On: 11 Aug 2021 21:58:56

Condition	CATARACTS BILATERAL
Start date (dd MMM yyyy)	UN UNK 2015
Start date completely unknown	False
Condition ongoing at study entry	Yes <input checked="" type="radio"/> No <input type="radio"/>
If No, please specify the stop date (dd MMM yyyy) _____	
Stop date completely unknown	False
Start Month and Year (derived)	JAN 2015
Start Year (derived)	2015
Stop Month and Year (derived)	_____
Stop Year (derived)	_____

US3142034

Folder: Screening

Form: Medical History (3)

Data signed: (b) (4) 18 Apr 2021 19:03:48

Generated On: 11 Aug 2021 21:58:56

Condition	HEARING LOSS BILATERAL
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)	_____

US3142034

Folder: Screening

Form: Medical History (4)

Data signed: (b) (4) 18 Apr 2021 19:03:48

Generated On: 11 Aug 2021 21:58:56

Condition	HEMORRHOIDS
Start date (dd MMM yyyy)	UN UNK 1973
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 1973
Start Year (derived)	1973
Stop Month and Year (derived)	_____
Stop Year (derived)	_____

US3142034

Folder: Screening

Form: Medical History (5)

Data signed: (b) (4) 18 Apr 2021 19:03:48

Generated On: 11 Aug 2021 21:58:56

Condition	OVERACTIVE BLADDER
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)	_____

US3142034

Folder: Screening

Form: Medical History (6)

Data signed: (b) (4) 18 Apr 2021 19:03:48

Generated On: 11 Aug 2021 21:58:56

Condition	HYPERCHOLESTEROLEMIA
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)	_____

US3142034

Folder: Screening

Form: Medical History (7)

Data signed: (b) (4) 18 Apr 2021 19:03:48

Generated On: 11 Aug 2021 21:58:56

Condition	OSTEOPOROSIS
Start date (dd MMM yyyy)	UN UNK 2015
Start date completely unknown	False
Condition ongoing at study entry	Yes <input checked="" type="radio"/> No <input type="radio"/>
If No, please specify the stop date (dd MMM yyyy) _____	
Stop date completely unknown	False
Start Month and Year (derived)	JAN 2015
Start Year (derived)	2015
Stop Month and Year (derived)	_____
Stop Year (derived)	_____

US3142034

Folder: Screening

Form: Medical History (8)

Data signed: (b) (4) 18 Apr 2021 19:03:48

Generated On: 11 Aug 2021 21:58:56

Condition	OSTEOARTHRITIS IN WRISTS, FINGERS, SHOULDERS AND KNEES
Start date (dd MMM yyyy)	UN UNK 2006
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 2006
Start Year (derived)	2006
Stop Month and Year (derived)	
Stop Year (derived)	

US3142034

Folder: Screening

Form: Medical History (9)

Data signed: (b) (4) 18 Apr 2021 19:03:48

Generated On: 11 Aug 2021 21:58:56

Condition	NEUROPATHY IN BOTH FEET - SENSORY
Start date (dd MMM yyyy)	UN DEC 2019
Start date completely unknown	False
Condition ongoing at study entry	Yes <input checked="" type="radio"/> No <input type="radio"/>
If No, please specify the stop date (dd MMM yyyy)	_____
Stop date completely unknown	False
Start Month and Year (derived)	DEC 2019
Start Year (derived)	2019
Stop Month and Year (derived)	_____
Stop Year (derived)	_____

US3142034

Folder: Screening

Form: Medical History (10)

Data signed: (b) (4) 18 Apr 2021 19:03:48

Generated On: 11 Aug 2021 21:58:56

Condition	POST-MENOPAUSAL
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)	_____

US3142034

Folder: Screening

Form: Medical History (11)

Data signed: (b) (4) 18 Apr 2021 19:03:48

Generated On: 11 Aug 2021 21:58:56

Condition	HYPERTENSION
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)	_____

US3142034

Folder: Screening

Form: Medical History (12)

Data signed: (b) (4) 18 Apr 2021 19:03:48

Generated On: 11 Aug 2021 21:58:56

Condition	PHLEBITIS - UNKNOWN LOCATION
Start date (dd MMM yyyy)	UN UNK 1974
Start date completely unknown	False
Condition ongoing at study entry	Yes <input type="radio"/> No <input checked="" type="radio"/>
If No, please specify the stop date (dd MMM yyyy)	UN UNK 1974
Stop date completely unknown	False
Start Month and Year (derived)	JAN 1974
Start Year (derived)	1974
Stop Month and Year (derived)	JAN 1974
Stop Year (derived)	1974

US3142034

Folder: Screening

Form: Vital Signs

Data signed: (b) (4) 18 Apr 2021 19:03:49

Generated On: 11 Aug 2021 21:58:56

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (<i>dd MMM yyyy</i>)	31 JUL 2020
Time of assessment (<i>00:00-23:59</i>)	11:37 (24 HR)
Vital Signs Date and Time (derived)	31 JUL 2020 11:37
Height (<i>xxx.x</i>)	64 in
Weight (<i>xxx.x</i>)	196.2 lb
BMI (<i>xxx.x</i>)	33.74807 kg/m ²
BMI units	KG/M2
Temperature (<i>xxx.x</i>)	ND - Not Done
Route of measurement	Oral <input type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	_____
Pulse (<i>xxx</i>)	ND - Not Done
Pulse units	BPM
Respiratory Rate (<i>xxx</i>)	ND - Not Done
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (<i>xxx</i>)	ND - Not Done
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (<i>xxx</i>)	ND - Not Done
Diastolic Blood Pressure units	MMHG
Height (derived)	_____
Weight (derived)	_____

US3142034

Folder: Screening

Form: Physical Examination

Data signed: (b) (4) 18 Apr 2021 19:03:49

Generated On: 11 Aug 2021 21:58:56

Was the physical examination performed?

Yes

No

Date of examination (dd MMM yyyy)

31 JUL 2020

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

US3142034

Folder: Screening

Form: Childbearing Potential

Data signed: (b) (4) 18 Apr 2021 19:03:48

Generated On: 11 Aug 2021 21:58:56

Date of assessment (*dd MMM yyyy*) 31 JUL 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*) UN NOV 1999

Date of last menstruation unknown False

US3142034

Folder: Screening

Form: Risk of Exposure

Data signed: (b) (4) 18 Apr 2021 19:03:49

Generated On: 11 Aug 2021 21:58:56

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

Location and Living Circumstances Risk (check all that apply)

No Risk Identified False

Resides in Nursing Home or Assisted Living Facility False

US3142034

Folder: Screening

Form: Risk of Exposure

Data signed: (b) (4) 18 Apr 2021 19:03:49

Generated On: 11 Aug 2021 21:58:56

Resides in Multi-family dwelling (e.g., cohabitation in dwelling with > 5 people, includes grandparents living with children < 18yrs)	False
Resides in high density housing (e.g., high rise apartments with shared entrances or elevators)	False
Resides in low density, multi-family setting without (e.g., apartments complex without shared entrances or elevators, duplexes)	False
Resides in a single family home (i.e., detached housing)	True
Other	False
Specify	

US3142034

Folder: Visit 1 Day 1

Form: Visit Date

Data signed: (b) (4) 18 Apr 2021 19:03:49

Generated On: 11 Aug 2021 21:58:56

Was this visit performed? Yes
No

Visit date (dd MMM yyyy) 31 JUL 2020

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

Folder OID VISIT1

US3142034

Folder: Visit 1 Day 1

Form: Randomization

Data signed: (b) (4) 18 Apr 2021 19:03:49

Generated On: 11 Aug 2021 21:58:56

What was the date of randomization? (dd MMM yyyy) 31 JUL 2020

What was the participant's randomization number? 184364

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

US3142034

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Data signed: (b) (4) 18 Apr 2021 19:03:49

Generated On: 11 Aug 2021 21:58:56

Height	ND - Not Done
Weight	ND - Not Done

US3142034

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 18 Apr 2021 19:03:49

Generated On: 11 Aug 2021 21:58:56

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 (<i>dd MMM yyyy</i>)	31 JUL 2020
Time of assessment (<i>00:00-23:59</i>)	11:37 (24 HR)
Vital Signs Date and Time (derived)	31 JUL 2020 11:37
Temperature (<i>xxx.x</i>)	97.1 F
Route of measurement	Oral <input type="radio"/> Axillary <input type="radio"/> Other <input checked="" type="radio"/>
If Other, specify	TEMPORAL
Pulse (<i>xxx</i>)	61 beats/min
Pulse units	BPM
Respiratory Rate (<i>xxx</i>)	15 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (<i>xxx</i>)	141 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (<i>xxx</i>)	84 mmHg
Diastolic Blood Pressure units	MMHG

US3142034

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 18 Apr 2021 19:03:49

Generated On: 11 Aug 2021 21:58:56

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 (<i>dd MMM yyyy</i>)	31 JUL 2020
Time of assessment (<i>00:00-23:59</i>)	14:21 (24 HR)
Vital Signs Date and Time (derived)	31 JUL 2020 14:21
Temperature (<i>xxx.x</i>)	96.6 F
Route of measurement	Oral <input type="radio"/> Axillary <input type="radio"/> Other <input checked="" type="radio"/>
If Other, specify	TEMPORAL
Pulse (<i>xxx</i>)	60 beats/min
Pulse units	BPM
Respiratory Rate (<i>xxx</i>)	20 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (<i>xxx</i>)	134 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (<i>xxx</i>)	102 mmHg
Diastolic Blood Pressure units	MMHG

US3142034

Folder: Visit 1 Day 1

Form: Physical Examination

Data signed: (b) (4) 18 Apr 2021 19:03:49

Generated On: 11 Aug 2021 21:58:56

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.

US3142034

Folder: Visit 1 Day 1

Form: Exposure

Data signed: (b) (4) 18 Apr 2021 19:03:49

Generated On: 11 Aug 2021 21:58:56

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) 31 JUL 2020

What was the treatment time? (00:00-23:59) 13:50 (24 HR)

Treatment Date and Time (derived) 31 JUL 2020 13:50

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

US3142034

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Data signed: (b) (4) 18 Apr 2021 19:03:49

Generated On: 11 Aug 2021 21:58:56

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (<i>dd MMM yyyy</i>)	31 JUL 2020
Collection time (<i>00:00-23:59</i>)	13:10 (24 HR)
Collection date and time (derived)	31 JUL 2020 13:10

US3142034

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab

Data signed: (b) (4) 18 Apr 2021 19:03:49

Generated On: 11 Aug 2021 21:58:56

Collection date (<i>dd MMM yyyy</i>)			31 JUL 2020
Lab Test	Was the sample collected?	Collection time (<i>00:00 - 23:59</i>)	Collection date and time (derived)
Nasopharyngeal Swab 1	Yes	13:10	31 JUL 2020 13:10
Nasopharyngeal Swab 2	Yes	13:10	31 JUL 2020 13:10

US3142034

Folder: Visit 1 Day 1

Form: Continuing

Data signed: (b) (4) 18 Apr 2021 19:03:49

Generated On: 11 Aug 2021 21:58:56

Is the participant continuing to the next visit?

Yes

No

Continuing Flag

1

US3142034

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 11 Aug 2021 21:58:56

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 96.6 °F

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

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

PC Time Stamp 31 JUL 2020 14:40

PC Open Date & Time 31 JUL 2020 14:10

PC Close Date & Time 31 JUL 2020 16:40

US3142034

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 11 Aug 2021 21:58:56

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 95.5 °F

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

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

PC Time Stamp 01 AUG 2020 07:44
PC Open Date & Time 31 JUL 2020 17:35
PC Close Date & Time 01 AUG 2020 11:59

US3142034

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 11 Aug 2021 21:58:56

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 <input checked="" type="radio"/>
	No <input type="radio"/>
Please record your TEMPERATURE in °F	97.8 °F
Was any MEDICATION TAKEN today for pain or fever?	Yes <input type="radio"/>
	No <input checked="" type="radio"/>

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

PC Time Stamp	01 AUG 2020 18:26
PC Open Date & Time	01 AUG 2020 12:00
PC Close Date & Time	02 AUG 2020 11:59

US3142034

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 11 Aug 2021 21:58:56

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 <input checked="" type="radio"/>
	No <input type="radio"/>
Please record your TEMPERATURE in °F	98.1 °F
Was any MEDICATION TAKEN today for pain or fever?	Yes <input type="radio"/>
	No <input checked="" type="radio"/>

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

PC Time Stamp	02 AUG 2020 17:49
PC Open Date & Time	02 AUG 2020 12:00
PC Close Date & Time	03 AUG 2020 11:59

US3142034

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 11 Aug 2021 21:58:56

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 <input checked="" type="radio"/>
	No <input type="radio"/>
Please record your TEMPERATURE in °F	96.1 °F
Was any MEDICATION TAKEN today for pain or fever?	Yes <input type="radio"/>
	No <input checked="" type="radio"/>

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

PC Time Stamp	03 AUG 2020 19:27
PC Open Date & Time	03 AUG 2020 12:00
PC Close Date & Time	04 AUG 2020 11:59

US3142034

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 11 Aug 2021 21:58:56

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 <input checked="" type="radio"/>
	No <input type="radio"/>
Please record your TEMPERATURE in °F	97.6 °F
Was any MEDICATION TAKEN today for pain or fever?	Yes <input type="radio"/>
	No <input checked="" type="radio"/>

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

PC Time Stamp	04 AUG 2020 20:15
PC Open Date & Time	04 AUG 2020 12:00
PC Close Date & Time	05 AUG 2020 11:59

US3142034

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 11 Aug 2021 21:58:56

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 <input checked="" type="radio"/>
	No <input type="radio"/>
Please record your TEMPERATURE in °F	98.1 °F
Was any MEDICATION TAKEN today for pain or fever?	Yes <input type="radio"/>
	No <input checked="" type="radio"/>

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

PC Time Stamp	05 AUG 2020 16:50
PC Open Date & Time	05 AUG 2020 12:00
PC Close Date & Time	06 AUG 2020 11:59

US3142034

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 11 Aug 2021 21:58:56

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 <input checked="" type="radio"/>
	No <input type="radio"/>
Please record your TEMPERATURE in °F	98.3 °F
Was any MEDICATION TAKEN today for pain or fever?	Yes <input type="radio"/>
	No <input checked="" type="radio"/>

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

PC Time Stamp	06 AUG 2020 18:35
PC Open Date & Time	06 AUG 2020 12:00
PC Close Date & Time	07 AUG 2020 11:59

US3142034

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 11 Aug 2021 21:58:56

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

31 JUL 2020 14:41

PC Open Date & Time

31 JUL 2020 14:10

PC Close Date & Time

31 JUL 2020 16:40

US3142034

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 11 Aug 2021 21:58:56

TIMEPOINT

DAY 1, AFTER VACCINATION
(AT HOME)

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

Please select one response below

None

Does not interfere with activity

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

Any use of prescription pain
reliever or prevents daily activity

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

Yes

No

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

Yes

No

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

Please select one response below

None

Does not interfere with activity

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

Any use of prescription pain
reliever or prevents daily activity

PC Time Stamp

01 AUG 2020 07:46

PC Open Date & Time

31 JUL 2020 17:35

PC Close Date & Time

01 AUG 2020 11:59

US3142034

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 11 Aug 2021 21:58:56

TIMEPOINT

DAY 2

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

Please select one response below

None

Does not interfere with activity

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

Any use of prescription pain
reliever or prevents daily activity

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

Yes

No

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

Yes

No

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

Please select one response below

None

Does not interfere with activity

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

Any use of prescription pain
reliever or prevents daily activity

PC Time Stamp

01 AUG 2020 18:27

PC Open Date & Time

01 AUG 2020 12:00

PC Close Date & Time

02 AUG 2020 11:59

US3142034

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 11 Aug 2021 21:58:56

TIMEPOINT

DAY 3

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	02 AUG 2020 17:50
PC Open Date & Time	02 AUG 2020 12:00
PC Close Date & Time	03 AUG 2020 11:59

US3142034

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 11 Aug 2021 21:58:56

TIMEPOINT

DAY 4

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

Please select one response below

None

Does not interfere with activity

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

Any use of prescription pain
reliever or prevents daily activity

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

Yes

No

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

Yes

No

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

Please select one response below

None

Does not interfere with activity

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

Any use of prescription pain
reliever or prevents daily activity

PC Time Stamp

03 AUG 2020 19:27

PC Open Date & Time

03 AUG 2020 12:00

PC Close Date & Time

04 AUG 2020 11:59

US3142034

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 11 Aug 2021 21:58:56

TIMEPOINT

DAY 5

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	04 AUG 2020 20:15
PC Open Date & Time	04 AUG 2020 12:00
PC Close Date & Time	05 AUG 2020 11:59

US3142034

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 11 Aug 2021 21:58:56

TIMEPOINT

DAY 6

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

05 AUG 2020 16:50

PC Open Date & Time

05 AUG 2020 12:00

PC Close Date & Time

06 AUG 2020 11:59

US3142034

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 11 Aug 2021 21:58:56

TIMEPOINT

DAY 7

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

06 AUG 2020 18:36

PC Open Date & Time

06 AUG 2020 12:00

PC Close Date & Time

07 AUG 2020 11:59

US3142034

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 11 Aug 2021 21:58:56

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

US3142034

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 11 Aug 2021 21:58:56

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

No

Yes

PC Time stamp	31 JUL 2020 14:42
PC Open Date & Time	31 JUL 2020 14:10
PC Close Date & Time	31 JUL 2020 16:40

US3142034

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 11 Aug 2021 21:58:56

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

US3142034

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 11 Aug 2021 21:58:56

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

No

Yes

PC Time stamp	01 AUG 2020 07:45
PC Open Date & Time	31 JUL 2020 17:35
PC Close Date & Time	01 AUG 2020 11:59

US3142034

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 11 Aug 2021 21:58:56

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

US3142034

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 11 Aug 2021 21:58:56

Yes

PC Time stamp	01 AUG 2020 18:26
PC Open Date & Time	01 AUG 2020 12:00
PC Close Date & Time	02 AUG 2020 11:59

US3142034

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 11 Aug 2021 21:58:56

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

US3142034

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 11 Aug 2021 21:58:56

	Yes <input type="checkbox"/>
PC Time stamp	02 AUG 2020 17:50
PC Open Date & Time	02 AUG 2020 12:00
PC Close Date & Time	03 AUG 2020 11:59

US3142034

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 11 Aug 2021 21:58:56

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

US3142034

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 11 Aug 2021 21:58:56

	Yes <input type="checkbox"/>
PC Time stamp	03 AUG 2020 19:28
PC Open Date & Time	03 AUG 2020 12:00
PC Close Date & Time	04 AUG 2020 11:59

US3142034

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 11 Aug 2021 21:58:56

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

US3142034

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 11 Aug 2021 21:58:56

Yes

PC Time stamp	04 AUG 2020 20:16
PC Open Date & Time	04 AUG 2020 12:00
PC Close Date & Time	05 AUG 2020 11:59

US3142034

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 11 Aug 2021 21:58:56

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

US3142034

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 11 Aug 2021 21:58:56

	Yes <input type="checkbox"/>
PC Time stamp	05 AUG 2020 16:51
PC Open Date & Time	05 AUG 2020 12:00
PC Close Date & Time	06 AUG 2020 11:59

US3142034

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 11 Aug 2021 21:58:56

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

US3142034

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 11 Aug 2021 21:58:56

	Yes <input type="checkbox"/>
PC Time stamp	06 AUG 2020 18:36
PC Open Date & Time	06 AUG 2020 12:00
PC Close Date & Time	07 AUG 2020 11:59

US3142034

Folder: Safety Call Day 8 (1)

Form: Safety Call

Data signed: (b) (4) 18 Apr 2021 19:03:48

Generated On: 11 Aug 2021 21:58:56

Was Contact Attempted? Yes
No

Date of Contact or Contact Attempt (*dd MMM yyyy*) 9 AUG 2020

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

Comments

If Contact Not Made, please provide Comments

US3142034

Folder: Safety Call Day 8 (1)

Form: Continuing

Data signed: (b) (4) 18 Apr 2021 19:03:48

Generated On: 11 Aug 2021 21:58:56

Is the participant continuing to the next visit?

Yes

No

Continuing Flag

1

US3142034

Folder: Safety Call Day 15 (1)

Form: Safety Call

Data signed: (b) (4) 18 Apr 2021 19:03:48

Generated On: 11 Aug 2021 21:58:56

Was Contact Attempted? Yes
No

Date of Contact or Contact Attempt (*dd MMM yyyy*) 18 AUG 2020

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

Comments

If Contact Not Made, please provide Comments

US3142034

Folder: Safety Call Day 15 (1)

Form: Continuing

Data signed: (b) (4) 18 Apr 2021 19:03:48

Generated On: 11 Aug 2021 21:58:56

Is the participant continuing to the next visit?

Yes

No

Continuing Flag

1

US3142034

Folder: Safety Call Day 22 (1)

Form: Safety Call

Data signed: (b) (4) 18 Apr 2021 19:03:48

Generated On: 11 Aug 2021 21:58:56

Was Contact Attempted? Yes
No

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

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

Comments

If Contact Not Made, please provide Comments

US3142034

Folder: Safety Call Day 22 (1)

Form: Continuing

Data signed: (b) (4) 18 Apr 2021 19:03:48

Generated On: 11 Aug 2021 21:58:56

Is the participant continuing to the next visit?

Yes

No

Continuing Flag

1

US3142034

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Data signed: (b) (4) 18 Apr 2021 19:03:49

Generated On: 11 Aug 2021 21:58:56

Was this visit performed? Yes
No

Visit date (dd MMM yyyy) 27 AUG 2020

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

Folder OID VISIT2

US3142034

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 18 Apr 2021 19:03:49

Generated On: 11 Aug 2021 21:58:56

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 (<i>dd MMM yyyy</i>)	27 AUG 2020
Time of assessment (<i>00:00-23:59</i>)	14:10 (24 HR)
Vital Signs Date and Time (derived)	27 AUG 2020 14:10
Temperature (<i>xxx.x</i>)	97.1 F
Route of measurement	Oral <input type="radio"/>
	Axillary <input type="radio"/>
	Other <input checked="" type="radio"/>
If Other, specify	TEMPORAL
Pulse (<i>xxx</i>)	67 beats/min
Pulse units	BPM
Respiratory Rate (<i>xxx</i>)	14 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (<i>xxx</i>)	100 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (<i>xxx</i>)	60 mmHg
Diastolic Blood Pressure units	MMHG

US3142034

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 18 Apr 2021 19:03:49

Generated On: 11 Aug 2021 21:58:56

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 (<i>dd MMM yyyy</i>)	27 AUG 2020
Time of assessment (<i>00:00-23:59</i>)	15:25 (24 HR)
Vital Signs Date and Time (derived)	27 AUG 2020 15:25
Temperature (<i>xxx.x</i>)	97.5 F
Route of measurement	Oral <input type="radio"/>
	Axillary <input type="radio"/>
	Other <input checked="" type="radio"/>
If Other, specify	TEMPORAL
Pulse (<i>xxx</i>)	61 beats/min
Pulse units	BPM
Respiratory Rate (<i>xxx</i>)	12 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (<i>xxx</i>)	132 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (<i>xxx</i>)	72 mmHg
Diastolic Blood Pressure units	MMHG

US3142034

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Data signed: (b) (4) 18 Apr 2021 19:03:49

Generated On: 11 Aug 2021 21:58:56

Was the physical examination performed?

Yes

No

Date of examination (dd MMM yyyy)

27 AUG 2020

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

US3142034

Folder: Visit 2 Day 29 (1)

Form: Exposure

Data signed: (b) (4) 18 Apr 2021 19:03:49

Generated On: 11 Aug 2021 21:58:56

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) 27 AUG 2020

What was the treatment time? (00:00-23:59) 14:55 (24 HR)

Treatment Date and Time (derived) 27 AUG 2020 14:55

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

US3142034

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 18 Apr 2021 19:03:49

Generated On: 11 Aug 2021 21:58:56

Was the sample collected? Yes No

Collection date (*dd MMM yyyy*) 27 AUG 2020

Collection time (*00:00-23:59*) 14:24 (24 HR)

Collection date and time (derived) 27 AUG 2020 14:24

US3142034

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab

Data signed: (b) (4) 18 Apr 2021 19:03:49

Generated On: 11 Aug 2021 21:58:56

Collection date (<i>dd MMM yyyy</i>)			27 AUG 2020
Lab Test	Was the sample collected?	Collection time (<i>00:00 - 23:59</i>)	Collection date and time (derived)
Nasopharyngeal Swab 1	Yes	14:19	27 AUG 2020 14:19
Nasopharyngeal Swab 2	Yes	14:19	27 AUG 2020 14:19

US3142034

Folder: Visit 2 Day 29 (1)

Form: Continuing

Data signed: (b) (4) 18 Apr 2021 19:03:49

Generated On: 11 Aug 2021 21:58:56

Is the participant continuing to the next visit?

Yes

No

Continuing Flag

1

US3142034

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 11 Aug 2021 21:58:56

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 97.5 °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 27 AUG 2020 15:22

PC Open Date & Time 27 AUG 2020 15:15

PC Close Date & Time 27 AUG 2020 17:45

US3142034

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 11 Aug 2021 21:58:56

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** 97.6 °F

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

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

PC Time Stamp 27 AUG 2020 19:39
PC Open Date & Time 27 AUG 2020 18:40
PC Close Date & Time 28 AUG 2020 11:59

US3142034

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 11 Aug 2021 21:58:56

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 <input checked="" type="radio"/>
	No <input type="radio"/>
Please record your TEMPERATURE in °F	97.4 °F
Was any MEDICATION TAKEN today for pain or fever?	Yes <input type="radio"/>
	No <input checked="" type="radio"/>

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

PC Time Stamp	28 AUG 2020 16:29
PC Open Date & Time	28 AUG 2020 12:00
PC Close Date & Time	29 AUG 2020 11:59

US3142034

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 11 Aug 2021 21:58:56

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 <input checked="" type="radio"/>
	No <input type="radio"/>
Please record your TEMPERATURE in °F	97.0 °F
Was any MEDICATION TAKEN today for pain or fever?	Yes <input type="radio"/>
	No <input checked="" type="radio"/>

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

PC Time Stamp	29 AUG 2020 18:16
PC Open Date & Time	29 AUG 2020 12:00
PC Close Date & Time	30 AUG 2020 11:59

US3142034

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 11 Aug 2021 21:58:56

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 <input checked="" type="radio"/>
	No <input type="radio"/>
Please record your TEMPERATURE in °F	96.9 °F
Was any MEDICATION TAKEN today for pain or fever?	Yes <input type="radio"/>
	No <input checked="" type="radio"/>

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

PC Time Stamp	30 AUG 2020 16:50
PC Open Date & Time	30 AUG 2020 12:00
PC Close Date & Time	31 AUG 2020 11:59

US3142034

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 11 Aug 2021 21:58:56

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 <input checked="" type="radio"/>
	No <input type="radio"/>
Please record your TEMPERATURE in °F	96.9 °F
Was any MEDICATION TAKEN today for pain or fever?	Yes <input type="radio"/>
	No <input checked="" type="radio"/>

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

PC Time Stamp	31 AUG 2020 17:35
PC Open Date & Time	31 AUG 2020 12:00
PC Close Date & Time	01 SEP 2020 11:59

US3142034

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 11 Aug 2021 21:58:56

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 <input checked="" type="radio"/>
	No <input type="radio"/>
Please record your TEMPERATURE in °F	98.4 °F
Was any MEDICATION TAKEN today for pain or fever?	Yes <input type="radio"/>
	No <input checked="" type="radio"/>

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

PC Time Stamp	01 SEP 2020 17:20
PC Open Date & Time	01 SEP 2020 12:00
PC Close Date & Time	02 SEP 2020 11:59

US3142034

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 11 Aug 2021 21:58:56

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 <input checked="" type="radio"/>
	No <input type="radio"/>
Please record your TEMPERATURE in °F	96.3 °F
Was any MEDICATION TAKEN today for pain or fever?	Yes <input type="radio"/>
	No <input checked="" type="radio"/>

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

PC Time Stamp	02 SEP 2020 16:39
PC Open Date & Time	02 SEP 2020 12:00
PC Close Date & Time	03 SEP 2020 11:59

US3142034

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 11 Aug 2021 21:58:56

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

27 AUG 2020 15:22

PC Open Date & Time

27 AUG 2020 15:15

PC Close Date & Time

27 AUG 2020 17:45

US3142034

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 11 Aug 2021 21:58:56

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

27 AUG 2020 19:39

PC Open Date & Time

27 AUG 2020 18:40

PC Close Date & Time

28 AUG 2020 11:59

US3142034

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 11 Aug 2021 21:58:56

TIMEPOINT

DAY 2

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	28 AUG 2020 16:30
PC Open Date & Time	28 AUG 2020 12:00
PC Close Date & Time	29 AUG 2020 11:59

US3142034

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 11 Aug 2021 21:58:56

TIMEPOINT

DAY 3

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	29 AUG 2020 18:17
PC Open Date & Time	29 AUG 2020 12:00
PC Close Date & Time	30 AUG 2020 11:59

US3142034

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 11 Aug 2021 21:58:56

TIMEPOINT

DAY 4

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	30 AUG 2020 16:51
PC Open Date & Time	30 AUG 2020 12:00
PC Close Date & Time	31 AUG 2020 11:59

US3142034

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 11 Aug 2021 21:58:56

TIMEPOINT

DAY 5

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	31 AUG 2020 17:36
PC Open Date & Time	31 AUG 2020 12:00
PC Close Date & Time	01 SEP 2020 11:59

US3142034

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 11 Aug 2021 21:58:56

TIMEPOINT

DAY 6

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

Please select one response below

- None
- Does not interfere with activity
- Repeated use of over-the-counter pain reliever > 24 hours or interferes with activity
- Any use of prescription pain reliever or prevents daily activity

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

- Yes
- No

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

- Yes
- No

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

Please select one response below

- None
- Does not interfere with activity
- Repeated use of over-the-counter pain reliever > 24 hours or interferes with some activity
- Any use of prescription pain reliever or prevents daily activity

PC Time Stamp	01 SEP 2020 17:20
PC Open Date & Time	01 SEP 2020 12:00
PC Close Date & Time	02 SEP 2020 11:59

US3142034

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 11 Aug 2021 21:58:56

TIMEPOINT

DAY 7

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

02 SEP 2020 16:39

PC Open Date & Time

02 SEP 2020 12:00

PC Close Date & Time

03 SEP 2020 11:59

US3142034

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 11 Aug 2021 21:58:56

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

US3142034

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 11 Aug 2021 21:58:56

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

No

Yes

PC Time stamp

PC Open Date & Time

27 AUG 2020 15:15

PC Close Date & Time

27 AUG 2020 17:45

US3142034

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 11 Aug 2021 21:58:56

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

US3142034

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 11 Aug 2021 21:58:56

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

No

Yes

PC Time stamp	27 AUG 2020 19:40
PC Open Date & Time	27 AUG 2020 18:40
PC Close Date & Time	28 AUG 2020 11:59

US3142034

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 11 Aug 2021 21:58:56

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

US3142034

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 11 Aug 2021 21:58:56

Yes

PC Time stamp	28 AUG 2020 16:31
PC Open Date & Time	28 AUG 2020 12:00
PC Close Date & Time	29 AUG 2020 11:59

US3142034

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 11 Aug 2021 21:58:56

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

US3142034

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 11 Aug 2021 21:58:56

	Yes <input type="checkbox"/>
PC Time stamp	29 AUG 2020 18:18
PC Open Date & Time	29 AUG 2020 12:00
PC Close Date & Time	30 AUG 2020 11:59

US3142034

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 11 Aug 2021 21:58:56

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

US3142034

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 11 Aug 2021 21:58:56

Yes

PC Time stamp	30 AUG 2020 16:51
PC Open Date & Time	30 AUG 2020 12:00
PC Close Date & Time	31 AUG 2020 11:59

US3142034

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 11 Aug 2021 21:58:56

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

US3142034

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 11 Aug 2021 21:58:56

	Yes <input type="checkbox"/>
PC Time stamp	31 AUG 2020 17:36
PC Open Date & Time	31 AUG 2020 12:00
PC Close Date & Time	01 SEP 2020 11:59

US3142034

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 11 Aug 2021 21:58:56

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

US3142034

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 11 Aug 2021 21:58:56

	Yes <input type="checkbox"/>
PC Time stamp	01 SEP 2020 17:21
PC Open Date & Time	01 SEP 2020 12:00
PC Close Date & Time	02 SEP 2020 11:59

US3142034

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 11 Aug 2021 21:58:56

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

US3142034

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 11 Aug 2021 21:58:56

	Yes <input type="checkbox"/>
PC Time stamp	02 SEP 2020 16:40
PC Open Date & Time	02 SEP 2020 12:00
PC Close Date & Time	03 SEP 2020 11:59

US3142034

Folder: Safety Call Day 36 (1)

Form: Safety Call

Data signed: (b) (4) 18 Apr 2021 19:03:48

Generated On: 11 Aug 2021 21:58:56

Was Contact Attempted? Yes
No

Date of Contact or Contact Attempt (*dd MMM yyyy*) 04 SEP 2020

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

Comments

If Contact Not Made, please provide Comments

US3142034

Folder: Safety Call Day 36 (1)

Form: Continuing

Data signed: (b) (4) 18 Apr 2021 19:03:48

Generated On: 11 Aug 2021 21:58:56

Is the participant continuing to the next visit?

Yes

No

Continuing Flag

1

US3142034

Folder: Safety Call Day 43 (1)

Form: Safety Call

Data signed: (b) (4) 18 Apr 2021 19:03:48

Generated On: 11 Aug 2021 21:58:56

Was Contact Attempted? Yes
No

Date of Contact or Contact Attempt (*dd MMM yyyy*) 09 SEP 2020

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

Comments

If Contact Not Made, please provide Comments

US3142034

Folder: Safety Call Day 43 (1)

Form: Continuing

Data signed: (b) (4) 18 Apr 2021 19:03:48

Generated On: 11 Aug 2021 21:58:56

Is the participant continuing to the next visit?

Yes

No

Continuing Flag

1

US3142034

Folder: Safety Call Day 50 (1)

Form: Safety Call

Data signed: (b) (4) 18 Apr 2021 19:03:48

Generated On: 11 Aug 2021 21:58:56

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

US3142034

Folder: Safety Call Day 50 (1)

Form: Continuing

Data signed: (b) (4) 18 Apr 2021 19:03:48

Generated On: 11 Aug 2021 21:58:56

Is the participant continuing to the next visit?

Yes

No

Continuing Flag

1

US3142034

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Data signed: (b) (4) 18 Apr 2021 19:03:49

Generated On: 11 Aug 2021 21:58:56

Was this visit performed? Yes
No

Visit date (dd MMM yyyy) 29 SEP 2020

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

Folder OID VISIT3

US3142034

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Data signed: (b) (4) 18 Apr 2021 19:03:49

Generated On: 11 Aug 2021 21:58:56

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (<i>dd MMM yyyy</i>)	29 SEP 2020
Time of assessment (<i>00:00-23:59</i>)	14:00 (24 HR)
Vital Signs Date and Time (derived)	29 SEP 2020 14:00
Temperature (<i>xxx.x</i>)	98.0 F
Route of measurement	Oral <input type="radio"/>
	Axillary <input type="radio"/>
	Other <input checked="" type="radio"/>
If Other, specify	TEMPORAL
Pulse (<i>xxx</i>)	67 beats/min
Pulse units	BPM
Respiratory Rate (<i>xxx</i>)	10 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (<i>xxx</i>)	103 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (<i>xxx</i>)	69 mmHg
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

US3142034

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Data signed: (b) (4) 18 Apr 2021 19:03:49

Generated On: 11 Aug 2021 21:58:56

Was the physical examination performed?

Yes

No

Date of examination (dd MMM yyyy)

29 SEP 2020

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

US3142034

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 18 Apr 2021 19:03:49

Generated On: 11 Aug 2021 21:58:56

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (<i>dd MMM yyyy</i>)	29 SEP 2020
Collection time (<i>00:00-23:59</i>)	14:15 (24 HR)
Collection date and time (derived)	29 SEP 2020 14:15

US3142034

Folder: Visit 3 Day 57 (1)

Form: Continuing

Data signed: (b) (4) 18 Apr 2021 19:03:49

Generated On: 11 Aug 2021 21:58:56

Is the participant continuing to the next visit?

Yes

No

Continuing Flag

1

US3142034

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:58:56

TIMEPOINT	DAY 64
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature \geq 100.4°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"/>

US3142034

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:58:56

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

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

Date and time of submission

Patient Cloud Open Date & Time

30 SEP 2020 00:01

Patient Cloud Close Date & Time

04 OCT 2020 23:59

US3142034

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:58:56

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 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"/>

US3142034

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:58:56

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

Patient Cloud Close Date & Time

11 OCT 2020 23:59

US3142034

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:58:56

TIMEPOINT

DAY 78

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

No

Yes

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

No

Yes

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

Date and time of submission 17 OCT 2020 18:00:48

Patient Cloud Open Date & Time 14 OCT 2020 00:01

Patient Cloud Close Date & Time 18 OCT 2020 23:59

US3142034

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:58:56

TIMEPOINT	DAY 92
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input 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"/>

US3142034

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:58:56

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

Patient Cloud Close Date & Time

01 NOV 2020 23:59

US3142034

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:58:56

TIMEPOINT	DAY 99
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	08 NOV 2020 18:58:35
Patient Cloud Open Date & Time	04 NOV 2020 00:01
Patient Cloud Close Date & Time	08 NOV 2020 23:59

US3142034

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:58:56

TIMEPOINT	DAY 106
Have you 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"/>

US3142034

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:58:56

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

Patient Cloud Close Date & Time

15 NOV 2020 23:59

US3142034

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:58:56

TIMEPOINT

DAY 113

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

No

Yes

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

No

Yes

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

Date and time of submission 18 NOV 2020 08:48:35

Patient Cloud Open Date & Time 18 NOV 2020 00:01

Patient Cloud Close Date & Time 22 NOV 2020 23:59

US3142034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:58:56

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	19 NOV 2020 16:30:30
Patient Cloud Open Date & Time	15 NOV 2020 00:01
Patient Cloud Close Date & Time	19 NOV 2020 23:59

US3142034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:58:56

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

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

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

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

Chills _____

Cough _____

Shortness of breath _____

Difficulty breathing _____

Fatigue _____

Muscle aches _____

Body aches _____

Headache _____

New loss of taste _____

New loss of smell _____

Sore throat _____

Congestion _____

Runny nose _____

Nausea _____

Vomiting _____

Diarrhea _____

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

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

US3142034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:58:56

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

US3142034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:58:56

TIMEPOINT

DAY 124

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

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

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

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

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

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

Chills _____

Cough _____

Shortness of breath _____

Difficulty breathing _____

Fatigue _____

Muscle aches _____

Body aches _____

Headache _____

New loss of taste _____

New loss of smell _____

Sore throat _____

Congestion _____

Runny nose _____

Nausea _____

Vomiting _____

Diarrhea _____

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

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

US3142034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:58:56

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

[Patient Cloud Close Date & Time](#)

03 DEC 2020 23:59

US3142034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:58:56

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

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

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

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

Chills _____

Cough _____

Shortness of breath _____

Difficulty breathing _____

Fatigue _____

Muscle aches _____

Body aches _____

Headache _____

New loss of taste _____

New loss of smell _____

Sore throat _____

Congestion _____

Runny nose _____

Nausea _____

Vomiting _____

Diarrhea _____

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

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

US3142034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:58:56

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

[Patient Cloud Close Date & Time](#) 10 DEC 2020 23:59

US3142034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:58:56

TIMEPOINT

DAY 138

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

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

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

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

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

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

Chills _____

Cough _____

Shortness of breath _____

Difficulty breathing _____

Fatigue _____

Muscle aches _____

Body aches _____

Headache _____

New loss of taste _____

New loss of smell _____

Sore throat _____

Congestion _____

Runny nose _____

Nausea _____

Vomiting _____

Diarrhea _____

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

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

US3142034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:58:56

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

[Patient Cloud Close Date & Time](#)

17 DEC 2020 23:59

US3142034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:58:56

TIMEPOINT	DAY 145
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input 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 checked="" type="radio"/> Yes <input type="radio"/>
Date and time of submission	21 DEC 2020 09:25:17
Patient Cloud Open Date & Time	20 DEC 2020 00:01
Patient Cloud Close Date & Time	24 DEC 2020 23:59

US3142034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:58:56

TIMEPOINT	DAY 152
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input checked="" type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input checked="" type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	27 DEC 2020 13:03:57
Patient Cloud Open Date & Time	27 DEC 2020 00:01
Patient Cloud Close Date & Time	31 DEC 2020 23:59

US3142034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:58:56

TIMEPOINT

DAY 159

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

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

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

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

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

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

Chills _____

Cough _____

Shortness of breath _____

Difficulty breathing _____

Fatigue _____

Muscle aches _____

Body aches _____

Headache _____

New loss of taste _____

New loss of smell _____

Sore throat _____

Congestion _____

Runny nose _____

Nausea _____

Vomiting _____

Diarrhea _____

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

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

US3142034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:58:56

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

[Patient Cloud Close Date & Time](#)

07 JAN 2021 23:59

US3142034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:58:56

TIMEPOINT

DAY 166

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

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

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

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

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

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

Chills _____

Cough _____

Shortness of breath _____

Difficulty breathing _____

Fatigue _____

Muscle aches _____

Body aches _____

Headache _____

New loss of taste _____

New loss of smell _____

Sore throat _____

Congestion _____

Runny nose _____

Nausea _____

Vomiting _____

Diarrhea _____

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

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

US3142034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:58:56

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

[Patient Cloud Close Date & Time](#)

14 JAN 2021 23:59

US3142034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:58:56

TIMEPOINT	DAY 173
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input 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	17 JAN 2021 15:26:39
Patient Cloud Open Date & Time	17 JAN 2021 00:01
Patient Cloud Close Date & Time	21 JAN 2021 23:59

US3142034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:58:56

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

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

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

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

Chills _____

Cough _____

Shortness of breath _____

Difficulty breathing _____

Fatigue _____

Muscle aches _____

Body aches _____

Headache _____

New loss of taste _____

New loss of smell _____

Sore throat _____

Congestion _____

Runny nose _____

Nausea _____

Vomiting _____

Diarrhea _____

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

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

US3142034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:58:56

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

[Patient Cloud Close Date & Time](#)

28 JAN 2021 23:59

US3142034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:58:56

TIMEPOINT

DAY 187

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

US3142034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:58:56

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

[Patient Cloud Close Date & Time](#)

04 FEB 2021 23:59

US3142034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:58:56

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
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

US3142034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:58:56

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

[Patient Cloud Close Date & Time](#)

11 FEB 2021 23:59

US3142034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:58:56

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

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

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

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

Chills _____

Cough _____

Shortness of breath _____

Difficulty breathing _____

Fatigue _____

Muscle aches _____

Body aches _____

Headache _____

New loss of taste _____

New loss of smell _____

Sore throat _____

Congestion _____

Runny nose _____

Nausea _____

Vomiting _____

Diarrhea _____

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

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

US3142034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:58:56

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

[Patient Cloud Close Date & Time](#)

18 FEB 2021 23:59

US3142034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:58:56

TIMEPOINT

DAY 208

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

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

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

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

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

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

Chills _____

Cough _____

Shortness of breath _____

Difficulty breathing _____

Fatigue _____

Muscle aches _____

Body aches _____

Headache _____

New loss of taste _____

New loss of smell _____

Sore throat _____

Congestion _____

Runny nose _____

Nausea _____

Vomiting _____

Diarrhea _____

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

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

US3142034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:58:56

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

[Patient Cloud Close Date & Time](#)

25 FEB 2021 23:59

US3142034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:58:56

TIMEPOINT	DAY 215
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input 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	01 MAR 2021 07:00:05
Patient Cloud Open Date & Time	28 FEB 2021 00:01
Patient Cloud Close Date & Time	04 MAR 2021 23:59

US3142034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:58:56

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

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

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

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

Chills _____

Cough _____

Shortness of breath _____

Difficulty breathing _____

Fatigue _____

Muscle aches _____

Body aches _____

Headache _____

New loss of taste _____

New loss of smell _____

Sore throat _____

Congestion _____

Runny nose _____

Nausea _____

Vomiting _____

Diarrhea _____

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

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

US3142034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:58:56

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

[Patient Cloud Close Date & Time](#)

11 MAR 2021 23:59

US3142034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:58:56

TIMEPOINT	DAY 229
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input 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	14 MAR 2021 10:09:01
Patient Cloud Open Date & Time	14 MAR 2021 00:01
Patient Cloud Close Date & Time	18 MAR 2021 23:59

US3142034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:58:56

TIMEPOINT	DAY 236
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input 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	23 MAR 2021 07:16:29
Patient Cloud Open Date & Time	21 MAR 2021 00:01
Patient Cloud Close Date & Time	25 MAR 2021 23:59

US3142034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:58:56

TIMEPOINT

DAY 243

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

No

Yes

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

No

Yes

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

Date and time of submission 28 MAR 2021 17:53:06

Patient Cloud Open Date & Time 28 MAR 2021 00:01

Patient Cloud Close Date & Time 01 APR 2021 23:59

US3142034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:58:56

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

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 APR 2021 07:24:00

Patient Cloud Open Date & Time 04 APR 2021 00:01

Patient Cloud Close Date & Time 08 APR 2021 23:59

US3142034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:58:56

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 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	12 APR 2021 12:13:52
Patient Cloud Open Date & Time	11 APR 2021 00:01
Patient Cloud Close Date & Time	15 APR 2021 23:59

US3142034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:58:56

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 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

US3142034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:58:56

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

[Patient Cloud Close Date & Time](#)

22 APR 2021 23:59

US3142034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:58:56

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
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

US3142034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:58:56

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

[Patient Cloud Close Date & Time](#)

29 APR 2021 23:59

US3142034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:58:56

TIMEPOINT

DAY 278

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

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

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

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

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

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

Chills _____

Cough _____

Shortness of breath _____

Difficulty breathing _____

Fatigue _____

Muscle aches _____

Body aches _____

Headache _____

New loss of taste _____

New loss of smell _____

Sore throat _____

Congestion _____

Runny nose _____

Nausea _____

Vomiting _____

Diarrhea _____

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

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

US3142034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:58:56

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

[Patient Cloud Close Date & Time](#)

06 MAY 2021 23:59

US3142034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:58:56

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 Yes

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

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

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

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

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

Chills _____

Cough _____

Shortness of breath _____

Difficulty breathing _____

Fatigue _____

Muscle aches _____

Body aches _____

Headache _____

New loss of taste _____

New loss of smell _____

Sore throat _____

Congestion _____

Runny nose _____

Nausea _____

Vomiting _____

Diarrhea _____

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

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

US3142034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:58:56

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

US3142034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:58:56

TIMEPOINT

DAY 292

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

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

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

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

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

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

Chills _____

Cough _____

Shortness of breath _____

Difficulty breathing _____

Fatigue _____

Muscle aches _____

Body aches _____

Headache _____

New loss of taste _____

New loss of smell _____

Sore throat _____

Congestion _____

Runny nose _____

Nausea _____

Vomiting _____

Diarrhea _____

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

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

US3142034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:58:56

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

[Patient Cloud Close Date & Time](#)

20 MAY 2021 23:59

US3142034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:58:56

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 Yes

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

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

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

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

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

Chills _____

Cough _____

Shortness of breath _____

Difficulty breathing _____

Fatigue _____

Muscle aches _____

Body aches _____

Headache _____

New loss of taste _____

New loss of smell _____

Sore throat _____

Congestion _____

Runny nose _____

Nausea _____

Vomiting _____

Diarrhea _____

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

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

US3142034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:58:56

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

US3142034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:58:56

TIMEPOINT

DAY 306

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

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

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

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

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

- Fever (Temperature \geq 100.4°F/38°C) _____
- Chills _____
- Cough _____
- Shortness of breath _____
- Difficulty breathing _____
- Fatigue _____
- Muscle aches _____
- Body aches _____
- Headache _____
- New loss of taste _____
- New loss of smell _____
- Sore throat _____
- Congestion _____
- Runny nose _____
- Nausea _____
- Vomiting _____
- Diarrhea _____

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

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

US3142034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:58:56

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

US3142034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:58:56

TIMEPOINT

DAY 313

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

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

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

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

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

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

Chills _____

Cough _____

Shortness of breath _____

Difficulty breathing _____

Fatigue _____

Muscle aches _____

Body aches _____

Headache _____

New loss of taste _____

New loss of smell _____

Sore throat _____

Congestion _____

Runny nose _____

Nausea _____

Vomiting _____

Diarrhea _____

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

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

US3142034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:58:56

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

US3142034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:58:56

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 Yes

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

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

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

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

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

Chills _____

Cough _____

Shortness of breath _____

Difficulty breathing _____

Fatigue _____

Muscle aches _____

Body aches _____

Headache _____

New loss of taste _____

New loss of smell _____

Sore throat _____

Congestion _____

Runny nose _____

Nausea _____

Vomiting _____

Diarrhea _____

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

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

US3142034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:58:56

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

US3142034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:58:56

TIMEPOINT

DAY 327

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

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

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

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

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

- Fever (Temperature \geq 100.4°F/38°C) _____
- Chills _____
- Cough _____
- Shortness of breath _____
- Difficulty breathing _____
- Fatigue _____
- Muscle aches _____
- Body aches _____
- Headache _____
- New loss of taste _____
- New loss of smell _____
- Sore throat _____
- Congestion _____
- Runny nose _____
- Nausea _____
- Vomiting _____
- Diarrhea _____

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

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

US3142034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:58:56

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

US3142034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:58:56

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
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

US3142034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:58:56

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

US3142034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:58:56

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 Yes

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

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

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

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

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

Chills _____

Cough _____

Shortness of breath _____

Difficulty breathing _____

Fatigue _____

Muscle aches _____

Body aches _____

Headache _____

New loss of taste _____

New loss of smell _____

Sore throat _____

Congestion _____

Runny nose _____

Nausea _____

Vomiting _____

Diarrhea _____

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

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

US3142034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:58:56

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

US3142034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:58:56

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 Yes

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

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

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

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

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

Chills _____

Cough _____

Shortness of breath _____

Difficulty breathing _____

Fatigue _____

Muscle aches _____

Body aches _____

Headache _____

New loss of taste _____

New loss of smell _____

Sore throat _____

Congestion _____

Runny nose _____

Nausea _____

Vomiting _____

Diarrhea _____

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

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

US3142034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:58:56

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

US3142034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:58:56

TIMEPOINT

DAY 355

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

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

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

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

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

- Fever (Temperature \geq 100.4°F/38°C) _____
- Chills _____
- Cough _____
- Shortness of breath _____
- Difficulty breathing _____
- Fatigue _____
- Muscle aches _____
- Body aches _____
- Headache _____
- New loss of taste _____
- New loss of smell _____
- Sore throat _____
- Congestion _____
- Runny nose _____
- Nausea _____
- Vomiting _____
- Diarrhea _____

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

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

US3142034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:58:56

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

US3142034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:58:56

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 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

US3142034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:58:56

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

US3142034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:58:56

TIMEPOINT

DAY 369

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

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

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

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

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

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

Chills _____

Cough _____

Shortness of breath _____

Difficulty breathing _____

Fatigue _____

Muscle aches _____

Body aches _____

Headache _____

New loss of taste _____

New loss of smell _____

Sore throat _____

Congestion _____

Runny nose _____

Nausea _____

Vomiting _____

Diarrhea _____

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

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

US3142034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:58:56

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

US3142034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:58:56

TIMEPOINT

DAY 376

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

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

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

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

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

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

Chills _____

Cough _____

Shortness of breath _____

Difficulty breathing _____

Fatigue _____

Muscle aches _____

Body aches _____

Headache _____

New loss of taste _____

New loss of smell _____

Sore throat _____

Congestion _____

Runny nose _____

Nausea _____

Vomiting _____

Diarrhea _____

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

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

US3142034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:58:56

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

US3142034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:58:56

TIMEPOINT

DAY 383

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

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

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

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

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

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

Chills _____

Cough _____

Shortness of breath _____

Difficulty breathing _____

Fatigue _____

Muscle aches _____

Body aches _____

Headache _____

New loss of taste _____

New loss of smell _____

Sore throat _____

Congestion _____

Runny nose _____

Nausea _____

Vomiting _____

Diarrhea _____

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

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

US3142034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:58:56

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

US3142034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:58:56

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 Yes

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

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

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

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

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

Chills _____

Cough _____

Shortness of breath _____

Difficulty breathing _____

Fatigue _____

Muscle aches _____

Body aches _____

Headache _____

New loss of taste _____

New loss of smell _____

Sore throat _____

Congestion _____

Runny nose _____

Nausea _____

Vomiting _____

Diarrhea _____

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

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

US3142034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:58:56

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

US3142034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:58:56

TIMEPOINT

DAY 397

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

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

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

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

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

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

Chills _____

Cough _____

Shortness of breath _____

Difficulty breathing _____

Fatigue _____

Muscle aches _____

Body aches _____

Headache _____

New loss of taste _____

New loss of smell _____

Sore throat _____

Congestion _____

Runny nose _____

Nausea _____

Vomiting _____

Diarrhea _____

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

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

US3142034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:58:56

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

US3142034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:58:56

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 Yes

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

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

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

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

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

Chills _____

Cough _____

Shortness of breath _____

Difficulty breathing _____

Fatigue _____

Muscle aches _____

Body aches _____

Headache _____

New loss of taste _____

New loss of smell _____

Sore throat _____

Congestion _____

Runny nose _____

Nausea _____

Vomiting _____

Diarrhea _____

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

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

US3142034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:58:56

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

[Patient Cloud Close Date & Time](#)

09 SEP 2021 23:59

US3142034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:58:56

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 Yes

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

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

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

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

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

Chills _____

Cough _____

Shortness of breath _____

Difficulty breathing _____

Fatigue _____

Muscle aches _____

Body aches _____

Headache _____

New loss of taste _____

New loss of smell _____

Sore throat _____

Congestion _____

Runny nose _____

Nausea _____

Vomiting _____

Diarrhea _____

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

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

US3142034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:58:56

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

US3142034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:58:56

TIMEPOINT

DAY 418

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

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

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

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

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

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

Chills

Cough

Shortness of breath

Difficulty breathing

Fatigue

Muscle aches

Body aches

Headache

New loss of taste

New loss of smell

Sore throat

Congestion

Runny nose

Nausea

Vomiting

Diarrhea

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

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

US3142034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:58:56

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

US3142034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:58:56

TIMEPOINT

DAY 425

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

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

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

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

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

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

Chills _____

Cough _____

Shortness of breath _____

Difficulty breathing _____

Fatigue _____

Muscle aches _____

Body aches _____

Headache _____

New loss of taste _____

New loss of smell _____

Sore throat _____

Congestion _____

Runny nose _____

Nausea _____

Vomiting _____

Diarrhea _____

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

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

US3142034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:58:56

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

US3142034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:58:56

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
Yes

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

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

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

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

- Fever (Temperature \geq 100.4°F/38°C) _____
- Chills _____
- Cough _____
- Shortness of breath _____
- Difficulty breathing _____
- Fatigue _____
- Muscle aches _____
- Body aches _____
- Headache _____
- New loss of taste _____
- New loss of smell _____
- Sore throat _____
- Congestion _____
- Runny nose _____
- Nausea _____
- Vomiting _____
- Diarrhea _____

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

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

US3142034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:58:56

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

US3142034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:58:56

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
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

US3142034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:58:56

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

US3142034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:58:56

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 Yes

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

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

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

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

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

Chills _____

Cough _____

Shortness of breath _____

Difficulty breathing _____

Fatigue _____

Muscle aches _____

Body aches _____

Headache _____

New loss of taste _____

New loss of smell _____

Sore throat _____

Congestion _____

Runny nose _____

Nausea _____

Vomiting _____

Diarrhea _____

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

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

US3142034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:58:56

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

US3142034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:58:56

TIMEPOINT

DAY 453

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

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

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

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

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

- Fever (Temperature \geq 100.4°F/38°C) _____
- Chills _____
- Cough _____
- Shortness of breath _____
- Difficulty breathing _____
- Fatigue _____
- Muscle aches _____
- Body aches _____
- Headache _____
- New loss of taste _____
- New loss of smell _____
- Sore throat _____
- Congestion _____
- Runny nose _____
- Nausea _____
- Vomiting _____
- Diarrhea _____

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

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

US3142034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:58:56

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

US3142034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:58:56

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 Yes

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

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

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

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

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

Chills _____

Cough _____

Shortness of breath _____

Difficulty breathing _____

Fatigue _____

Muscle aches _____

Body aches _____

Headache _____

New loss of taste _____

New loss of smell _____

Sore throat _____

Congestion _____

Runny nose _____

Nausea _____

Vomiting _____

Diarrhea _____

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

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

US3142034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:58:56

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

US3142034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:58:56

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
Yes

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

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

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

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

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

Chills _____

Cough _____

Shortness of breath _____

Difficulty breathing _____

Fatigue _____

Muscle aches _____

Body aches _____

Headache _____

New loss of taste _____

New loss of smell _____

Sore throat _____

Congestion _____

Runny nose _____

Nausea _____

Vomiting _____

Diarrhea _____

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

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

US3142034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:58:56

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

US3142034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:58:56

TIMEPOINT

DAY 474

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

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

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

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

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

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

Chills _____

Cough _____

Shortness of breath _____

Difficulty breathing _____

Fatigue _____

Muscle aches _____

Body aches _____

Headache _____

New loss of taste _____

New loss of smell _____

Sore throat _____

Congestion _____

Runny nose _____

Nausea _____

Vomiting _____

Diarrhea _____

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

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

US3142034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:58:56

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

US3142034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:58:56

TIMEPOINT

DAY 481

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

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

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

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

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

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

Chills _____

Cough _____

Shortness of breath _____

Difficulty breathing _____

Fatigue _____

Muscle aches _____

Body aches _____

Headache _____

New loss of taste _____

New loss of smell _____

Sore throat _____

Congestion _____

Runny nose _____

Nausea _____

Vomiting _____

Diarrhea _____

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

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

US3142034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:58:56

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

US3142034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:58:56

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 Yes

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

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

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

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

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

Chills _____

Cough _____

Shortness of breath _____

Difficulty breathing _____

Fatigue _____

Muscle aches _____

Body aches _____

Headache _____

New loss of taste _____

New loss of smell _____

Sore throat _____

Congestion _____

Runny nose _____

Nausea _____

Vomiting _____

Diarrhea _____

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

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

US3142034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:58:56

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

US3142034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:58:56

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
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

US3142034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:58:56

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

US3142034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:58:56

TIMEPOINT

DAY 502

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

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

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

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

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

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

Chills _____

Cough _____

Shortness of breath _____

Difficulty breathing _____

Fatigue _____

Muscle aches _____

Body aches _____

Headache _____

New loss of taste _____

New loss of smell _____

Sore throat _____

Congestion _____

Runny nose _____

Nausea _____

Vomiting _____

Diarrhea _____

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

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

US3142034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:58:56

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

US3142034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:58:56

TIMEPOINT

DAY 509

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

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

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

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

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

- Fever (Temperature \geq 100.4°F/38°C) _____
- Chills _____
- Cough _____
- Shortness of breath _____
- Difficulty breathing _____
- Fatigue _____
- Muscle aches _____
- Body aches _____
- Headache _____
- New loss of taste _____
- New loss of smell _____
- Sore throat _____
- Congestion _____
- Runny nose _____
- Nausea _____
- Vomiting _____
- Diarrhea _____

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

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

US3142034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:58:56

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

US3142034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:58:56

TIMEPOINT

DAY 516

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

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

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

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

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

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

Chills _____

Cough _____

Shortness of breath _____

Difficulty breathing _____

Fatigue _____

Muscle aches _____

Body aches _____

Headache _____

New loss of taste _____

New loss of smell _____

Sore throat _____

Congestion _____

Runny nose _____

Nausea _____

Vomiting _____

Diarrhea _____

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

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

US3142034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:58:56

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

US3142034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:58:56

TIMEPOINT

DAY 523

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

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

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

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

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

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

Chills _____

Cough _____

Shortness of breath _____

Difficulty breathing _____

Fatigue _____

Muscle aches _____

Body aches _____

Headache _____

New loss of taste _____

New loss of smell _____

Sore throat _____

Congestion _____

Runny nose _____

Nausea _____

Vomiting _____

Diarrhea _____

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

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

US3142034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:58:56

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

US3142034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:58:56

TIMEPOINT

DAY 530

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

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

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

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

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

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

Chills _____

Cough _____

Shortness of breath _____

Difficulty breathing _____

Fatigue _____

Muscle aches _____

Body aches _____

Headache _____

New loss of taste _____

New loss of smell _____

Sore throat _____

Congestion _____

Runny nose _____

Nausea _____

Vomiting _____

Diarrhea _____

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

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

US3142034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:58:56

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

09 JAN 2022 00:01

[Patient Cloud Close Date & Time](#)

13 JAN 2022 23:59

US3142034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:58:56

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°F/38°C) _____

Chills _____

Cough _____

Shortness of breath _____

Difficulty breathing _____

Fatigue _____

Muscle aches _____

Body aches _____

Headache _____

New loss of taste _____

New loss of smell _____

Sore throat _____

Congestion _____

Runny nose _____

Nausea _____

Vomiting _____

Diarrhea _____

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

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

US3142034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:58:56

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

[Patient Cloud Close Date & Time](#)

20 JAN 2022 23:59

US3142034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:58:56

TIMEPOINT

DAY 544

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

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

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

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

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

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

Chills _____

Cough _____

Shortness of breath _____

Difficulty breathing _____

Fatigue _____

Muscle aches _____

Body aches _____

Headache _____

New loss of taste _____

New loss of smell _____

Sore throat _____

Congestion _____

Runny nose _____

Nausea _____

Vomiting _____

Diarrhea _____

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

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

US3142034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:58:56

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

23 JAN 2022 00:01

[Patient Cloud Close Date & Time](#)

27 JAN 2022 23:59

US3142034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:58:56

TIMEPOINT

DAY 551

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

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

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

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

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

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

Chills _____

Cough _____

Shortness of breath _____

Difficulty breathing _____

Fatigue _____

Muscle aches _____

Body aches _____

Headache _____

New loss of taste _____

New loss of smell _____

Sore throat _____

Congestion _____

Runny nose _____

Nausea _____

Vomiting _____

Diarrhea _____

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

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

US3142034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:58:56

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

[Patient Cloud Close Date & Time](#)

03 FEB 2022 23:59

US3142034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:58:56

TIMEPOINT

DAY 558

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

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

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

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

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

- Fever (Temperature \geq 100.4°F/38°C) _____
- Chills _____
- Cough _____
- Shortness of breath _____
- Difficulty breathing _____
- Fatigue _____
- Muscle aches _____
- Body aches _____
- Headache _____
- New loss of taste _____
- New loss of smell _____
- Sore throat _____
- Congestion _____
- Runny nose _____
- Nausea _____
- Vomiting _____
- Diarrhea _____

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

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

US3142034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:58:56

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

06 FEB 2022 00:01

[Patient Cloud Close Date & Time](#)

10 FEB 2022 23:59

US3142034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:58:56

TIMEPOINT

DAY 565

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

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

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

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

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

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

Chills _____

Cough _____

Shortness of breath _____

Difficulty breathing _____

Fatigue _____

Muscle aches _____

Body aches _____

Headache _____

New loss of taste _____

New loss of smell _____

Sore throat _____

Congestion _____

Runny nose _____

Nausea _____

Vomiting _____

Diarrhea _____

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

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

US3142034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:58:56

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

13 FEB 2022 00:01

[Patient Cloud Close Date & Time](#)

17 FEB 2022 23:59

US3142034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:58:56

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

US3142034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:58:56

Please contact your study clinic immediately. Click below to confirm that you have read this 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 FEB 2022 00:01
Patient Cloud Close Date & Time	24 FEB 2022 23:59

US3142034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:58:56

TIMEPOINT

DAY 579

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

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

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

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

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

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

Chills _____

Cough _____

Shortness of breath _____

Difficulty breathing _____

Fatigue _____

Muscle aches _____

Body aches _____

Headache _____

New loss of taste _____

New loss of smell _____

Sore throat _____

Congestion _____

Runny nose _____

Nausea _____

Vomiting _____

Diarrhea _____

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

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

US3142034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:58:56

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

Date and time of submission	
Patient Cloud Open Date & Time	27 FEB 2022 00:01
Patient Cloud Close Date & Time	03 MAR 2022 23:59

US3142034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:58:56

TIMEPOINT

DAY 586

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

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

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

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

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

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

Chills _____

Cough _____

Shortness of breath _____

Difficulty breathing _____

Fatigue _____

Muscle aches _____

Body aches _____

Headache _____

New loss of taste _____

New loss of smell _____

Sore throat _____

Congestion _____

Runny nose _____

Nausea _____

Vomiting _____

Diarrhea _____

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

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

US3142034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:58:56

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

06 MAR 2022 00:01

[Patient Cloud Close Date & Time](#)

10 MAR 2022 23:59

US3142034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:58:56

TIMEPOINT

DAY 593

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

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

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

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

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

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

Chills _____

Cough _____

Shortness of breath _____

Difficulty breathing _____

Fatigue _____

Muscle aches _____

Body aches _____

Headache _____

New loss of taste _____

New loss of smell _____

Sore throat _____

Congestion _____

Runny nose _____

Nausea _____

Vomiting _____

Diarrhea _____

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

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

US3142034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:58:56

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

[Patient Cloud Close Date & Time](#)

17 MAR 2022 23:59

US3142034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:58:56

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
Yes

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

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

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

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

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

Chills _____

Cough _____

Shortness of breath _____

Difficulty breathing _____

Fatigue _____

Muscle aches _____

Body aches _____

Headache _____

New loss of taste _____

New loss of smell _____

Sore throat _____

Congestion _____

Runny nose _____

Nausea _____

Vomiting _____

Diarrhea _____

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

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

US3142034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:58:56

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

US3142034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:58:56

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 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

US3142034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:58:56

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

US3142034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:58:56

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 Yes

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

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

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

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

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

Chills _____

Cough _____

Shortness of breath _____

Difficulty breathing _____

Fatigue _____

Muscle aches _____

Body aches _____

Headache _____

New loss of taste _____

New loss of smell _____

Sore throat _____

Congestion _____

Runny nose _____

Nausea _____

Vomiting _____

Diarrhea _____

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

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

US3142034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:58:56

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

US3142034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:58:56

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 Yes

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

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

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

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

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

Chills _____

Cough _____

Shortness of breath _____

Difficulty breathing _____

Fatigue _____

Muscle aches _____

Body aches _____

Headache _____

New loss of taste _____

New loss of smell _____

Sore throat _____

Congestion _____

Runny nose _____

Nausea _____

Vomiting _____

Diarrhea _____

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

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

US3142034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:58:56

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

US3142034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:58:56

TIMEPOINT

DAY 628

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

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

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

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

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

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

Chills _____

Cough _____

Shortness of breath _____

Difficulty breathing _____

Fatigue _____

Muscle aches _____

Body aches _____

Headache _____

New loss of taste _____

New loss of smell _____

Sore throat _____

Congestion _____

Runny nose _____

Nausea _____

Vomiting _____

Diarrhea _____

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

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

US3142034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:58:56

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

US3142034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:58:56

TIMEPOINT

DAY 635

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

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

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

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

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

- Fever (Temperature \geq 100.4°F/38°C) _____
- Chills _____
- Cough _____
- Shortness of breath _____
- Difficulty breathing _____
- Fatigue _____
- Muscle aches _____
- Body aches _____
- Headache _____
- New loss of taste _____
- New loss of smell _____
- Sore throat _____
- Congestion _____
- Runny nose _____
- Nausea _____
- Vomiting _____
- Diarrhea _____

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

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

US3142034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:58:56

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

US3142034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:58:56

TIMEPOINT

DAY 642

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

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

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

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

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

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

Chills _____

Cough _____

Shortness of breath _____

Difficulty breathing _____

Fatigue _____

Muscle aches _____

Body aches _____

Headache _____

New loss of taste _____

New loss of smell _____

Sore throat _____

Congestion _____

Runny nose _____

Nausea _____

Vomiting _____

Diarrhea _____

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

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

US3142034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:58:56

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

US3142034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:58:56

TIMEPOINT

DAY 649

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

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

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

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

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

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

Chills _____

Cough _____

Shortness of breath _____

Difficulty breathing _____

Fatigue _____

Muscle aches _____

Body aches _____

Headache _____

New loss of taste _____

New loss of smell _____

Sore throat _____

Congestion _____

Runny nose _____

Nausea _____

Vomiting _____

Diarrhea _____

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

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

US3142034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:58:56

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

[Patient Cloud Close Date & Time](#)

12 MAY 2022 23:59

US3142034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:58:56

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
Yes

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

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

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

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

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

Chills _____

Cough _____

Shortness of breath _____

Difficulty breathing _____

Fatigue _____

Muscle aches _____

Body aches _____

Headache _____

New loss of taste _____

New loss of smell _____

Sore throat _____

Congestion _____

Runny nose _____

Nausea _____

Vomiting _____

Diarrhea _____

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

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

US3142034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:58:56

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

US3142034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:58:56

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°F/38°C) _____

Chills _____

Cough _____

Shortness of breath _____

Difficulty breathing _____

Fatigue _____

Muscle aches _____

Body aches _____

Headache _____

New loss of taste _____

New loss of smell _____

Sore throat _____

Congestion _____

Runny nose _____

Nausea _____

Vomiting _____

Diarrhea _____

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

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

US3142034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:58:56

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

US3142034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:58:56

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 Yes

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

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

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

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

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

Chills _____

Cough _____

Shortness of breath _____

Difficulty breathing _____

Fatigue _____

Muscle aches _____

Body aches _____

Headache _____

New loss of taste _____

New loss of smell _____

Sore throat _____

Congestion _____

Runny nose _____

Nausea _____

Vomiting _____

Diarrhea _____

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

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

US3142034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:58:56

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

US3142034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:58:56

TIMEPOINT

DAY 677

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

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

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

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

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

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

Chills _____

Cough _____

Shortness of breath _____

Difficulty breathing _____

Fatigue _____

Muscle aches _____

Body aches _____

Headache _____

New loss of taste _____

New loss of smell _____

Sore throat _____

Congestion _____

Runny nose _____

Nausea _____

Vomiting _____

Diarrhea _____

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

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

US3142034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:58:56

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

05 JUN 2022 00:01

[Patient Cloud Close Date & Time](#)

09 JUN 2022 23:59

US3142034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:58:56

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 Yes

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

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

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

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

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

Chills _____

Cough _____

Shortness of breath _____

Difficulty breathing _____

Fatigue _____

Muscle aches _____

Body aches _____

Headache _____

New loss of taste _____

New loss of smell _____

Sore throat _____

Congestion _____

Runny nose _____

Nausea _____

Vomiting _____

Diarrhea _____

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

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

US3142034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:58:56

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

[Patient Cloud Close Date & Time](#)

16 JUN 2022 23:59

US3142034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:58:56

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
Yes

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

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

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

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

- Fever (Temperature \geq 100.4°F/38°C) _____
- Chills _____
- Cough _____
- Shortness of breath _____
- Difficulty breathing _____
- Fatigue _____
- Muscle aches _____
- Body aches _____
- Headache _____
- New loss of taste _____
- New loss of smell _____
- Sore throat _____
- Congestion _____
- Runny nose _____
- Nausea _____
- Vomiting _____
- Diarrhea _____

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

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

US3142034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:58:56

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

19 JUN 2022 00:01

[Patient Cloud Close Date & Time](#)

23 JUN 2022 23:59

US3142034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:58:56

TIMEPOINT

DAY 698

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

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

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

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

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

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

Chills _____

Cough _____

Shortness of breath _____

Difficulty breathing _____

Fatigue _____

Muscle aches _____

Body aches _____

Headache _____

New loss of taste _____

New loss of smell _____

Sore throat _____

Congestion _____

Runny nose _____

Nausea _____

Vomiting _____

Diarrhea _____

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

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

US3142034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:58:56

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

Date and time of submission

[Patient Cloud Open Date & Time](#) 26 JUN 2022 00:01

[Patient Cloud Close Date & Time](#) 30 JUN 2022 23:59

US3142034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:58:56

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 Yes

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

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

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

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

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

Chills _____

Cough _____

Shortness of breath _____

Difficulty breathing _____

Fatigue _____

Muscle aches _____

Body aches _____

Headache _____

New loss of taste _____

New loss of smell _____

Sore throat _____

Congestion _____

Runny nose _____

Nausea _____

Vomiting _____

Diarrhea _____

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

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

US3142034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:58:56

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

03 JUL 2022 00:01

[Patient Cloud Close Date & Time](#)

07 JUL 2022 23:59

US3142034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:58:56

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 Yes

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

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

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

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

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

Chills _____

Cough _____

Shortness of breath _____

Difficulty breathing _____

Fatigue _____

Muscle aches _____

Body aches _____

Headache _____

New loss of taste _____

New loss of smell _____

Sore throat _____

Congestion _____

Runny nose _____

Nausea _____

Vomiting _____

Diarrhea _____

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

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

US3142034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:58:56

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

[Patient Cloud Close Date & Time](#)

14 JUL 2022 23:59

US3142034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:58:56

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 Yes

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

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

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

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

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

Chills _____

Cough _____

Shortness of breath _____

Difficulty breathing _____

Fatigue _____

Muscle aches _____

Body aches _____

Headache _____

New loss of taste _____

New loss of smell _____

Sore throat _____

Congestion _____

Runny nose _____

Nausea _____

Vomiting _____

Diarrhea _____

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

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

US3142034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:58:56

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

[Patient Cloud Close Date & Time](#)

21 JUL 2022 23:59

US3142034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:58:56

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
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

US3142034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:58:56

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

24 JUL 2022 00:01

[Patient Cloud Close Date & Time](#)

28 JUL 2022 23:59

US3142034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:58:56

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 Yes

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

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

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

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

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

Chills _____

Cough _____

Shortness of breath _____

Difficulty breathing _____

Fatigue _____

Muscle aches _____

Body aches _____

Headache _____

New loss of taste _____

New loss of smell _____

Sore throat _____

Congestion _____

Runny nose _____

Nausea _____

Vomiting _____

Diarrhea _____

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

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

US3142034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:58:56

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

31 JUL 2022 00:01

[Patient Cloud Close Date & Time](#)

04 AUG 2022 23:59

US3142034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:58:56

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 Yes

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

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

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

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

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

Chills _____

Cough _____

Shortness of breath _____

Difficulty breathing _____

Fatigue _____

Muscle aches _____

Body aches _____

Headache _____

New loss of taste _____

New loss of smell _____

Sore throat _____

Congestion _____

Runny nose _____

Nausea _____

Vomiting _____

Diarrhea _____

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

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

US3142034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:58:56

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

[Patient Cloud Close Date & Time](#)

11 AUG 2022 23:59

US3142034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:58:56

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 Yes

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

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

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

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

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

Chills _____

Cough _____

Shortness of breath _____

Difficulty breathing _____

Fatigue _____

Muscle aches _____

Body aches _____

Headache _____

New loss of taste _____

New loss of smell _____

Sore throat _____

Congestion _____

Runny nose _____

Nausea _____

Vomiting _____

Diarrhea _____

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

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

US3142034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:58:56

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

Date and time of submission

[Patient Cloud Open Date & Time](#) 14 AUG 2022 00:01

[Patient Cloud Close Date & Time](#) 18 AUG 2022 23:59

US3142034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:58:56

TIMEPOINT

DAY 754

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

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

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

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

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

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

Chills _____

Cough _____

Shortness of breath _____

Difficulty breathing _____

Fatigue _____

Muscle aches _____

Body aches _____

Headache _____

New loss of taste _____

New loss of smell _____

Sore throat _____

Congestion _____

Runny nose _____

Nausea _____

Vomiting _____

Diarrhea _____

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

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

US3142034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:58:56

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

21 AUG 2022 00:01

[Patient Cloud Close Date & Time](#)

25 AUG 2022 23:59

US3142034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:58:56

TIMEPOINT

DAY 761

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

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

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

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

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

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

Chills _____

Cough _____

Shortness of breath _____

Difficulty breathing _____

Fatigue _____

Muscle aches _____

Body aches _____

Headache _____

New loss of taste _____

New loss of smell _____

Sore throat _____

Congestion _____

Runny nose _____

Nausea _____

Vomiting _____

Diarrhea _____

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

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

US3142034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:58:56

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

US3142034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:58:56

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 Yes

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

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

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

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

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

Chills _____

Cough _____

Shortness of breath _____

Difficulty breathing _____

Fatigue _____

Muscle aches _____

Body aches _____

Headache _____

New loss of taste _____

New loss of smell _____

Sore throat _____

Congestion _____

Runny nose _____

Nausea _____

Vomiting _____

Diarrhea _____

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

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

US3142034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:58:56

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

US3142034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:58:56

TIMEPOINT

DAY 775

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

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

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

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

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

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

Chills _____

Cough _____

Shortness of breath _____

Difficulty breathing _____

Fatigue _____

Muscle aches _____

Body aches _____

Headache _____

New loss of taste _____

New loss of smell _____

Sore throat _____

Congestion _____

Runny nose _____

Nausea _____

Vomiting _____

Diarrhea _____

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

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

US3142034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:58:56

Please contact your study clinic immediately. Click below to confirm that you have read this 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
Patient Cloud Close Date & Time	15 SEP 2022 23:59

US3142034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:58:56

TIMEPOINT

DAY 782

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

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

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

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

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

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

Chills _____

Cough _____

Shortness of breath _____

Difficulty breathing _____

Fatigue _____

Muscle aches _____

Body aches _____

Headache _____

New loss of taste _____

New loss of smell _____

Sore throat _____

Congestion _____

Runny nose _____

Nausea _____

Vomiting _____

Diarrhea _____

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

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

US3142034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:58:56

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

US3142034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:58:56

TIMEPOINT

DAY 789

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

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

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

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

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

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

Chills _____

Cough _____

Shortness of breath _____

Difficulty breathing _____

Fatigue _____

Muscle aches _____

Body aches _____

Headache _____

New loss of taste _____

New loss of smell _____

Sore throat _____

Congestion _____

Runny nose _____

Nausea _____

Vomiting _____

Diarrhea _____

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

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

US3142034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:58:56

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

US3142034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:58:56

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 Yes

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

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

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

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

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

Chills _____

Cough _____

Shortness of breath _____

Difficulty breathing _____

Fatigue _____

Muscle aches _____

Body aches _____

Headache _____

New loss of taste _____

New loss of smell _____

Sore throat _____

Congestion _____

Runny nose _____

Nausea _____

Vomiting _____

Diarrhea _____

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

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

US3142034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:58:56

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

US3142034

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection_ Dermal Filler eDiary

Generated On: 11 Aug 2021 21:58:56

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 07:00:26

US3142034

Folder: Safety Call Day 85 (1)

Form: Safety Call

Data signed: (b) (4) 18 Apr 2021 19:03:48

Generated On: 11 Aug 2021 21:58:56

Was Contact Attempted? Yes
No

Date of Contact or Contact Attempt (*dd MMM yyyy*) 19 OCT 2020

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

Comments

If Contact Not Made, please provide Comments

US3142034

Folder: Safety Call Day 85 (1)

Form: Continuing

Data signed: (b) (4) 18 Apr 2021 19:03:48

Generated On: 11 Aug 2021 21:58:56

Is the participant continuing to the next visit?

Yes

No

Continuing Flag

1

US3142034

Folder: Safety Call Day 119 (1)

Form: Safety Call

Data signed: (b) (4) 18 Apr 2021 19:03:48

Generated On: 11 Aug 2021 21:58:56

Was Contact Attempted? Yes
No

Date of Contact or Contact Attempt (*dd MMM yyyy*) 30 NOV 2020

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

Comments

If Contact Not Made, please provide Comments

US3142034

Folder: Safety Call Day 119 (1)

Form: Continuing

Data signed: (b) (4) 18 Apr 2021 19:03:48

Generated On: 11 Aug 2021 21:58:56

Is the participant continuing to the next visit?

Yes

No

Continuing Flag

1

US3142034

Folder: Safety Call Day 149 (1)

Form: Safety Call

Data signed: (b) (4) 18 Apr 2021 19:03:48

Generated On: 11 Aug 2021 21:58:56

Was Contact Attempted? Yes
No

Date of Contact or Contact Attempt (*dd MMM yyyy*) 22 DEC 2020

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

Comments

If Contact Not Made, please provide Comments

US3142034

Folder: Safety Call Day 149 (1)

Form: Continuing

Data signed: (b) (4) 18 Apr 2021 19:03:48

Generated On: 11 Aug 2021 21:58:56

Is the participant continuing to the next visit?

Yes

No

Continuing Flag

1

US3142034

Folder: Safety Call Day 179 (1)

Form: Safety Call

Data signed: (b) (4) 18 Apr 2021 19:03:48

Generated On: 11 Aug 2021 21:58:56

Was Contact Attempted? Yes
No

Date of Contact or Contact Attempt (*dd MMM yyyy*) 26 JAN 2021

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

Comments

If Contact Not Made, please provide Comments

US3142034

Folder: Safety Call Day 179 (1)

Form: Continuing

Data signed: (b) (4) 18 Apr 2021 19:03:48

Generated On: 11 Aug 2021 21:58:56

Is the participant continuing to the next visit?

Yes

No

Continuing Flag

1

US3142034

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Data signed: (b) (4) 18 Apr 2021 19:03:49

Generated On: 11 Aug 2021 21:58:56

Was this visit performed? Yes
No

Visit date (dd MMM yyyy) 02 MAR 2021

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

Folder OID VISIT4

US3142034

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Data signed: (b) (4) 18 Apr 2021 19:03:49

Generated On: 11 Aug 2021 21:58:56

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (<i>dd MMM yyyy</i>)	2 MAR 2021
Time of assessment (<i>00:00-23:59</i>)	10:16 (24 HR)
Vital Signs Date and Time (derived)	2 MAR 2021 10:16
Temperature (<i>xxx.x</i>)	97.8 F
Route of measurement	Oral <input type="radio"/>
	Axillary <input type="radio"/>
	Other <input checked="" type="radio"/>
If Other, specify	TEMPORAL
Pulse (<i>xxx</i>)	64 beats/min
Pulse units	BPM
Respiratory Rate (<i>xxx</i>)	10 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (<i>xxx</i>)	113 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (<i>xxx</i>)	70 mmHg
Diastolic Blood Pressure units	MMHG
Height (derived)	_____
Weight (derived)	_____

US3142034

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Data signed: (b) (4) 18 Apr 2021 19:03:49

Generated On: 11 Aug 2021 21:58:56

Was the physical examination performed?

Yes

No

Date of examination (dd MMM yyyy)

02 MAR 2021

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

US3142034

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 18 Apr 2021 19:03:49

Generated On: 11 Aug 2021 21:58:56

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (<i>dd MMM yyyy</i>)	02 MAR 2021
Collection time (<i>00:00-23:59</i>)	10:56 (24 HR)
Collection date and time (derived)	02 MAR 2021 10:56

US3142034

Folder: Visit 4 Day 209 (1)

Form: Continuing

Data signed: (b) (4) 18 Apr 2021 19:03:49

Generated On: 11 Aug 2021 21:58:56

Is the participant continuing to the next visit?

Yes

No

Continuing Flag

1

US3142034

Folder: Safety Call Day 239 (1)

Form: Safety Call

Data signed: (b) (4) 18 Apr 2021 19:03:48

Generated On: 11 Aug 2021 21:58:56

Was Contact Attempted? Yes
No

Date of Contact or Contact Attempt (*dd MMM yyyy*) 23 MAR 2021

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

Comments

If Contact Not Made, please provide Comments

US3142034

Folder: Safety Call Day 239 (1)

Form: Continuing

Data signed: (b) (4) 18 Apr 2021 19:03:48

Generated On: 11 Aug 2021 21:58:56

Is the participant continuing to the next visit?

Yes

No

Continuing Flag

1

US3142034

Folder: Safety Call Day 269 (1)

Form: Safety Call

Data signed: (b) (4) 26 Apr 2021 02:38:24

Generated On: 11 Aug 2021 21:58:56

Was Contact Attempted?

Yes

No

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

21 APR 2021

Please select one status for the follow-up contact

Contact Made

Contact Not Made

Comments

If Contact Not Made, please provide Comments

US3142034

Folder: Safety Call Day 269 (1)

Form: Continuing

Data signed: (b) (4) 26 Apr 2021 02:38:24

Generated On: 11 Aug 2021 21:58:56

Is the participant continuing to the next visit?

Yes

No

Continuing Flag

1

US3142034

Folder: Safety Call Day 299 (1)

Form: Safety Call

Generated On: 11 Aug 2021 21:58:56

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 _____

US3142034

Folder: Safety Call Day 299 (1)

Form: Continuing

Generated On: 11 Aug 2021 21:58:56

Is the participant continuing to the next visit?

Yes

No

Continuing Flag

US3142034

Folder: Covid-19 Assessment 14 Dec 2020

Form: COVID-19 Contact

Data signed: (b) (4) 18 Apr 2021 19:03:29

Generated On: 11 Aug 2021 21:58:56

Date of Contact	14 DEC 2020
Time of Contact	09:30
Date and Time of Contact (derived)	14 DEC 2020 09:30
Type of Contact	Clinic Visit - Scheduled <input type="checkbox"/> Clinical Visit - Unscheduled <input checked="" type="checkbox"/> Safety Call <input type="checkbox"/> Convalescent Tele-visit <input type="checkbox"/>
Has the subject reported symptoms of SARS-COV-2?	Yes <input checked="" type="checkbox"/> No <input type="checkbox"/>

US3142034

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (1)

Data signed: (b) (4) 18 Apr 2021 19:03:29

Generated On: 11 Aug 2021 21:58:56

Symptom Day

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

US3142034

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (1)

Data signed: (b) (4) 18 Apr 2021 19:03:29

Generated On: 11 Aug 2021 21:58:56

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

Date	10 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 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"/>

PRODUCTION RELEASE (v12.003
EAB) (1725)

344 of 2945

US3142034

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (1)

Data signed: (b) (4) 18 Apr 2021 19:03:29

Generated On: 11 Aug 2021 21:58:56

Not Done

Fatigue None

Mild

Moderate

Severe

Not Done

Muscle Aches (Myalgia) None

Mild

Moderate

Severe

Not Done

Body Aches None

Mild

Moderate

Severe

Not Done

Headache None

Mild

Moderate

Severe

Not Done

New Loss of Taste None

Mild

Moderate

Severe

Not Done

New Loss of Smell None

Mild

Moderate

Severe

Not Done

US3142034

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (1)

Data signed: (b) (4) 18 Apr 2021 19:03:29

Generated On: 11 Aug 2021 21:58:56

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

US3142034

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (2)

Data signed: (b) (4) 18 Apr 2021 19:03:29

Generated On: 11 Aug 2021 21:58:56

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"/>

US3142034

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (2)

Data signed: (b) (4) 18 Apr 2021 19:03:29

Generated On: 11 Aug 2021 21:58:56

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

Date	11 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 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"/>

PRODUCTION RELEASE (v12.003
EAB) (1725)

348 of 2945

US3142034

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (2)

Data signed: (b) (4) 18 Apr 2021 19:03:29

Generated On: 11 Aug 2021 21:58:56

Not Done

Fatigue None

Mild

Moderate

Severe

Not Done

Muscle Aches (Myalgia) None

Mild

Moderate

Severe

Not Done

Body Aches None

Mild

Moderate

Severe

Not Done

Headache None

Mild

Moderate

Severe

Not Done

New Loss of Taste None

Mild

Moderate

Severe

Not Done

New Loss of Smell None

Mild

Moderate

Severe

Not Done

US3142034

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (2)

Data signed: (b) (4) 18 Apr 2021 19:03:29

Generated On: 11 Aug 2021 21:58:56

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

US3142034

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (3)

Data signed: (b) (4) 18 Apr 2021 19:03:29

Generated On: 11 Aug 2021 21:58:56

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"/>

US3142034

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (3)

Data signed: (b) (4) 18 Apr 2021 19:03:29

Generated On: 11 Aug 2021 21:58:56

	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 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 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"/>

PRODUCTION RELEASE (v12.003
EAB) (1725)

352 of 2945

US3142034

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (3)

Data signed: (b) (4) 18 Apr 2021 19:03:29

Generated On: 11 Aug 2021 21:58:56

	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 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"/>

US3142034

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (3)

Data signed: (b) (4) 18 Apr 2021 19:03:29

Generated On: 11 Aug 2021 21:58:56

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

US3142034

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (4)

Data signed: (b) (4) 18 Apr 2021 19:03:29

Generated On: 11 Aug 2021 21:58:56

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"/>

US3142034

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (4)

Data signed: (b) (4) 18 Apr 2021 19:03:29

Generated On: 11 Aug 2021 21:58:56

	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 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 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"/>

PRODUCTION RELEASE (v12.003
EAB) (1725)

356 of 2945

US3142034

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (4)

Data signed: (b) (4) 18 Apr 2021 19:03:29

Generated On: 11 Aug 2021 21:58:56

	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 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"/>

US3142034

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (4)

Data signed: (b) (4) 18 Apr 2021 19:03:29

Generated On: 11 Aug 2021 21:58:56

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

US3142034

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (5)

Data signed: (b) (4) 18 Apr 2021 19:03:29

Generated On: 11 Aug 2021 21:58:56

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"/>

US3142034

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (5)

Data signed: (b) (4) 18 Apr 2021 19:03:29

Generated On: 11 Aug 2021 21:58:56

	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 DEC 2020
------	-------------

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

O2 Saturation	93 %
---------------	------

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

Temperature	97.8 F
-------------	--------

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

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

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

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

PRODUCTION RELEASE (v12.003

EAB) (1725)

360 of 2945

US3142034

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (5)

Data signed: (b) (4) 18 Apr 2021 19:03:29

Generated On: 11 Aug 2021 21:58:56

	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"/>

US3142034

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (5)

Data signed: (b) (4) 18 Apr 2021 19:03:29

Generated On: 11 Aug 2021 21:58:56

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

US3142034

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (6)

Data signed: (b) (4) 18 Apr 2021 19:03:29

Generated On: 11 Aug 2021 21:58:56

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"/>

US3142034

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (6)

Data signed: (b) (4) 18 Apr 2021 19:03:29

Generated On: 11 Aug 2021 21:58:56

	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 DEC 2020

Assessment Not Done False

O2 Saturation 93 %

O2 Saturation Units %

Temperature 97.6 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)

364 of 2945

US3142034

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (6)

Data signed: (b) (4) 18 Apr 2021 19:03:29

Generated On: 11 Aug 2021 21:58:56

Not Done

Fatigue None

Mild

Moderate

Severe

Not Done

Muscle Aches (Myalgia) None

Mild

Moderate

Severe

Not Done

Body Aches None

Mild

Moderate

Severe

Not Done

Headache None

Mild

Moderate

Severe

Not Done

New Loss of Taste None

Mild

Moderate

Severe

Not Done

New Loss of Smell None

Mild

Moderate

Severe

Not Done

US3142034

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (6)

Data signed: (b) (4) 18 Apr 2021 19:03:29

Generated On: 11 Aug 2021 21:58:56

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

US3142034

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (7)

Data signed: (b) (4) 18 Apr 2021 19:03:29

Generated On: 11 Aug 2021 21:58:56

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"/>

US3142034

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (7)

Data signed: (b) (4) 18 Apr 2021 19:03:29

Generated On: 11 Aug 2021 21:58:56

	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	17 DEC 2020
------	-------------

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

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

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

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

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

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

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

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

US3142034

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (7)

Data signed: (b) (4) 18 Apr 2021 19:03:29

Generated On: 11 Aug 2021 21:58:56

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

US3142034

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (7)

Data signed: (b) (4) 18 Apr 2021 19:03:29

Generated On: 11 Aug 2021 21:58:56

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

US3142034

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (8)

Data signed: (b) (4) 18 Apr 2021 19:03:29

Generated On: 11 Aug 2021 21:58:56

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"/>

US3142034

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (8)

Data signed: (b) (4) 18 Apr 2021 19:03:29

Generated On: 11 Aug 2021 21:58:56

	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	18 DEC 2020
------	-------------

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

O2 Saturation	<hr/>
---------------	-------

O2 Saturation Units	<hr/>
---------------------	-------

Temperature	<hr/>
-------------	-------

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

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

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

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

US3142034

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (8)

Data signed: (b) (4) 18 Apr 2021 19:03:29

Generated On: 11 Aug 2021 21:58:56

Not Done

Fatigue None

Mild

Moderate

Severe

Not Done

Muscle Aches (Myalgia) None

Mild

Moderate

Severe

Not Done

Body Aches None

Mild

Moderate

Severe

Not Done

Headache None

Mild

Moderate

Severe

Not Done

New Loss of Taste None

Mild

Moderate

Severe

Not Done

New Loss of Smell None

Mild

Moderate

Severe

Not Done

US3142034

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (8)

Data signed: (b) (4) 18 Apr 2021 19:03:29

Generated On: 11 Aug 2021 21:58:56

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

US3142034

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (9)

Data signed: (b) (4) 18 Apr 2021 19:03:29

Generated On: 11 Aug 2021 21:58:56

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"/>

US3142034

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (9)

Data signed: (b) (4) 18 Apr 2021 19:03:29

Generated On: 11 Aug 2021 21:58:56

	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	19 DEC 2020
------	-------------

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

O2 Saturation	<hr/>
---------------	-------

O2 Saturation Units	<hr/>
---------------------	-------

Temperature	<hr/>
-------------	-------

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

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

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

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

US3142034

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (9)

Data signed: (b) (4) 18 Apr 2021 19:03:29

Generated On: 11 Aug 2021 21:58:56

Not Done

Fatigue

None

Mild

Moderate

Severe

Not Done

Muscle Aches (Myalgia)

None

Mild

Moderate

Severe

Not Done

Body Aches

None

Mild

Moderate

Severe

Not Done

Headache

None

Mild

Moderate

Severe

Not Done

New Loss of Taste

None

Mild

Moderate

Severe

Not Done

New Loss of Smell

None

Mild

Moderate

Severe

Not Done

US3142034

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (9)

Data signed: (b) (4) 18 Apr 2021 19:03:29

Generated On: 11 Aug 2021 21:58:56

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

US3142034

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (10)

Data signed: (b) (4) 18 Apr 2021 19:03:29

Generated On: 11 Aug 2021 21:58:56

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"/>

US3142034

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (10)

Data signed: (b) (4) 18 Apr 2021 19:03:29

Generated On: 11 Aug 2021 21:58:56

	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 20 DEC 2020

Assessment Not Done False

O2 Saturation 94 %

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"/>

US3142034

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (10)

Data signed: (b) (4) 18 Apr 2021 19:03:29

Generated On: 11 Aug 2021 21:58:56

Not Done

Fatigue None

Mild

Moderate

Severe

Not Done

Muscle Aches (Myalgia) None

Mild

Moderate

Severe

Not Done

Body Aches None

Mild

Moderate

Severe

Not Done

Headache None

Mild

Moderate

Severe

Not Done

New Loss of Taste None

Mild

Moderate

Severe

Not Done

New Loss of Smell None

Mild

Moderate

Severe

Not Done

US3142034

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (10)

Data signed: (b) (4) 18 Apr 2021 19:03:29

Generated On: 11 Aug 2021 21:58:56

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

US3142034

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (11)

Data signed: (b) (4) 18 Apr 2021 19:03:29

Generated On: 11 Aug 2021 21:58:56

Symptom Day

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

US3142034

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (11)

Data signed: (b) (4) 18 Apr 2021 19:03:29

Generated On: 11 Aug 2021 21:58:56

	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	21 DEC 2020
------	-------------

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

O2 Saturation	93 %
---------------	------

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

Temperature	97.8 F
-------------	--------

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

Cough	None	<input 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

384 of 2945

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US3142034

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (11)

Data signed: (b) (4) 18 Apr 2021 19:03:29

Generated On: 11 Aug 2021 21:58:56

	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"/>

US3142034

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (11)

Data signed: (b) (4) 18 Apr 2021 19:03:29

Generated On: 11 Aug 2021 21:58:56

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

US3142034

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (12)

Data signed: (b) (4) 18 Apr 2021 19:03:29

Generated On: 11 Aug 2021 21:58:56

Symptom Day

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

US3142034

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (12)

Data signed: (b) (4) 18 Apr 2021 19:03:29

Generated On: 11 Aug 2021 21:58:56

	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 22 DEC 2020

Assessment Not Done False

O2 Saturation 94 %

O2 Saturation Units %

Temperature 97.9 F

Chills

None

Mild

Moderate

Severe

Not Done

Cough

None

Mild

Moderate

Severe

Not Done

Shortness of Breath

None

Mild

Moderate

Severe

Not Done

Difficulty Breathing

None

Mild

Moderate

Severe

US3142034

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (12)

Data signed: (b) (4) 18 Apr 2021 19:03:29

Generated On: 11 Aug 2021 21:58:56

Not Done

Fatigue None

Mild

Moderate

Severe

Not Done

Muscle Aches (Myalgia) None

Mild

Moderate

Severe

Not Done

Body Aches None

Mild

Moderate

Severe

Not Done

Headache None

Mild

Moderate

Severe

Not Done

New Loss of Taste None

Mild

Moderate

Severe

Not Done

New Loss of Smell None

Mild

Moderate

Severe

Not Done

US3142034

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (12)

Data signed: (b) (4) 18 Apr 2021 19:03:29

Generated On: 11 Aug 2021 21:58:56

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

US3142034

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (13)

Data signed: (b) (4) 18 Apr 2021 19:03:29

Generated On: 11 Aug 2021 21:58:56

Symptom Day

- Day 1
- Day 2
- Day 3
- Day 4
- Day 5
- Day 6
- Day 7
- Day 8
- Day 9
- Day 10
- Day 11
- Day 12
- Day 13
- Day 14
- Day 15
- Day 16
- Day 17
- Day 18
- Day 19
- Day 20
- Day 21
- Day 22
- Day 23
- Day 24
- Day 25
- Day 26
- Day 27
- Day 28
- Day 29
- Day 30
- Day 31
- Day 32

US3142034

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (13)

Data signed: (b) (4) 18 Apr 2021 19:03:29

Generated On: 11 Aug 2021 21:58:56

	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	23 DEC 2020
------	-------------

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

O2 Saturation	_____
---------------	-------

O2 Saturation Units	_____
---------------------	-------

Temperature	_____
-------------	-------

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

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

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

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

US3142034

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (13)

Data signed: (b) (4) 18 Apr 2021 19:03:29

Generated On: 11 Aug 2021 21:58:56

Not Done

Fatigue None

Mild

Moderate

Severe

Not Done

Muscle Aches (Myalgia) None

Mild

Moderate

Severe

Not Done

Body Aches None

Mild

Moderate

Severe

Not Done

Headache None

Mild

Moderate

Severe

Not Done

New Loss of Taste None

Mild

Moderate

Severe

Not Done

New Loss of Smell None

Mild

Moderate

Severe

Not Done

US3142034

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (13)

Data signed: (b) (4) 18 Apr 2021 19:03:29

Generated On: 11 Aug 2021 21:58:56

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

US3142034

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (14)

Data signed: (b) (4) 18 Apr 2021 19:03:29

Generated On: 11 Aug 2021 21:58:56

Symptom Day

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

US3142034

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (14)

Data signed: (b) (4) 18 Apr 2021 19:03:29

Generated On: 11 Aug 2021 21:58:56

	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	24 DEC 2020
------	-------------

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

O2 Saturation	<hr/>
---------------	-------

O2 Saturation Units	<hr/>
---------------------	-------

Temperature	<hr/>
-------------	-------

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

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

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

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

US3142034

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (14)

Data signed: (b) (4) 18 Apr 2021 19:03:29

Generated On: 11 Aug 2021 21:58:56

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

US3142034

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (14)

Data signed: (b) (4) 18 Apr 2021 19:03:29

Generated On: 11 Aug 2021 21:58:56

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

US3142034

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (15)

Data signed: (b) (4) 18 Apr 2021 19:03:29

Generated On: 11 Aug 2021 21:58:56

Symptom Day

- Day 1
- Day 2
- Day 3
- Day 4
- Day 5
- Day 6
- Day 7
- Day 8
- Day 9
- Day 10
- Day 11
- Day 12
- Day 13
- Day 14
- Day 15
- Day 16
- Day 17
- Day 18
- Day 19
- Day 20
- Day 21
- Day 22
- Day 23
- Day 24
- Day 25
- Day 26
- Day 27
- Day 28
- Day 29
- Day 30
- Day 31
- Day 32

US3142034

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (15)

Data signed: (b) (4) 18 Apr 2021 19:03:29

Generated On: 11 Aug 2021 21:58:56

	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	25 DEC 2020
------	-------------

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

O2 Saturation	_____
---------------	-------

O2 Saturation Units	_____
---------------------	-------

Temperature	_____
-------------	-------

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

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

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

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

US3142034

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (15)

Data signed: (b) (4) 18 Apr 2021 19:03:29

Generated On: 11 Aug 2021 21:58:56

Not Done

Fatigue None

Mild

Moderate

Severe

Not Done

Muscle Aches (Myalgia) None

Mild

Moderate

Severe

Not Done

Body Aches None

Mild

Moderate

Severe

Not Done

Headache None

Mild

Moderate

Severe

Not Done

New Loss of Taste None

Mild

Moderate

Severe

Not Done

New Loss of Smell None

Mild

Moderate

Severe

Not Done

US3142034

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (15)

Data signed: (b) (4) 18 Apr 2021 19:03:29

Generated On: 11 Aug 2021 21:58:56

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

US3142034

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (16)

Data signed: (b) (4) 18 Apr 2021 19:03:29

Generated On: 11 Aug 2021 21:58:56

Symptom Day

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

US3142034

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (16)

Data signed: (b) (4) 18 Apr 2021 19:03:29

Generated On: 11 Aug 2021 21:58:56

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

Date	26 DEC 2020
------	-------------

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

O2 Saturation	_____
---------------	-------

O2 Saturation Units	_____
---------------------	-------

Temperature	_____
-------------	-------

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

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

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

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

US3142034

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (16)

Data signed: (b) (4) 18 Apr 2021 19:03:29

Generated On: 11 Aug 2021 21:58:56

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

US3142034

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (16)

Data signed: (b) (4) 18 Apr 2021 19:03:29

Generated On: 11 Aug 2021 21:58:56

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

US3142034

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (17)

Data signed: (b) (4) 18 Apr 2021 19:03:29

Generated On: 11 Aug 2021 21:58:56

Symptom Day

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

US3142034

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (17)

Data signed: (b) (4) 18 Apr 2021 19:03:29

Generated On: 11 Aug 2021 21:58:56

	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 DEC 2020

Assessment Not Done True

O2 Saturation _____

O2 Saturation Units _____

Temperature _____

Chills

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

Cough

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

Shortness of Breath

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

Difficulty Breathing

None	<input type="checkbox"/>
Mild	<input type="checkbox"/>
Moderate	<input type="checkbox"/>
Severe	<input type="checkbox"/>

PRODUCTION RELEASE (v12.003
EAB) (1725)

408 of 2945

US3142034

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (17)

Data signed: (b) (4) 18 Apr 2021 19:03:29

Generated On: 11 Aug 2021 21:58:56

Not Done

Fatigue

None

Mild

Moderate

Severe

Not Done

Muscle Aches (Myalgia)

None

Mild

Moderate

Severe

Not Done

Body Aches

None

Mild

Moderate

Severe

Not Done

Headache

None

Mild

Moderate

Severe

Not Done

New Loss of Taste

None

Mild

Moderate

Severe

Not Done

New Loss of Smell

None

Mild

Moderate

Severe

Not Done

US3142034

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (17)

Data signed: (b) (4) 18 Apr 2021 19:03:29

Generated On: 11 Aug 2021 21:58:56

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

US3142034

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (18)

Data signed: (b) (4) 18 Apr 2021 19:03:29

Generated On: 11 Aug 2021 21:58:56

Symptom Day

Day 1	<input type="checkbox"/>
Day 2	<input type="checkbox"/>
Day 3	<input type="checkbox"/>
Day 4	<input type="checkbox"/>
Day 5	<input type="checkbox"/>
Day 6	<input type="checkbox"/>
Day 7	<input type="checkbox"/>
Day 8	<input type="checkbox"/>
Day 9	<input type="checkbox"/>
Day 10	<input type="checkbox"/>
Day 11	<input type="checkbox"/>
Day 12	<input type="checkbox"/>
Day 13	<input type="checkbox"/>
Day 14	<input type="checkbox"/>
Day 15	<input type="checkbox"/>
Day 16	<input type="checkbox"/>
Day 17	<input type="checkbox"/>
Day 18	<input type="checkbox"/>
Day 19	<input type="checkbox"/>
Day 20	<input type="checkbox"/>
Day 21	<input 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 checked="" 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"/>

US3142034

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (18)

Data signed: (b) (4) 18 Apr 2021 19:03:29

Generated On: 11 Aug 2021 21:58:56

	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 JAN 2021
------	-------------

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

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

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

Temperature	98.0 F
-------------	--------

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

Cough	None	<input 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)

412 of 2945

US3142034

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (18)

Data signed: (b) (4) 18 Apr 2021 19:03:29

Generated On: 11 Aug 2021 21:58:56

Not Done

Fatigue None

Mild

Moderate

Severe

Not Done

Muscle Aches (Myalgia) None

Mild

Moderate

Severe

Not Done

Body Aches None

Mild

Moderate

Severe

Not Done

Headache None

Mild

Moderate

Severe

Not Done

New Loss of Taste None

Mild

Moderate

Severe

Not Done

New Loss of Smell None

Mild

Moderate

Severe

Not Done

US3142034

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (18)

Data signed: (b) (4) 18 Apr 2021 19:03:29

Generated On: 11 Aug 2021 21:58:56

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

US3142034

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (19)

Data signed: (b) (4) 18 Apr 2021 19:03:29

Generated On: 11 Aug 2021 21:58:56

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"/>

US3142034

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (19)

Data signed: (b) (4) 18 Apr 2021 19:03:29

Generated On: 11 Aug 2021 21:58:56

	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 DEC 2020
------	-------------

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

O2 Saturation	94 %
---------------	------

O2 Saturation Units	%
---------------------	---

Temperature	98.0 F
-------------	--------

Chills	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>

Cough	None	<input type="radio"/>
	Mild	<input checked="" type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>

Shortness of Breath	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>

Difficulty Breathing	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>

PRODUCTION RELEASE (v12.003 EAB) (1725)	416 of 2945
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US3142034

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (19)

Data signed: (b) (4) 18 Apr 2021 19:03:29

Generated On: 11 Aug 2021 21:58:56

Not Done

Fatigue None

Mild

Moderate

Severe

Not Done

Muscle Aches (Myalgia) None

Mild

Moderate

Severe

Not Done

Body Aches None

Mild

Moderate

Severe

Not Done

Headache None

Mild

Moderate

Severe

Not Done

New Loss of Taste None

Mild

Moderate

Severe

Not Done

New Loss of Smell None

Mild

Moderate

Severe

Not Done

US3142034

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (19)

Data signed: (b) (4) 18 Apr 2021 19:03:29

Generated On: 11 Aug 2021 21:58:56

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

US3142034

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (20)

Data signed: (b) (4) 18 Apr 2021 19:03:29

Generated On: 11 Aug 2021 21:58:56

Symptom Day

Day 1	<input type="checkbox"/>
Day 2	<input type="checkbox"/>
Day 3	<input type="checkbox"/>
Day 4	<input type="checkbox"/>
Day 5	<input type="checkbox"/>
Day 6	<input type="checkbox"/>
Day 7	<input type="checkbox"/>
Day 8	<input type="checkbox"/>
Day 9	<input type="checkbox"/>
Day 10	<input type="checkbox"/>
Day 11	<input type="checkbox"/>
Day 12	<input type="checkbox"/>
Day 13	<input type="checkbox"/>
Day 14	<input type="checkbox"/>
Day 15	<input type="checkbox"/>
Day 16	<input type="checkbox"/>
Day 17	<input type="checkbox"/>
Day 18	<input type="checkbox"/>
Day 19	<input checked="" type="checkbox"/>
Day 20	<input type="checkbox"/>
Day 21	<input type="checkbox"/>
Day 22	<input type="checkbox"/>
Day 23	<input type="checkbox"/>
Day 24	<input type="checkbox"/>
Day 25	<input type="checkbox"/>
Day 26	<input type="checkbox"/>
Day 27	<input type="checkbox"/>
Day 28	<input type="checkbox"/>
Day 29	<input type="checkbox"/>
Day 30	<input type="checkbox"/>
Day 31	<input type="checkbox"/>
Day 32	<input type="checkbox"/>

US3142034

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (20)

Data signed: (b) (4) 18 Apr 2021 19:03:29

Generated On: 11 Aug 2021 21:58:56

	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 DEC 2020
------	-------------

Assessment Not Done	False
---------------------	-------

O2 Saturation	_____
---------------	-------

O2 Saturation Units	_____
---------------------	-------

Temperature	_____
-------------	-------

Chills	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>

Cough	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>

Shortness of Breath	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>

Difficulty Breathing	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>

US3142034

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (20)

Data signed: (b) (4) 18 Apr 2021 19:03:29

Generated On: 11 Aug 2021 21:58:56

Not Done

Fatigue None

Mild

Moderate

Severe

Not Done

Muscle Aches (Myalgia) None

Mild

Moderate

Severe

Not Done

Body Aches None

Mild

Moderate

Severe

Not Done

Headache None

Mild

Moderate

Severe

Not Done

New Loss of Taste None

Mild

Moderate

Severe

Not Done

New Loss of Smell None

Mild

Moderate

Severe

Not Done

US3142034

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (20)

Data signed: (b) (4) 18 Apr 2021 19:03:29

Generated On: 11 Aug 2021 21:58:56

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

US3142034

Folder: Covid-19 Assessment 14 Dec 2020

Form: COVID Diagnostic Test

Data signed: (b) (4) 18 Apr 2021 19:03:29

Generated On: 11 Aug 2021 21:58:56

Date of Visit 14 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 14 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) 1

US3142034

Folder: Covid-19 Assessment 14 Dec 2020

Form: Covid-19 Severity Assessment

Data signed: (b) (4) 18 Apr 2021 19:03:29

Generated On: 11 Aug 2021 21:58:56

Did the subject have Respiratory Rates \geq 30 per Minute? Yes
No

If Yes, provide:

Start Date _____

End Date _____

Respiratory Rate _____

Did the subject have Heart Rate \geq 125 beats per minute? Yes
No

If Yes, provide:

Start Date _____

End Date _____

Heart Rate _____

Did the subject have Oxygen Saturation of SpO₂ \leq 93% on room air at sea level? Yes
No

If Yes, provide:

Start Date 14 DEC 2020

End Date 21 DEC 2020

Oxygen Saturation 93 %

Did the subject have PaO₂/FIO₂ Ratio $<$ 300 mm Hg? Yes
No

If Yes, provide:

Start Date _____

End Date _____

PaO₂ _____

Did the subject have Respiratory failure? Yes
No

Start Date _____

Did the subject have Acute Respiratory Distress Syndrome (ARDS)? Yes
No

Start Date _____

US3142034

Folder: Covid-19 Assessment 14 Dec 2020

Form: Covid-19 Severity Assessment

Data signed: (b) (4) 18 Apr 2021 19:03:29

Generated On: 11 Aug 2021 21:58:56

If Yes to either Did subject require any of the following:

Ventilator Support:

High-Flow Oxygen? Yes
No

Start Date _____

End Date _____

Non-Invasive Ventilation? Yes
No

Start Date _____

End Date _____

Mechanical Ventilation? Yes
No

Start Date _____

End Date _____

ECMO? Yes
No

Start Date _____

End Date _____

Evidence of Shock:

Systolic Blood Pressure < 90 mmHg, Diastolic Blood Pressure < 60 mmHg Yes
No

Start Date _____

End Date _____

Evidence of Shock Requires Vasopressors Yes
No

Start Date _____

End Date _____

Acute Renal Dysfunction? Yes
No

Start Date _____

US3142034

Folder: Covid-19 Assessment 14 Dec 2020

Form: Covid-19 Severity Assessment

Data signed: (b) (4) 18 Apr 2021 19:03:29

Generated On: 11 Aug 2021 21:58:56

Hepatic Dysfunction? Yes
No

Start Date _____

Neurologic Dysfunction? Yes
No

Start Date _____

Evidence of Pneumonia:

Clinical Evidence Yes
No

Date of Assessment _____

Radiographical Evidence Yes
No

Date of Assessment _____

Admission to an intensive care unit due to SARS-CoV-2 Yes
No

Start Date _____

End Date _____

US3142034

Folder: Covid-19 Assessment 14 Dec 2020

Form: Generate Next COVID-19 Assessment

Data signed: (b) (4) 18 Apr 2021 19:03:29

Generated On: 11 Aug 2021 21:58:56

[Generate Next COVID-19 Assessment](#)

Yes

No

US3142034

Folder: Illness Visit (1)

Form: Saliva Collection

Data signed: (b) (4) 18 Apr 2021 19:03:47

Generated On: 11 Aug 2021 21:58:56

Visit	Was Saliva Collected?	Date of Collection
Day 3	Yes	17 DEC 2020
Day 5	Yes	19 DEC 2020
Day 7	Yes	21 DEC 2020
Day 9	Yes	23 DEC 2020
Day 14	Yes	28 DEC 2020
Day 21	Yes	04 JAN 2021
Day 28	No	

US3142034

Folder: Illness Visit Day 1 (1)

Form: Visit Date

Data signed: (b) (4) 18 Apr 2021 19:03:47

Generated On: 11 Aug 2021 21:58:56

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	14 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

US3142034

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Data signed: (b) (4) 18 Apr 2021 19:03:47

Generated On: 11 Aug 2021 21:58:56

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (<i>dd MMM yyyy</i>)	14 DEC 2020
Time of assessment (<i>00:00-23:59</i>)	09:47 (24 HR)
Vital Signs Date and Time (derived)	14 DEC 2020 09:47
Height (<i>xxx.x</i>)	ND - Not Done
Weight (<i>xxx.x</i>)	ND - Not Done
Temperature (<i>xxx.x</i>)	97.8 F
Route of measurement	Oral <input type="radio"/>
	Axillary <input type="radio"/>
	Other <input checked="" type="radio"/>
If Other, specify	TEMPORAL
Pulse (<i>xxx</i>)	75 beats/min
Pulse units	BPM
Respiratory Rate (<i>xxx</i>)	14 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (<i>xxx</i>)	127 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (<i>xxx</i>)	83 mmHg
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

US3142034

Folder: Illness Visit Day 1 (1)

Form: Physical Examination

Data signed: (b) (4) 18 Apr 2021 19:03:47

Generated On: 11 Aug 2021 21:58:56

Was the physical examination performed?

Yes

No

Date of examination (dd MMM yyyy)

14 DEC 2020

Any abnormal and clinically significant findings should be recorded on the Adverse Event or Medical History eCRF, as applicable.

US3142034

Folder: Illness Visit Day 1 (1)

Form: Blood Sample Collection for Immunologic Assessment of SARS-CoV-2 Infection

Data signed: (b) (4) 18 Apr 2021 19:03:47

Generated On: 11 Aug 2021 21:58:56

Was Blood Sample Taken for Immunologic Assessment of SARS_COV-2 Infection?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
	NA (COVID-19 Negative) <input type="radio"/>

Date of Collection	14 DEC 2020
--------------------	-------------

US3142034

Folder: Convalescence Visit Day 28 (1)

Form: Visit Date

Data signed: (b) (4) 18 Apr 2021 19:03:29

Generated On: 11 Aug 2021 21:58:56

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	SICKD28

US3142034

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Data signed: (b) (4) 18 Apr 2021 19:03:29

Generated On: 11 Aug 2021 21:58:56

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (<i>dd MMM yyyy</i>)	12 JAN 2021
Time of assessment (<i>00:00-23:59</i>)	10:09 (24 HR)
Vital Signs Date and Time (derived)	12 JAN 2021 10:09
Height (<i>xxx.x</i>)	ND - Not Done
Weight (<i>xxx.x</i>)	ND - Not Done
Temperature (<i>xxx.x</i>)	97.8 F
Route of measurement	Oral <input type="radio"/>
	Axillary <input type="radio"/>
	Other <input checked="" type="radio"/>
If Other, specify	TEMPORAL
Pulse (<i>xxx</i>)	82 beats/min
Pulse units	BPM
Respiratory Rate (<i>xxx</i>)	12 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (<i>xxx</i>)	112 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (<i>xxx</i>)	77 mmHg
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

US3142034

Folder: Convalescence Visit Day 28 (1)

Form: Physical Examination

Data signed: (b) (4) 18 Apr 2021 19:03:29

Generated On: 11 Aug 2021 21:58:56

Was the physical examination performed?

Yes

No

Date of examination (dd MMM yyyy)

12 JAN 2021

Any abnormal and clinically significant findings should be recorded on the Adverse Event or Medical History eCRF, as applicable.

US3142034

Folder: Convalescence Visit Day 28 (1)

Form: Blood Sample Collection for Immunologic Assessment of SARS-CoV-2 Infection

Data signed: (b) (4) 18 Apr 2021 19:03:29

Generated On: 11 Aug 2021 21:58:56

Was Blood Sample Taken for Immunologic Assessment of
SARS_COV-2 Infection?

Yes

No

NA (COVID-19 Negative)

Date of Collection

12 JAN 2021

US3142034

Folder: Participant Decision Visit / OL-D1 (1)

Form: Visit Date

Data signed: (b) (4) 18 Apr 2021 19:03:48

Generated On: 11 Aug 2021 21:58:56

Was this visit performed? Yes
No

Visit date (dd MMM yyyy) 2 MAR 2021

Was visit performed at the participant's home or at the clinic? Home
Clinic

Folder OID UNBLND_DECIDE

US3142034

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Data signed: (b) (4) 18 Apr 2021 19:03:48

Generated On: 11 Aug 2021 21:58:56

Date of updated informed consent (<i>dd MMM yyyy</i>)	12 JAN 2021
N/A - Subject Unblinded under Amendment 5 and Discontinued from Study	False
Was the participant unblinded?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Under what version of the Protocol was the Participant unblinded?	Amendment 5 <input type="radio"/> Amendment 6 or later <input checked="" type="radio"/>
Date of unblinding (<i>dd MMM yyyy</i>)	12 JAN 2021
Participant randomization assignment	mRNA-1273 <input type="radio"/> Placebo <input checked="" type="radio"/>
Actual Dose 1	mRNA-1273 <input type="radio"/> Placebo <input checked="" type="radio"/> Not Administered <input type="radio"/>
Actual Dose 2	mRNA-1273 <input type="radio"/> Placebo <input checked="" type="radio"/> Not Administered <input type="radio"/>
Will participant receive mRNA-1273?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Placebo Only Flag	1
Continuing with mRNA-1273	1

US3142034

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing

Data signed: (b) (4) 18 Apr 2021 19:03:48

Generated On: 11 Aug 2021 21:58:56

Height	ND - Not Done
Weight	ND - Not Done
BMI (xxx.x)	

US3142034

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 18 Apr 2021 19:03:48

Generated On: 11 Aug 2021 21:58:56

Height	ND - Not Done
Weight	ND - Not Done
BMI (xxx.x)	
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)	2 MAR 2021
Time of assessment (00:00-23:59)	10:16 (24 HR)
Vital Signs Date and Time (derived)	2 MAR 2021 10:16
Temperature (xxx.x)	97.8 F
Route of measurement	Oral <input type="radio"/> Axillary <input type="radio"/> Other <input checked="" type="radio"/>
If Other, specify	TEMPORAL
Pulse (xxx)	64 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	10 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	113 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	70 mmHg
Diastolic Blood Pressure units	MMHG

US3142034

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 18 Apr 2021 19:03:48

Generated On: 11 Aug 2021 21:58:56

Height	ND - Not Done
Weight	ND - Not Done
BMI (xxx.x)	
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)	2 MAR 2021
Time of assessment (00:00-23:59)	11:40 (24 HR)
Vital Signs Date and Time (derived)	2 MAR 2021 11:40
Temperature (xxx.x)	97.3 F
Route of measurement	Oral <input type="radio"/> Axillary <input type="radio"/> Other <input checked="" type="radio"/>
If Other, specify	TEMPORAL
Pulse (xxx)	64 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	10 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	136 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	66 mmHg
Diastolic Blood Pressure units	MMHG

US3142034

Folder: Participant Decision Visit / OL-D1 (1)

Form: Physical Examination

Data signed: (b) (4) 18 Apr 2021 19:03:48

Generated On: 11 Aug 2021 21:58:56

Was the physical examination performed?

Yes

No

Date of examination (dd MMM yyyy)

2 MAR 2021

Any abnormal and clinically significant findings should be recorded on the Adverse Event or Medical History eCRF, as applicable.

US3142034

Folder: Participant Decision Visit / OL-D1 (1)

Form: Exposure

Data signed: (b) (4) 18 Apr 2021 19:03:48

Generated On: 11 Aug 2021 21:58:56

Was study treatment given? Yes
No

If No, reason not given

Participant declined due to Adverse Event
Physician withheld dose due to Adverse Event
Death
Lost To Follow-Up
Physician Decision
Pregnancy
Protocol Deviation
Study Terminated by Sponsor
Withdrawal of Consent by Participant
Confirmed COVID-19
Other

If reason is Physician Decision, Withdrawal of Consent by Participant, Protocol Deviation, or Other, specify _____

What was the study treatment? (Unblinded) MRNA-1273

What was the treatment date? (dd MMM yyyy) 2 MAR 2021

What was the treatment time? (00:00-23:59) 11:10 (24 HR)

Treatment Date and Time (derived) 2 MAR 2021 11:10

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

US3142034

Folder: Participant Decision Visit / OL-D1 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 18 Apr 2021 19:03:48

Generated On: 11 Aug 2021 21:58:56

Was the sample collected? Yes No

Collection date (*dd MMM yyyy*) 2 MAR 2021

Collection time (*00:00-23:59*) 10:56 (24 HR)

Collection date and time (derived) 2 MAR 2021 10:56

US3142034

Folder: Participant Decision Visit / OL-D1 (1)

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Data signed: (b) (4) 18 Apr 2021 19:03:48

Generated On: 11 Aug 2021 21:58:56

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (<i>dd MMM yyyy</i>)	01 MAR 2021
Collection time (<i>00:00 - 23:59</i>)	10:54
Collection Date and Time (derived)	01 MAR 2021 10:54

US3142034

Folder: Participant Decision Visit / OL-D1 (1)

Form: Continuing

Data signed: (b) (4) 18 Apr 2021 19:03:48

Generated On: 11 Aug 2021 21:58:56

Is the participant continuing to the next visit?

Yes

No

Continuing Flag

1

US3142034

Folder: Safety Call OL-D8 (1)

Form: Safety Call

Data signed: (b) (4) 18 Apr 2021 19:03:48

Generated On: 11 Aug 2021 21:58:56

Was Contact Attempted? Yes
No

Date of Contact or Contact Attempt (*dd MMM yyyy*) 09 MAR 2021

Please select one status for the follow-up contact Contact Made
Contact Not Made

Comments

If Contact Not Made, please provide Comments

US3142034

Folder: Safety Call OL-D8 (1)

Form: Continuing

Data signed: (b) (4) 18 Apr 2021 19:03:48

Generated On: 11 Aug 2021 21:58:56

Is the participant continuing to the next visit?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Continuing Flag	1
OLD29 Placebo Flag	1

US3142034

Folder: OL-D29 (1)

Form: Visit Date

Data signed: (b) (4) 18 Apr 2021 19:03:47

Generated On: 11 Aug 2021 21:58:56

Was this visit performed? Yes
No

Visit date (dd MMM yyyy) 01 APR 2021

Was visit performed at the participant's home or at the clinic? Home
Clinic

Folder OID OLD29

US3142034

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 18 Apr 2021 19:03:47

Generated On: 11 Aug 2021 21:58:56

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 (<i>dd MMM yyyy</i>)	01 APR 2021
Time of assessment (<i>00:00-23:59</i>)	12:11 (24 HR)
Vital Signs Date and Time (derived)	01 APR 2021 12:11
Temperature (<i>xxx.x</i>)	97.9 F
Route of measurement	Oral <input type="radio"/>
	Axillary <input type="radio"/>
	Other <input checked="" type="radio"/>
If Other, specify	TEMPORAL
Pulse (<i>xxx</i>)	67 beats/min
Pulse units	BPM
Respiratory Rate (<i>xxx</i>)	14 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (<i>xxx</i>)	132 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (<i>xxx</i>)	73 mmHg
Diastolic Blood Pressure units	MMHG

US3142034

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 18 Apr 2021 19:03:47

Generated On: 11 Aug 2021 21:58:56

Timepoint Pre-Dose
Post-Dose

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 _____

US3142034

Folder: OL-D29 (1)

Form: Physical Examination

Data signed: (b) (4) 18 Apr 2021 19:03:47

Generated On: 11 Aug 2021 21:58:56

Was the physical examination performed?

Yes

No

Date of examination (*dd MMM yyyy*)

01 APR 2021

Any abnormal and clinically significant findings should be recorded on the Adverse Event or Medical History eCRF, as applicable.

US3142034

Folder: OL-D29 (1)

Form: Exposure

Data signed: (b) (4) 18 Apr 2021 19:03:47

Generated On: 11 Aug 2021 21:58:56

Was study treatment given? Yes
No

If No, reason not given

Participant declined due to Adverse Event

Physician withheld dose due to Adverse Event

Death

Lost To Follow-Up

Physician Decision

Pregnancy

Protocol Deviation

Study Terminated by Sponsor

Withdrawal of Consent by Participant

Confirmed COVID-19

Other

If reason is Physician Decision, Withdrawal of Consent by Participant, Protocol Deviation, or Other, specify _____

What was the study treatment? (Unblinded) MRNA-1273

What was the treatment date? (dd MMM yyyy) 01 APR 2021

What was the treatment time? (00:00-23:59) 12:42 (24 HR)

Treatment Date and Time (derived) 01 APR 2021 12:42

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

US3142034

Folder: OL-D29 (1)

Form: Continuing

Data signed: (b) (4) 18 Apr 2021 19:03:47

Generated On: 11 Aug 2021 21:58:56

Is the participant continuing to the next visit?

Yes

No

Continuing Flag

1

US3142034

Folder: Safety Call OL-D36 (1)

Form: Safety Call

Data signed: (b) (4) 18 Apr 2021 19:03:48

Generated On: 11 Aug 2021 21:58:56

Was Contact Attempted? Yes
No

Date of Contact or Contact Attempt (*dd MMM yyyy*) 12 APR 2021

Please select one status for the follow-up contact Contact Made
Contact Not Made

Comments

If Contact Not Made, please provide Comments

US3142034

Folder: Safety Call OL-D36 (1)

Form: Continuing

Data signed: (b) (4) 18 Apr 2021 19:03:48

Generated On: 11 Aug 2021 21:58:56

Is the participant continuing to the next visit?

Yes

No

Continuing Flag

1

US3142034

Folder: OL-D57 (1)

Form: Visit Date

Data signed: (b) (4) 03 May 2021 15:03:28

Generated On: 11 Aug 2021 21:58:56

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	26 APR 2021
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	OLD57

US3142034

Folder: OL-D57 (1)

Form: Vital Signs

Data signed: (b) (4) 03 May 2021 15:03:28

Generated On: 11 Aug 2021 21:58:56

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (<i>dd MMM yyyy</i>)	26 APR 2021
Time of assessment (<i>00:00-23:59</i>)	10:00 (24 HR)
Vital Signs Date and Time (derived)	26 APR 2021 10:00
Temperature (<i>xxx.x</i>)	98.0 F
Route of measurement	Oral <input type="radio"/>
	Axillary <input type="radio"/>
	Other <input checked="" type="radio"/>
If Other, specify	TEMPORAL
Pulse (<i>xxx</i>)	80 beats/min
Pulse units	BPM
Respiratory Rate (<i>xxx</i>)	14 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (<i>xxx</i>)	115 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (<i>xxx</i>)	76 mmHg
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

US3142034

Folder: OL-D57 (1)

Form: Physical Examination

Data signed: (b) (4) 03 May 2021 15:03:28

Generated On: 11 Aug 2021 21:58:56

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.

US3142034

Folder: OL-D57 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 03 May 2021 15:03:28

Generated On: 11 Aug 2021 21:58:56

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (<i>dd MMM yyyy</i>)	26 APR 2021
Collection time (<i>00:00-23:59</i>)	10:05 (24 HR)
Collection date and time (derived)	26 APR 2021 10:05

US3142034

Folder: Adverse Events

Form: Adverse Events Summary

Data signed: (b) (4) 18 Apr 2021 19:03:28

Generated On: 11 Aug 2021 21:58:56

Did the participant experience any adverse events?

Yes

No

If Yes, enter details on the Adverse Events form.

US3142034

Folder: Adverse Events

Form: Adverse Events (1)

Data signed: (b) (4) 18 Apr 2021 19:03:28

Generated On: 11 Aug 2021 21:58:56

AEID USA-US064-2021-MRNA-1273-P30
1000007

Adverse event POSITIVE COVID-19 DIAGNOSIS

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) 14 DEC 2020

Start time (00:00-23:59)

AE start date and time (derived)

Ongoing? Yes
No

If not Ongoing, end date (dd MMM yyyy) 28 DEC 2020

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

US3142034

Folder: Adverse Events

Form: Adverse Events (1)

Data signed: (b) (4) 18 Apr 2021 19:03:28

Generated On: 11 Aug 2021 21:58:56

Number of Days in ICU	
Persistent or significant disability or incapacity	False
Congenital anomaly or birth defect	False
Other medically important event	False
Relationship to investigational product	Not Related <input checked="" type="radio"/> Related <input type="radio"/> Not Applicable <input type="radio"/>
Relationship to Study Procedure	Not Related <input type="radio"/> Related <input type="radio"/> Not Applicable <input checked="" type="radio"/>
Action taken with investigational product	None <input type="radio"/> Dose Delayed <input type="radio"/> Investigational Product Withdrawn <input type="radio"/> Not Applicable <input checked="" type="radio"/>
Other action taken (check all that apply)	
None	True
Concomitant Medication	False
Concomitant Procedure	False
Outcome	Fatal <input type="radio"/> Not Recovered/Not Resolved <input type="radio"/> Recovered/Resolved <input checked="" type="radio"/> Recovered/Resolved with Sequelae <input type="radio"/> Recovering/Resolving <input type="radio"/> Unknown <input type="radio"/>
If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:	
Narrative	
Serious Adverse Event Derived (CSA Programming Field Only)	0
Medically Attended AE Derived (CSA Programming Field Only)	1
Admitted to ICU Derived (CSA Programming Field Only)	

US3142034

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Data signed: (b) (4) 18 Apr 2021 19:03:29

Generated On: 11 Aug 2021 21:58:56

Were any prior/concomitant medications and/or vaccinations taken?

Yes

No

If Yes, please complete Prior/Concomitant Medication and Vaccination form.

US3142034

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Data signed: (b) (4) 18 Apr 2021 19:03:28

Generated On: 11 Aug 2021 21:58:56

Name of Medication LISINOPRIL

Prophylaxis Yes
No

Indication HYPERTENSION

Dose per administration 40

Dose unit mg
ug
mL
g
IU
tablet
capsule
puff
Other

If dose unit is Other, specify

Frequency once daily
twice daily
three times daily
four times daily
every other day
every week
every month
as needed
once
unknown
other

If frequency is Other, specify

Route of administration Oral
Topical
Subcutaneous
Transdermal
Intraocular

PRODUCTION RELEASE (v12.003
EAB) (1725)

465 of 2945

US3142034

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Data signed: (b) (4) 18 Apr 2021 19:03:28

Generated On: 11 Aug 2021 21:58:56

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
No

If not Ongoing, End date (*dd MMM yyyy*) _____

Was this medication taken for solicited event? Yes
No

Separate Dosage Number (derived) 1

Interval Dosage Unit Number (derived) 1

Interval Dosage Definition (derived) 802
803
804

US3142034

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Data signed: (b) (4) 18 Apr 2021 19:03:28

Generated On: 11 Aug 2021 21:58:56

Name of Medication DILTIAZEM

Prophylaxis Yes
No

Indication HYPERTENSION

Dose per administration 240

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)

467 of 2945

US3142034

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Data signed: (b) (4) 18 Apr 2021 19:03:28

Generated On: 11 Aug 2021 21:58:56

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
No

If not Ongoing, End date (*dd MMM yyyy*) _____

Was this medication taken for solicited event? Yes
No

Separate Dosage Number (derived) 1

Interval Dosage Unit Number (derived) 1

Interval Dosage Definition (derived) 802
803
804

US3142034

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Data signed: (b) (4) 18 Apr 2021 19:03:28

Generated On: 11 Aug 2021 21:58:56

Name of Medication SIMVASTATIN

Prophylaxis Yes
No

Indication HYPERCHOLESTEROLEMIA

Dose per administration 40

Dose unit mg
ug
mL
g
IU
tablet
capsule
puff
Other

If dose unit is Other, specify

Frequency once daily
twice daily
three times daily
four times daily
every other day
every week
every month
as needed
once
unknown
other

If frequency is Other, specify

Route of administration Oral
Topical
Subcutaneous
Transdermal
Intraocular

PRODUCTION RELEASE (v12.003
EAB) (1725)

469 of 2945

US3142034

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Data signed: (b) (4) 18 Apr 2021 19:03:28

Generated On: 11 Aug 2021 21:58:56

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
No

If not Ongoing, End date (*dd MMM yyyy*) _____

Was this medication taken for solicited event? Yes
No

Separate Dosage Number (derived) 1

Interval Dosage Unit Number (derived) 1

Interval Dosage Definition (derived) 802
803
804

US3142034

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Data signed: (b) (4) 18 Apr 2021 19:03:28

Generated On: 11 Aug 2021 21:58:56

Name of Medication VIVELLE DOT

Prophylaxis Yes
No

Indication MENOPAUSE

Dose per administration 0.025

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

TWICE A WEEK

Route of administration Oral
Topical
Subcutaneous
Transdermal
Intraocular

PRODUCTION RELEASE (v12.003
EAB) (1725)

471 of 2945

US3142034

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Data signed: (b) (4) 18 Apr 2021 19:03:28

Generated On: 11 Aug 2021 21:58:56

	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
No

If not Ongoing, End date (*dd MMM yyyy*) _____

Was this medication taken for solicited event? Yes
No

Separate Dosage Number (derived) _____

Interval Dosage Unit Number (derived) _____

Interval Dosage Definition (derived) 802
803
804

US3142034

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Data signed: (b) (4) 18 Apr 2021 19:03:28

Generated On: 11 Aug 2021 21:58:56

Name of Medication MEDROXY PROGESTERONE

Prophylaxis Yes
No

Indication MENOPAUSE

Dose per administration 10

Dose unit mg
ug
mL
g
IU
tablet
capsule
puff
Other

If dose unit is Other, specify

Frequency once daily
twice daily
three times daily
four times daily
every other day
every week
every month
as needed
once
unknown
other

If frequency is Other, specify

EVERY 3 MONTHS

Route of administration Oral
Topical
Subcutaneous
Transdermal
Intraocular

PRODUCTION RELEASE (v12.003
EAB) (1725)

473 of 2945

US3142034

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Data signed: (b) (4) 18 Apr 2021 19:03:28

Generated On: 11 Aug 2021 21:58:56

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
No

If not Ongoing, End date (*dd MMM yyyy*) _____

Was this medication taken for solicited event? Yes
No

Separate Dosage Number (derived) _____

Interval Dosage Unit Number (derived) _____

Interval Dosage Definition (derived) 802
803
804

US3142034

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Data signed: (b) (4) 18 Apr 2021 19:03:28

Generated On: 11 Aug 2021 21:58:56

Name of Medication FOSAMAX

Prophylaxis Yes
No

Indication OSTEOPOROSIS

Dose per administration 70

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)

475 of 2945

US3142034

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Data signed: (b) (4) 18 Apr 2021 19:03:28

Generated On: 11 Aug 2021 21:58:56

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 2016

Start date completely unknown False

Ongoing? Yes
No

If not Ongoing, End date (*dd MMM yyyy*) _____

Was this medication taken for solicited event? Yes
No

Separate Dosage Number (derived) 1

Interval Dosage Unit Number (derived) 1

Interval Dosage Definition (derived) 802
803
804

US3142034

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Data signed: (b) (4) 18 Apr 2021 19:03:28

Generated On: 11 Aug 2021 21:58:56

Name of Medication VITAMIN D3

Prophylaxis Yes
No

Indication GENERAL HEALTH

Dose per administration 1000

Dose unit mg
ug
mL
g
IU
tablet
capsule
puff
Other

If dose unit is Other, specify

Frequency once daily
twice daily
three times daily
four times daily
every other day
every week
every month
as needed
once
unknown
other

If frequency is Other, specify

Route of administration Oral
Topical
Subcutaneous
Transdermal
Intraocular

PRODUCTION RELEASE (v12.003
EAB) (1725)

477 of 2945

US3142034

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Data signed: (b) (4) 18 Apr 2021 19:03:28

Generated On: 11 Aug 2021 21:58:56

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
No

If not Ongoing, End date (*dd MMM yyyy*) _____

Was this medication taken for solicited event? Yes
No

Separate Dosage Number (derived) 1

Interval Dosage Unit Number (derived) 1

Interval Dosage Definition (derived) 802
803
804

US3142034

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Data signed: (b) (4) 18 Apr 2021 19:03:28

Generated On: 11 Aug 2021 21:58:56

Name of Medication CITRACAL

Prophylaxis Yes
No

Indication GENERAL HEALTH

Dose per administration 400

Dose unit mg
ug
mL
g
IU
tablet
capsule
puff
Other

If dose unit is Other, specify

Frequency once daily
twice daily
three times daily
four times daily
every other day
every week
every month
as needed
once
unknown
other

If frequency is Other, specify

Route of administration Oral
Topical
Subcutaneous
Transdermal
Intraocular

PRODUCTION RELEASE (v12.003
EAB) (1725)

479 of 2945

US3142034

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Data signed: (b) (4) 18 Apr 2021 19:03:28

Generated On: 11 Aug 2021 21:58:56

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 2015

Start date completely unknown False

Ongoing? Yes
No

If not Ongoing, End date (*dd MMM yyyy*) _____

Was this medication taken for solicited event? Yes
No

Separate Dosage Number (derived) 1

Interval Dosage Unit Number (derived) 1

Interval Dosage Definition (derived) 802
803
804

US3142034

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Data signed: (b) (4) 18 Apr 2021 19:03:28

Generated On: 11 Aug 2021 21:58:56

Name of Medication CALCIUM

Prophylaxis Yes
No

Indication GENERAL HEALTH

Dose per administration 200

Dose unit mg
ug
mL
g
IU
tablet
capsule
puff
Other

If dose unit is Other, specify _____

Frequency once daily
twice daily
three times daily
four times daily
every other day
every week
every month
as needed
once
unknown
other

If frequency is Other, specify _____

Route of administration Oral
Topical
Subcutaneous
Transdermal
Intraocular

PRODUCTION RELEASE (v12.003
EAB) (1725)

481 of 2945

US3142034

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Data signed: (b) (4) 18 Apr 2021 19:03:28

Generated On: 11 Aug 2021 21:58:56

Intramuscular	<input type="checkbox"/>
Respiratory (Inhalation)	<input type="checkbox"/>
Intralesional	<input type="checkbox"/>
Intraperitoneal	<input type="checkbox"/>
Nasal	<input type="checkbox"/>
Vaginal	<input type="checkbox"/>
Rectal	<input type="checkbox"/>
Intravenous	<input type="checkbox"/>
Intravenous Bolus	<input type="checkbox"/>
Intravenous Drip	<input type="checkbox"/>
Other	<input type="checkbox"/>

If route of administration is Other, specify _____

Start date (*dd MMM yyyy*) UN UNK 2010

Start date completely unknown False

Ongoing? Yes
No

If not Ongoing, End date (*dd MMM yyyy*) _____

Was this medication taken for solicited event? Yes
No

Separate Dosage Number (derived) 1

Interval Dosage Unit Number (derived) 1

Interval Dosage Definition (derived) 802
803
804

US3142034

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Data signed: (b) (4) 18 Apr 2021 19:03:28

Generated On: 11 Aug 2021 21:58:56

Name of Medication MAGNESIUM

Prophylaxis Yes
No

Indication GENERAL HEALTH

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)

483 of 2945

US3142034

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Data signed: (b) (4) 18 Apr 2021 19:03:28

Generated On: 11 Aug 2021 21:58:56

Intramuscular	<input type="checkbox"/>
Respiratory (Inhalation)	<input type="checkbox"/>
Intralesional	<input type="checkbox"/>
Intraperitoneal	<input type="checkbox"/>
Nasal	<input type="checkbox"/>
Vaginal	<input type="checkbox"/>
Rectal	<input type="checkbox"/>
Intravenous	<input type="checkbox"/>
Intravenous Bolus	<input type="checkbox"/>
Intravenous Drip	<input type="checkbox"/>
Other	<input type="checkbox"/>

If route of administration is Other, specify _____

Start date (*dd MMM yyyy*) UN UNK 2010

Start date completely unknown False

Ongoing? Yes
No

If not Ongoing, End date (*dd MMM yyyy*) _____

Was this medication taken for solicited event? Yes
No

Separate Dosage Number (derived) 1

Interval Dosage Unit Number (derived) 1

Interval Dosage Definition (derived) 802
803
804

US3142034

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Data signed: (b) (4) 18 Apr 2021 19:03:28

Generated On: 11 Aug 2021 21:58:56

Name of Medication ZINC

Prophylaxis Yes
No

Indication GENERAL HEALTH

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)

485 of 2945

US3142034

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Data signed: (b) (4) 18 Apr 2021 19:03:28

Generated On: 11 Aug 2021 21:58:56

	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 MAR 2020

Start date completely unknown False

Ongoing? Yes
No

If not Ongoing, End date (dd MMM yyyy) _____

Was this medication taken for solicited event? Yes
No

Separate Dosage Number (derived) 1

Interval Dosage Unit Number (derived) 1

Interval Dosage Definition (derived) 802
803
804

US3142034

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Data signed: (b) (4) 18 Apr 2021 19:03:28

Generated On: 11 Aug 2021 21:58:56

Name of Medication FOLIC ACID

Prophylaxis Yes
No

Indication GENERAL HEALTH

Dose per administration 800

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)

487 of 2945

US3142034

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Data signed: (b) (4) 18 Apr 2021 19:03:28

Generated On: 11 Aug 2021 21:58:56

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
No

If not Ongoing, End date (dd MMM yyyy) _____

Was this medication taken for solicited event? Yes
No

Separate Dosage Number (derived) 1

Interval Dosage Unit Number (derived) 1

Interval Dosage Definition (derived) 802
803
804

US3142034

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Data signed: (b) (4) 18 Apr 2021 19:03:28

Generated On: 11 Aug 2021 21:58:56

Name of Medication VITAMIN B12

Prophylaxis Yes
No

Indication GENERAL HEALTH

Dose per administration 1000

Dose unit mg
ug
mL
g
IU
tablet
capsule
puff
Other

If dose unit is Other, specify

Frequency once daily
twice daily
three times daily
four times daily
every other day
every week
every month
as needed
once
unknown
other

If frequency is Other, specify

Route of administration Oral
Topical
Subcutaneous
Transdermal
Intraocular

PRODUCTION RELEASE (v12.003
EAB) (1725)

489 of 2945

US3142034

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Data signed: (b) (4) 18 Apr 2021 19:03:28

Generated On: 11 Aug 2021 21:58:56

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
No

If not Ongoing, End date (*dd MMM yyyy*) _____

Was this medication taken for solicited event? Yes
No

Separate Dosage Number (derived) 1

Interval Dosage Unit Number (derived) 1

Interval Dosage Definition (derived) 802
803
804

US3142034

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Data signed: (b) (4) 18 Apr 2021 19:03:28

Generated On: 11 Aug 2021 21:58:56

Name of Medication FISH OIL

Prophylaxis Yes
No

Indication GENERAL HEALTH

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)

491 of 2945

US3142034

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Data signed: (b) (4) 18 Apr 2021 19:03:28

Generated On: 11 Aug 2021 21:58:56

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
No

If not Ongoing, End date (dd MMM yyyy) _____

Was this medication taken for solicited event? Yes
No

Separate Dosage Number (derived) 1

Interval Dosage Unit Number (derived) 1

Interval Dosage Definition (derived) 802
803
804

US3142034

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Data signed: (b) (4) 18 Apr 2021 19:03:28

Generated On: 11 Aug 2021 21:58:56

Name of Medication ACIDOPHILUS

Prophylaxis Yes
No

Indication GENERAL HEALTH

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)

493 of 2945

US3142034

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Data signed: (b) (4) 18 Apr 2021 19:03:28

Generated On: 11 Aug 2021 21:58:56

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
No

If not Ongoing, End date (*dd MMM yyyy*) _____

Was this medication taken for solicited event? Yes
No

Separate Dosage Number (derived) 1

Interval Dosage Unit Number (derived) 1

Interval Dosage Definition (derived) 802
803
804

US3142034

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures Summary

Data signed: (b) (4) 18 Apr 2021 19:03:29

Generated On: 11 Aug 2021 21:58:56

Were any concomitant procedures performed?

Yes

No

If yes, please complete Concomitant Procedures form.

US3142034

Folder: End of Study (1)

Form: Dosing Discontinuation

Generated On: 11 Aug 2021 21:58:56

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

US3142034

Folder: End of Study (1)

Form: End of Study / Study Discontinuation

Generated On: 11 Aug 2021 21:58:56

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

US3142034

Folder: SAE USA-US064-2021-MRNA-1273-P301000007

Form: Safety Report Form

Data signed: (b) (4) 18 Apr 2021 19:03:48

Generated On: 11 Aug 2021 21:58:56

SAEID	USA-US064-2021-MRNA-1273-P30 1000007
Serious	Yes <input type="radio"/> No <input checked="" type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input type="radio"/> No <input checked="" type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input type="radio"/> No <input checked="" type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input type="radio"/> No <input checked="" type="radio"/>
Investigator's First Name	RIPLEY
Investigator's Last Name	HOLLISTER
Site Address: Street	4190 EAST WOODMEN ROAD SUITE 210
Site Address: City	COLORADO SPRINGS
Site Address: State	
Site Address: Postal Code	80920
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	1

US3142034

Folder: SAE USA-US064-2021-MRNA-1273-P301000007

Form: Safety Report Form (1)

Data signed: (b) (4) 18 Apr 2021 19:03:48

Generated On: 11 Aug 2021 21:58:56

SAEID USA-US064-2021-MRNA-1273-P30
1000007

Serious Yes
No

Death Yes
No

Life threatening Yes
No

Requires inpatient or prolongation of existing Hospitalization Yes
No

Persistent or significant disability or incapacity Yes
No

Congenital anomaly or birth defect Yes
No

Other medically important event Yes
No

Investigator's First Name RIPLEY

Investigator's Last Name HOLLISTER

Site Address: Street 4190 EAST WOODMEN ROAD
SUITE 210

Site Address: City COLORADO SPRINGS

Site Address: State

Site Address: Postal Code 80920

Investigator Country US

E2B Transmit Flag (Derived/Hidden) 1

Date of submission (Pre-filled from custom function) 26/MAR/2021 14:56

Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge. True

Audit

US3142034 (Prod: Lynn Institute of The Rockies - ERN-PPDS)

US3142034

Form: Participant Creation

Generated On: 11 Aug 2021 21:58:56

[Participant ID](#)

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 19:03:31
User entered 'US3142034'	RWS_ENDPOINT ENDPOINT (b) (4)	31 Jul 2020 17:24:16

US3142034

Folder: Screening

Form: Visit Date

Generated On: 11 Aug 2021 21:58:56

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:52:49
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 19:03:50
User entered 'Yes (Y)'	Shelby Pickle (b) (4) (b) (4)	31 Jul 2020 17:31:41

US3142034

Folder: Screening

Form: Visit Date

Generated On: 11 Aug 2021 21:58:56

[Visit date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:52:49
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:03:50
User entered '31 JUL 2020'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	31 Jul 2020 17:24:16

US3142034

Folder: Screening

Form: Visit Date

Generated On: 11 Aug 2021 21:58:56

[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 17:52:49
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 19:03:50
User entered 'Clinic (Clinic)'	Shelby Pickle (b) (4) (b) (4)	31 Jul 2020 17:31:41

US3142034

Folder: Screening

Form: Visit Date

Generated On: 11 Aug 2021 21:58:56

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:52:49
User entered 'SCRN'	System	31 Jul 2020 17:31:41

US3142034

Folder: Screening

Form: Demographics

Generated On: 11 Aug 2021 21:58:56

Date of Birth (MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:52:49
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 19:03:50
User entered '(b) (6)1946'	RWS_ENDPOINT ENDPOINT (b) (4)	31 Jul 2020 17:24:17

US3142034

Folder: Screening

Form: Demographics

Generated On: 11 Aug 2021 21:58:56

[Age](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:52:49
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 19:03:50
User entered '74'	Shelby Pickle (b) (4) (b) (4)	10 Aug 2020 19:15:22

US3142034

Folder: Screening

Form: Demographics

Generated On: 11 Aug 2021 21:58:56

[Age Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:52:49
User entered 'YEARS'	System	10 Aug 2020 19:15:22

US3142034

Folder: Screening

Form: Demographics

Generated On: 11 Aug 2021 21:58:56

[Age \(Derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:52:49
User entered '74'	System	31 Jul 2020 17:31:55

US3142034

Folder: Screening

Form: Demographics

Generated On: 11 Aug 2021 21:58:56

[Sex](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:52:49
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 19:03:50
User entered 'Female (F)'	Shelby Pickle (b) (4) (b) (4)	10 Aug 2020 19:15:22

US3142034

Folder: Screening

Form: Demographics

Generated On: 11 Aug 2021 21:58:56

[Ethnicity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:52:49
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 19:03:50
User entered 'Not Hispanic or Latino (NOT HISPANIC OR LATINO)'	Shelby Pickle (b) (4) (b) (4)	10 Aug 2020 19:15:22

US3142034

Folder: Screening

Form: Demographics

Generated On: 11 Aug 2021 21:58:56

White

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:52:49
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 19:03:50
User entered '1'	Shelby Pickle (b) (4) (b) (4)	10 Aug 2020 19:15:22

US3142034

Folder: Screening

Form: Demographics

Generated On: 11 Aug 2021 21:58:56

[Black](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:52:49
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 19:03:50
User entered '0'	Shelby Pickle (b) (4) (b) (4)	10 Aug 2020 19:15:22

US3142034

Folder: Screening

Form: Demographics

Generated On: 11 Aug 2021 21:58:56

[Asian](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:52:49
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 19:03:50
User entered '0'	Shelby Pickle (b) (4) (b) (4)	10 Aug 2020 19:15:22

US3142034

Folder: Screening

Form: Demographics

Generated On: 11 Aug 2021 21:58:56

[American Indian or Alaska Native](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:52:49
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 19:03:50
User entered '0'	Shelby Pickle (b) (4) (b) (4)	10 Aug 2020 19:15:22

US3142034

Folder: Screening

Form: Demographics

Generated On: 11 Aug 2021 21:58:56

Native Hawaiian or other Pacific Islander

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:52:49
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 19:03:50
User entered '0'	Shelby Pickle (b) (4) (b) (4)	10 Aug 2020 19:15:22

US3142034

Folder: Screening

Form: Demographics

Generated On: 11 Aug 2021 21:58:56

[Other](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:52:49
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 19:03:50
User entered '0'	Shelby Pickle (b) (4) (b) (4)	10 Aug 2020 19:15:22

US3142034

Folder: Screening

Form: Demographics

Generated On: 11 Aug 2021 21:58:56

If race is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:52:49
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 19:03:50
User entered empty.	Shelby Pickle (b) (4) (b) (4)	10 Aug 2020 19:15:22

US3142034

Folder: Screening

Form: Demographics

Generated On: 11 Aug 2021 21:58:56

[Unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:52:49
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 19:03:50
User entered '0'	Shelby Pickle (b) (4) (b) (4)	10 Aug 2020 19:15:22

US3142034

Folder: Screening

Form: Demographics

Generated On: 11 Aug 2021 21:58:56

Not reported

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:52:49
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 19:03:50
User entered '0'	Shelby Pickle (b) (4) (b) (4)	10 Aug 2020 19:15:22

US3142034

Folder: Screening

Form: Enrollment

Generated On: 11 Aug 2021 21:58:56

Date of Informed Consent (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:52:49
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 19:03:50
User entered '31 Jul 2020'	Shelby Pickle (b) (4) (b) (4)	31 Jul 2020 17:31:55

US3142034

Folder: Screening

Form: Enrollment

Generated On: 11 Aug 2021 21:58:56

[Month and Year of Informed Consent \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:52:49
User entered 'Jul 2020'	System	31 Jul 2020 17:31:55

US3142034

Folder: Screening

Form: Enrollment

Generated On: 11 Aug 2021 21:58:56

[Year of Informed Consent \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:52:49
User entered '2020'	System	31 Jul 2020 17:31:55

US3142034

Folder: Screening

Form: Enrollment

Generated On: 11 Aug 2021 21:58:56

[Protocol Version](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:52:49
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 19:03:50
User entered 'Amendment 2 (2)' reason for change: Data Entry Error	Meghan York (b) (4) (b) (4)	09 Dec 2020 22:52:42
User entered 'Amendment 1 (1)'	Shelby Pickle (b) (4) (b) (4)	31 Jul 2020 17:31:55

US3142034

Folder: Screening

Form: Enrollment

Generated On: 11 Aug 2021 21:58:56

[Was participant enrolled in the study?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:52:49
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 19:03:50
User entered 'Yes (Y)'	Shelby Pickle (b) (4) (b) (4)	31 Jul 2020 17:31:55

US3142034

Folder: Screening

Form: Enrollment

Generated On: 11 Aug 2021 21:58:56

If No, indicate reason for screen fail

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:52:49
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 19:03:50
User entered empty.	Shelby Pickle (b) (4) (b) (4)	31 Jul 2020 17:31:55

US3142034

Folder: Screening

Form: Enrollment

Generated On: 11 Aug 2021 21:58:56

If reason for screen fail is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:52:49
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 19:03:50
User entered empty.	Shelby Pickle (b) (4) (b) (4)	31 Jul 2020 17:31:55

US3142034

Folder: Screening

Form: Enrollment

Generated On: 11 Aug 2021 21:58:56

[Was this participant screened previously?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:52:49
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 19:03:50
User entered 'No (N)'	Shelby Pickle (b) (4) (b) (4)	31 Jul 2020 17:31:55

US3142034

Folder: Screening

Form: Enrollment

Generated On: 11 Aug 2021 21:58:56

[If Yes, previous participant number](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:52:49
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:03:50
User entered empty.	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	31 Jul 2020 17:24:16

US3142034

Folder: Screening

Form: Enrollment

Generated On: 11 Aug 2021 21:58:56

[Enrollment Trigger](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:52:49
User entered '1'	System	31 Jul 2020 17:32:01

US3142034

Folder: Screening

Form: Inclusion/Exclusion Criteria Summary

Generated On: 11 Aug 2021 21:58:56

[Did the participant meet all eligibility criteria?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:52:49
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 19:03:50
User entered 'Yes (Y)'	Shelby Pickle (b) (4) (b) (4)	31 Jul 2020 17:32:01

US3142034

Folder: Screening

Form: Medical History Summary

Generated On: 11 Aug 2021 21:58:56

[Were any significant conditions reported?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:52:49
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 19:03:50
User entered 'Yes (Y)'	Shelby Pickle (b) (4) (b) (4)	10 Aug 2020 19:15:33

US3142034

Folder: Screening

Form: Medical History (1)

Generated On: 11 Aug 2021 21:58:56

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:52:49
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:03:50
User closed query 'Per DM CLR: Please specify the laterality of eye that is NEARSIGHTED. Review and update Med History eCRF as appropriate. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	11 Oct 2020 12:42:49
User coded data point as SOC: Eye disorders, HLGT: Vision disorders, HLT: Refractive and accommodative disorders, PT: Myopia, LLT: Nearsighted - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	05 Oct 2020 14:28:25
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	05 Oct 2020 14:28:25
Data point term sent to Coder	System	05 Oct 2020 14:27:18
Query 'Per DM CLR: Please specify the laterality of eye that is NEARSIGHTED. Review and update Med History eCRF as appropriate. ' answered with 'Bilateral' (Site from DM).	Shelby Pickle (b) (4) (b) (4)	05 Oct 2020 14:27:10
Coding entries removed.	Shelby Pickle (b) (4) (b) (4)	05 Oct 2020 14:27:03
User entered 'NEARSIGHTED Bilateral' reason for change: Data Entry Error	Shelby Pickle (b) (4) (b) (4)	05 Oct 2020 14:27:03
User opened query 'Per DM CLR: Please specify the laterality of eye that is NEARSIGHTED. Review and update Med History eCRF as appropriate. ' (Site from DM).	(b) (4), (b) (6)	01 Sep 2020 07:36:44
User coded data point as SOC: Eye disorders, HLGT: Vision disorders, HLT: Refractive and accommodative disorders, PT: Myopia, LLT: Nearsighted - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	10 Aug 2020 19:17:22
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	10 Aug 2020 19:17:22
Data point term sent to Coder	System	10 Aug 2020 19:16:33
User entered 'Nearsighted'	Shelby Pickle (b) (4) (b) (4)	10 Aug 2020 19:15:50

US3142034

Folder: Screening

Form: Medical History (1)

Generated On: 11 Aug 2021 21:58:56

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:52:49
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 19:03:50
User entered 'UN UNK 1966'	Shelby Pickle (b) (4) (b) (4)	10 Aug 2020 19:15:50

US3142034

Folder: Screening

Form: Medical History (1)

Generated On: 11 Aug 2021 21:58:56

Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:52:49
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 19:03:50
User entered '0'	Shelby Pickle (b) (4) (b) (4)	10 Aug 2020 19:15:50

US3142034

Folder: Screening

Form: Medical History (1)

Generated On: 11 Aug 2021 21:58:56

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:52:49
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 19:03:50
User entered 'Yes (Y)'	Shelby Pickle (b) (4) (b) (4)	10 Aug 2020 19:15:50

US3142034

Folder: Screening

Form: Medical History (1)

Generated On: 11 Aug 2021 21:58:56

If No, please specify the stop date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:52:49
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 19:03:50
User entered empty.	Shelby Pickle (b) (4) (b) (4)	10 Aug 2020 19:15:50

US3142034

Folder: Screening

Form: Medical History (1)

Generated On: 11 Aug 2021 21:58:56

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:52:49
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 19:03:50
User entered '0'	Shelby Pickle (b) (4) (b) (4)	10 Aug 2020 19:15:50

US3142034

Folder: Screening

Form: Medical History (1)

Generated On: 11 Aug 2021 21:58:56

Start Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:52:49
User entered 'Jan 1966'	System	10 Aug 2020 19:15:50

US3142034

Folder: Screening

Form: Medical History (1)

Generated On: 11 Aug 2021 21:58:56

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:52:49
User entered '1966'	System	10 Aug 2020 19:15:50

US3142034

Folder: Screening

Form: Medical History (1)

Generated On: 11 Aug 2021 21:58:56

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:52:49
User entered empty.	System	10 Aug 2020 19:15:50

US3142034

Folder: Screening

Form: Medical History (1)

Generated On: 11 Aug 2021 21:58:56

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:52:49
User entered empty.	System	10 Aug 2020 19:15:50

US3142034

Folder: Screening

Form: Medical History (2)

Generated On: 11 Aug 2021 21:58:56

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:52:49
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:03:50
User closed query 'Per DM CLR: Please specify the eye laterality of CATARACTS. Review and update Med History eCRF as appropriate. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	11 Oct 2020 12:42:52
User coded data point as SOC: Eye disorders, HLGT: Anterior eye structural change, deposit and degeneration, HLT: Cataract conditions, PT: Cataract, LLT: Bilateral cataracts - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	05 Oct 2020 14:29:55
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	05 Oct 2020 14:29:55
Data point term sent to Coder	System	05 Oct 2020 14:28:21
Query 'Per DM CLR: Please specify the eye laterality of CATARACTS. Review and update Med History eCRF as appropriate. ' answered with 'Bilateral' (Site from DM).	Shelby Pickle (b) (4) (b) (4)	05 Oct 2020 14:27:36
Coding entries removed.	Shelby Pickle (b) (4) (b) (4)	05 Oct 2020 14:27:29
User entered 'CATARACTS Bilateral' reason for change: Data Entry Error	Shelby Pickle (b) (4) (b) (4)	05 Oct 2020 14:27:29
User opened query 'Per DM CLR: Please specify the eye laterality of CATARACTS. Review and update Med History eCRF as appropriate. ' (Site from DM).	(b) (4), (b) (6)	01 Sep 2020 07:37:06
User coded data point as SOC: Eye disorders, HLGT: Anterior eye structural change, deposit and degeneration, HLT: Cataract conditions, PT: Cataract, LLT: Cataracts - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	10 Aug 2020 19:17:21
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	10 Aug 2020 19:17:21
Data point term sent to Coder	System	10 Aug 2020 19:16:33
User entered 'Cataracts'	Shelby Pickle (b) (4) (b) (4)	10 Aug 2020 19:16:23

US3142034

Folder: Screening

Form: Medical History (2)

Generated On: 11 Aug 2021 21:58:56

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:52:49
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 19:03:50
User entered 'UN UNK 2015'	Shelby Pickle (b) (4) (b) (4)	10 Aug 2020 19:16:23

US3142034

Folder: Screening

Form: Medical History (2)

Generated On: 11 Aug 2021 21:58:56

Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:52:49
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 19:03:50
User entered '0'	Shelby Pickle (b) (4) (b) (4)	10 Aug 2020 19:16:23

US3142034

Folder: Screening

Form: Medical History (2)

Generated On: 11 Aug 2021 21:58:56

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:52:49
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 19:03:50
User entered 'Yes (Y)'	Shelby Pickle (b) (4) (b) (4)	10 Aug 2020 19:16:23

US3142034

Folder: Screening

Form: Medical History (2)

Generated On: 11 Aug 2021 21:58:56

If No, please specify the stop date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:52:49
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 19:03:50
User entered empty.	Shelby Pickle (b) (4) (b) (4)	10 Aug 2020 19:16:23

US3142034

Folder: Screening

Form: Medical History (2)

Generated On: 11 Aug 2021 21:58:56

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:52:49
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 19:03:50
User entered '0'	Shelby Pickle (b) (4) (b) (4)	10 Aug 2020 19:16:23

US3142034

Folder: Screening

Form: Medical History (2)

Generated On: 11 Aug 2021 21:58:56

Start Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:52:49
User entered 'Jan 2015'	System	10 Aug 2020 19:16:23

US3142034

Folder: Screening

Form: Medical History (2)

Generated On: 11 Aug 2021 21:58:56

Start Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:52:49
User entered '2015'	System	10 Aug 2020 19:16:23

US3142034

Folder: Screening

Form: Medical History (2)

Generated On: 11 Aug 2021 21:58:56

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:52:49
User entered empty.	System	10 Aug 2020 19:16:23

US3142034

Folder: Screening

Form: Medical History (2)

Generated On: 11 Aug 2021 21:58:56

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:52:49
User entered empty.	System	10 Aug 2020 19:16:23

US3142034

Folder: Screening

Form: Medical History (3)

Generated On: 11 Aug 2021 21:58:56

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:52:49
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:03:50
User closed query 'Per DM CLR: Please specify the ear laterality with HEARING LOSS. Review and update Med History eCRF as appropriate. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	11 Oct 2020 12:42:55
User coded data point as SOC: Ear and labyrinth disorders, HLGT: Hearing disorders, HLT: Hearing losses, PT: Deafness bilateral, LLT: Hearing loss bilateral - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	05 Oct 2020 14:31:10
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	05 Oct 2020 14:31:10
Data point term sent to Coder	System	05 Oct 2020 14:29:22
Query 'Per DM CLR: Please specify the ear laterality with HEARING LOSS. Review and update Med History eCRF as appropriate. ' answered with 'Bilateral' (Site from DM).	Shelby Pickle (b) (4) (b) (4)	05 Oct 2020 14:29:19
Coding entries removed.	Shelby Pickle (b) (4) (b) (4)	05 Oct 2020 14:28:32
User entered 'HEARING LOSS Bilateral' reason for change: Data Entry Error	Shelby Pickle (b) (4) (b) (4)	05 Oct 2020 14:28:32
User opened query 'Per DM CLR: Please specify the ear laterality with HEARING LOSS. Review and update Med History eCRF as appropriate. ' (Site from DM).	(b) (4), (b) (6)	01 Sep 2020 07:37:21
User coded data point as SOC: Ear and labyrinth disorders, HLGT: Hearing disorders, HLT: Hearing losses, PT: Deafness, LLT: Hearing loss - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	10 Aug 2020 19:18:24
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	10 Aug 2020 19:18:24
Data point term sent to Coder	System	10 Aug 2020 19:17:34
User entered 'Hearing Loss'	Shelby Pickle (b) (4) (b) (4)	10 Aug 2020 19:16:38

US3142034

Folder: Screening

Form: Medical History (3)

Generated On: 11 Aug 2021 21:58:56

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:52:49
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 19:03:50
User entered 'UN UNK 2018'	Shelby Pickle (b) (4) (b) (4)	10 Aug 2020 19:16:38

US3142034

Folder: Screening

Form: Medical History (3)

Generated On: 11 Aug 2021 21:58:56

Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:52:49
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:03:50
User entered '0'	Shelby Pickle (b) (4)	10 Aug 2020 19:16:38

US3142034

Folder: Screening

Form: Medical History (3)

Generated On: 11 Aug 2021 21:58:56

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:52:49
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 19:03:50
User entered 'Yes (Y)'	Shelby Pickle (b) (4) (b) (4)	10 Aug 2020 19:16:38

US3142034

Folder: Screening

Form: Medical History (3)

Generated On: 11 Aug 2021 21:58:56

If No, please specify the stop date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:52:49
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:03:50
User entered empty.	(b) (4) Shelby Pickle (b) (4)	10 Aug 2020 19:16:38

US3142034

Folder: Screening

Form: Medical History (3)

Generated On: 11 Aug 2021 21:58:56

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:52:49
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:03:50
User entered '0'	Shelby Pickle (b) (4)	10 Aug 2020 19:16:38

US3142034

Folder: Screening

Form: Medical History (3)

Generated On: 11 Aug 2021 21:58:56

Start Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:52:49
User entered 'Jan 2018'	System	10 Aug 2020 19:16:38

US3142034

Folder: Screening

Form: Medical History (3)

Generated On: 11 Aug 2021 21:58:56

Start Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:52:49
User entered '2018'	System	10 Aug 2020 19:16:38

US3142034

Folder: Screening

Form: Medical History (3)

Generated On: 11 Aug 2021 21:58:56

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:52:49
User entered empty.	System	10 Aug 2020 19:16:38

US3142034

Folder: Screening

Form: Medical History (3)

Generated On: 11 Aug 2021 21:58:56

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:52:49
User entered empty.	System	10 Aug 2020 19:16:38

US3142034

Folder: Screening

Form: Medical History (4)

Generated On: 11 Aug 2021 21:58:56

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:52:49
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:03:50
User coded data point as SOC: Gastrointestinal disorders, HLGT: Gastrointestinal vascular conditions, HLT: Haemorrhoids and gastrointestinal varices (excl oesophageal), PT: Haemorrhoids, LLT: Hemorrhoids - version MedDRA\\23.0.	Coder Import (b) (4)	10 Aug 2020 19:18:24
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	10 Aug 2020 19:18:24
Data point term sent to Coder	System	10 Aug 2020 19:17:35
User entered 'Hemorrhoids'	Shelby Pickle (b) (4)	10 Aug 2020 19:17:00

US3142034

Folder: Screening

Form: Medical History (4)

Generated On: 11 Aug 2021 21:58:56

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:52:49
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:03:50
User entered 'UN UNK 1973'	Shelby Pickle (b) (4)	10 Aug 2020 19:17:00

US3142034

Folder: Screening

Form: Medical History (4)

Generated On: 11 Aug 2021 21:58:56

Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:52:49
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:03:50
User entered '0'	Shelby Pickle (b) (4)	10 Aug 2020 19:17:00

US3142034

Folder: Screening

Form: Medical History (4)

Generated On: 11 Aug 2021 21:58:56

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:52:49
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 19:03:50
User entered 'Yes (Y)'	Shelby Pickle (b) (4) (b) (4)	10 Aug 2020 19:17:00

US3142034

Folder: Screening

Form: Medical History (4)

Generated On: 11 Aug 2021 21:58:56

If No, please specify the stop date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:52:49
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:03:50
User entered empty.	(b) (4) Shelby Pickle (b) (4)	10 Aug 2020 19:17:00

US3142034

Folder: Screening

Form: Medical History (4)

Generated On: 11 Aug 2021 21:58:56

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:52:49
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:03:50
User entered '0'	Shelby Pickle (b) (4)	10 Aug 2020 19:17:00

US3142034

Folder: Screening

Form: Medical History (4)

Generated On: 11 Aug 2021 21:58:56

Start Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:52:49
User entered 'Jan 1973'	System	10 Aug 2020 19:17:00

US3142034

Folder: Screening

Form: Medical History (4)

Generated On: 11 Aug 2021 21:58:56

Start Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:52:49
User entered '1973'	System	10 Aug 2020 19:17:00

US3142034

Folder: Screening

Form: Medical History (4)

Generated On: 11 Aug 2021 21:58:56

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:52:49
User entered empty.	System	10 Aug 2020 19:17:00

US3142034

Folder: Screening

Form: Medical History (4)

Generated On: 11 Aug 2021 21:58:56

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:52:49
User entered empty.	System	10 Aug 2020 19:17:00

US3142034

Folder: Screening

Form: Medical History (5)

Generated On: 11 Aug 2021 21:58:56

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:52:49
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:03:50
User coded data point as SOC: Renal and urinary disorders, HLGT: Bladder and bladder neck disorders (excl calculi), HLT: Myoneurogenic bladder disorders, PT: Hypertonic bladder, LLT: Overactive bladder - version MedDRA\23.0.	Coder Import (b) (4)	10 Aug 2020 19:22:28
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4)	10 Aug 2020 19:22:28
Data point term sent to Coder	System	10 Aug 2020 19:20:44
User entered 'Overactive Bladder'	Shelby Pickle (b) (4)	10 Aug 2020 19:20:02

US3142034

Folder: Screening

Form: Medical History (5)

Generated On: 11 Aug 2021 21:58:56

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:52:49
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:03:50
User entered 'UN UNK 2000'	(b) (4) Shelby Pickle (b) (4) (b) (4)	10 Aug 2020 19:20:02

US3142034

Folder: Screening

Form: Medical History (5)

Generated On: 11 Aug 2021 21:58:56

Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:52:49
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:03:50
User entered '0'	Shelby Pickle (b) (4)	10 Aug 2020 19:20:02

US3142034

Folder: Screening

Form: Medical History (5)

Generated On: 11 Aug 2021 21:58:56

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:52:49
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:03:50
User entered 'Yes (Y)'	(b) (4) Shelby Pickle (b) (4)	10 Aug 2020 19:20:02

US3142034

Folder: Screening

Form: Medical History (5)

Generated On: 11 Aug 2021 21:58:56

If No, please specify the stop date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:52:49
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:03:50
User entered empty.	(b) (4) Shelby Pickle (b) (4)	10 Aug 2020 19:20:02

US3142034

Folder: Screening

Form: Medical History (5)

Generated On: 11 Aug 2021 21:58:56

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:52:49
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:03:50
User entered '0'	(b) (4) Shelby Pickle (b) (4)	10 Aug 2020 19:20:02

US3142034

Folder: Screening

Form: Medical History (5)

Generated On: 11 Aug 2021 21:58:56

Start Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:52:49
User entered 'Jan 2000'	System	10 Aug 2020 19:20:02

US3142034

Folder: Screening

Form: Medical History (5)

Generated On: 11 Aug 2021 21:58:56

Start Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:52:49
User entered '2000'	System	10 Aug 2020 19:20:02

US3142034

Folder: Screening

Form: Medical History (5)

Generated On: 11 Aug 2021 21:58:56

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:52:49
User entered empty.	System	10 Aug 2020 19:20:02

US3142034

Folder: Screening

Form: Medical History (5)

Generated On: 11 Aug 2021 21:58:56

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:52:49
User entered empty.	System	10 Aug 2020 19:20:02

US3142034

Folder: Screening

Form: Medical History (6)

Generated On: 11 Aug 2021 21:58:56

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:52:49
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:03:50
User coded data point as SOC: Metabolism and nutrition disorders, HLT: Elevated cholesterol, PT: Hypercholesterolaemia, LLT: Hypercholesterolemia - version MedDRA\23.0.	Coder Import (b) (4)	10 Aug 2020 19:22:28
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4)	10 Aug 2020 19:22:28
Data point term sent to Coder	System	10 Aug 2020 19:20:45
User entered 'Hypercholesterolemia'	Shelby Pickle (b) (4)	10 Aug 2020 19:20:28

US3142034

Folder: Screening

Form: Medical History (6)

Generated On: 11 Aug 2021 21:58:56

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:52:49
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:03:50
User entered 'UN UNK 2000'	(b) (4) Shelby Pickle (b) (4)	10 Aug 2020 19:20:28

US3142034

Folder: Screening

Form: Medical History (6)

Generated On: 11 Aug 2021 21:58:56

Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:52:49
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:03:50
User entered '0'	(b) (4) Shelby Pickle (b) (4)	10 Aug 2020 19:20:28

US3142034

Folder: Screening

Form: Medical History (6)

Generated On: 11 Aug 2021 21:58:56

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:52:49
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:03:50
User entered 'Yes (Y)'	(b) (4) Shelby Pickle (b) (4)	10 Aug 2020 19:20:28

US3142034

Folder: Screening

Form: Medical History (6)

Generated On: 11 Aug 2021 21:58:56

If No, please specify the stop date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:52:49
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:03:50
User entered empty.	(b) (4) Shelby Pickle (b) (4) (b) (4)	10 Aug 2020 19:20:28

US3142034

Folder: Screening

Form: Medical History (6)

Generated On: 11 Aug 2021 21:58:56

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:52:49
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:03:50
User entered '0'	(b) (4) Shelby Pickle (b) (4)	10 Aug 2020 19:20:28

US3142034

Folder: Screening

Form: Medical History (6)

Generated On: 11 Aug 2021 21:58:56

Start Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:52:49
User entered 'Jan 2000'	System	10 Aug 2020 19:20:28

US3142034

Folder: Screening

Form: Medical History (6)

Generated On: 11 Aug 2021 21:58:56

Start Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:52:49
User entered '2000'	System	10 Aug 2020 19:20:28

US3142034

Folder: Screening

Form: Medical History (6)

Generated On: 11 Aug 2021 21:58:56

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:52:49
User entered empty.	System	10 Aug 2020 19:20:28

US3142034

Folder: Screening

Form: Medical History (6)

Generated On: 11 Aug 2021 21:58:56

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:52:49
User entered empty.	System	10 Aug 2020 19:20:28

US3142034

Folder: Screening

Form: Medical History (7)

Generated On: 11 Aug 2021 21:58:56

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:52:49
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:03:50
User coded data point as SOC: Musculoskeletal and connective tissue disorders, HLGT: Bone disorders (excl congenital and fractures), HLT: Metabolic bone disorders, PT: Osteoporosis, LLT: Osteoporosis - version MedDRA\23.0.	Coder Import (b) (4)	11 Aug 2020 22:28:54
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4)	11 Aug 2020 22:28:54
Data point term sent to Coder	System	10 Aug 2020 19:21:50
User entered 'Osteoporosis'	Shelby Pickle (b) (4)	10 Aug 2020 19:20:50

US3142034

Folder: Screening

Form: Medical History (7)

Generated On: 11 Aug 2021 21:58:56

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:52:49
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:03:50
User entered 'UN UNK 2015'	(b) (4) Shelby Pickle (b) (4)	10 Aug 2020 19:20:50

US3142034

Folder: Screening

Form: Medical History (7)

Generated On: 11 Aug 2021 21:58:56

Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:52:49
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:03:50
User entered '0'	Shelby Pickle (b) (4)	10 Aug 2020 19:20:50

US3142034

Folder: Screening

Form: Medical History (7)

Generated On: 11 Aug 2021 21:58:56

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:52:49
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:03:50
User entered 'Yes (Y)'	(b) (4) Shelby Pickle (b) (4)	10 Aug 2020 19:20:50

US3142034

Folder: Screening

Form: Medical History (7)

Generated On: 11 Aug 2021 21:58:56

If No, please specify the stop date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:52:49
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:03:50
User entered empty.	(b) (4) Shelby Pickle (b) (4)	10 Aug 2020 19:20:50

US3142034

Folder: Screening

Form: Medical History (7)

Generated On: 11 Aug 2021 21:58:56

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:52:49
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:03:50
User entered '0'	Shelby Pickle (b) (4)	10 Aug 2020 19:20:50

US3142034

Folder: Screening

Form: Medical History (7)

Generated On: 11 Aug 2021 21:58:56

Start Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:52:49
User entered 'Jan 2015'	System	10 Aug 2020 19:20:50

US3142034

Folder: Screening

Form: Medical History (7)

Generated On: 11 Aug 2021 21:58:56

Start Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:52:49
User entered '2015'	System	10 Aug 2020 19:20:50

US3142034

Folder: Screening

Form: Medical History (7)

Generated On: 11 Aug 2021 21:58:56

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:52:49
User entered empty.	System	10 Aug 2020 19:20:50

US3142034

Folder: Screening

Form: Medical History (7)

Generated On: 11 Aug 2021 21:58:56

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:52:49
User entered empty.	System	10 Aug 2020 19:20:50

US3142034

Folder: Screening

Form: Medical History (8)

Generated On: 11 Aug 2021 21:58:56

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:52:49
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:03:50
User coded data point as SOC: Musculoskeletal and connective tissue disorders, HLG: Joint disorders, HLT: Osteoarthropathies, PT: Osteoarthritis, LLT: Osteoarthritis - version MedDRA\\23.0.	Coder Import (b) (4)	23 Aug 2020 14:06:34
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4)	23 Aug 2020 14:06:34
Data point term sent to Coder	System	10 Aug 2020 19:21:51
User entered 'Osteoarthritis in wrists, fingers, shoulders and knees'	Shelby Pickle (b) (4)	10 Aug 2020 19:21:26

US3142034

Folder: Screening

Form: Medical History (8)

Generated On: 11 Aug 2021 21:58:56

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:52:49
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 19:03:50
User entered 'Un UNK 2006'	Shelby Pickle (b) (4) (b) (4)	10 Aug 2020 19:21:26

US3142034

Folder: Screening

Form: Medical History (8)

Generated On: 11 Aug 2021 21:58:56

Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:52:49
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:03:50
User entered '0'	Shelby Pickle (b) (4)	10 Aug 2020 19:21:26

US3142034

Folder: Screening

Form: Medical History (8)

Generated On: 11 Aug 2021 21:58:56

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:52:49
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:03:50
User entered 'Yes (Y)'	(b) (4) Shelby Pickle (b) (4)	10 Aug 2020 19:21:26

US3142034

Folder: Screening

Form: Medical History (8)

Generated On: 11 Aug 2021 21:58:56

If No, please specify the stop date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:52:49
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:03:50
User entered empty.	(b) (4) Shelby Pickle (b) (4)	10 Aug 2020 19:21:26

US3142034

Folder: Screening

Form: Medical History (8)

Generated On: 11 Aug 2021 21:58:56

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:52:49
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:03:50
User entered '0'	Shelby Pickle (b) (4)	10 Aug 2020 19:21:26

US3142034

Folder: Screening

Form: Medical History (8)

Generated On: 11 Aug 2021 21:58:56

Start Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:52:49
User entered 'Jan 2006'	System	10 Aug 2020 19:21:26

US3142034

Folder: Screening

Form: Medical History (8)

Generated On: 11 Aug 2021 21:58:56

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:52:49
User entered '2006'	System	10 Aug 2020 19:21:26

US3142034

Folder: Screening

Form: Medical History (8)

Generated On: 11 Aug 2021 21:58:56

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:52:49
User entered empty.	System	10 Aug 2020 19:21:26

US3142034

Folder: Screening

Form: Medical History (8)

Generated On: 11 Aug 2021 21:58:56

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:52:49
User entered empty.	System	10 Aug 2020 19:21:26

US3142034

Folder: Screening

Form: Medical History (9)

Generated On: 11 Aug 2021 21:58:56

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:52:49
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:03:50
User coded data point as SOC: Nervous system disorders, HLGT: Peripheral neuropathies, HLT: Peripheral neuropathies NEC, PT: Peripheral sensory neuropathy, LLT: Peripheral sensory neuropathy - version MedDRA\23.0.	Coder Import (b) (4)	23 Nov 2020 09:54:13
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\23.0.	Coder Import (b) (4)	23 Nov 2020 09:54:13
User closed query 'Per DM CLR: Please verify the type of the NEUROPATHY (e.g. sensory or motor). Review and update medical history diagnosis as appropriate and ensure update to Med History is reconciled with any corresponding AE or ConMed entries, if applicable.' (Site from DM).	(b) (4), (b) (6)	11 Oct 2020 12:43:07
Data point term sent to Coder	System	05 Oct 2020 14:37:47
Query 'Per DM CLR: Please verify the type of the NEUROPATHY (e.g. sensory or motor). Review and update medical history diagnosis as appropriate and ensure update to Med History is reconciled with any corresponding AE or ConMed entries, if applicable.' answered with '!'. (Site from DM).	Jill York (b) (4)	05 Oct 2020 14:37:24
Coding entries removed.	Jill York (b) (4)	05 Oct 2020 14:37:19
User entered 'NEUROPATHY IN BOTH FEET - sensory' reason for change: Data Entry Error	Jill York (b) (4)	05 Oct 2020 14:37:19
User opened query 'Per DM CLR: Please verify the type of the NEUROPATHY (e.g. sensory or motor). Review and update medical history diagnosis as appropriate and ensure update to Med History is reconciled with any corresponding AE or ConMed entries, if applicable.' (Site from DM).	(b) (4), (b) (6)	01 Sep 2020 07:37:55
User coded data point as SOC: Nervous system disorders, HLGT: Peripheral neuropathies, HLT: Peripheral neuropathies NEC, PT: Neuropathy peripheral, LLT: Neuropathy peripheral - version MedDRA\23.0.	Coder Import (b) (4)	13 Aug 2020 12:52:22
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\23.0.	Coder Import (b) (4)	13 Aug 2020 12:52:22
Data point term sent to Coder	System	10 Aug 2020 19:21:51

US3142034

Folder: Screening

Form: Medical History (9)

Generated On: 11 Aug 2021 21:58:56

[Condition](#)

Audit	User	Time (GMT)
User entered 'Neuropathy in both feet'	Shelby Pickle (b) (4) (b) (4)	10 Aug 2020 19:21:47

US3142034

Folder: Screening

Form: Medical History (9)

Generated On: 11 Aug 2021 21:58:56

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:52:49
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:03:50
User entered 'UN Dec 2019'	(b) (4) Shelby Pickle (b) (4)	10 Aug 2020 19:21:47

US3142034

Folder: Screening

Form: Medical History (9)

Generated On: 11 Aug 2021 21:58:56

Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:52:49
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:03:50
User entered '0'	Shelby Pickle (b) (4)	10 Aug 2020 19:21:47

US3142034

Folder: Screening

Form: Medical History (9)

Generated On: 11 Aug 2021 21:58:56

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:52:49
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:03:50
User entered 'Yes (Y)'	(b) (4) Shelby Pickle (b) (4)	10 Aug 2020 19:21:47

US3142034

Folder: Screening

Form: Medical History (9)

Generated On: 11 Aug 2021 21:58:56

If No, please specify the stop date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:52:49
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:03:50
User entered empty.	(b) (4) Shelby Pickle (b) (4)	10 Aug 2020 19:21:47

US3142034

Folder: Screening

Form: Medical History (9)

Generated On: 11 Aug 2021 21:58:56

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:52:49
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:03:50
User entered '0'	Shelby Pickle (b) (4)	10 Aug 2020 19:21:47

US3142034

Folder: Screening

Form: Medical History (9)

Generated On: 11 Aug 2021 21:58:56

Start Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:52:49
User entered 'Dec 2019'	System	10 Aug 2020 19:21:47

US3142034

Folder: Screening

Form: Medical History (9)

Generated On: 11 Aug 2021 21:58:56

Start Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:52:49
User entered '2019'	System	10 Aug 2020 19:21:47

US3142034

Folder: Screening

Form: Medical History (9)

Generated On: 11 Aug 2021 21:58:56

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:52:49
User entered empty.	System	10 Aug 2020 19:21:47

US3142034

Folder: Screening

Form: Medical History (9)

Generated On: 11 Aug 2021 21:58:56

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:52:49
User entered empty.	System	10 Aug 2020 19:21:47

US3142034

Folder: Screening

Form: Medical History (10)

Generated On: 11 Aug 2021 21:58:56

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:52:49
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:03:50
User coded data point as SOC: Social circumstances, HLT: Age related factors, HLT: Age related issues, PT: Postmenopause, LLT: Postmenopause - version MedDRA\23.0.	Coder Import (b) (4)	11 Aug 2020 22:28:55
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4)	11 Aug 2020 22:28:55
Data point term sent to Coder	System	10 Aug 2020 19:22:52
User entered 'Post-Menopausal'	Shelby Pickle (b) (4)	10 Aug 2020 19:22:04

US3142034

Folder: Screening

Form: Medical History (10)

Generated On: 11 Aug 2021 21:58:56

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:52:49
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:03:50
User entered 'UN UNK 2000'	(b) (4) Shelby Pickle (b) (4)	10 Aug 2020 19:22:04

US3142034

Folder: Screening

Form: Medical History (10)

Generated On: 11 Aug 2021 21:58:56

Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:52:49
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:03:50
User entered '0'	Shelby Pickle (b) (4)	10 Aug 2020 19:22:04

US3142034

Folder: Screening

Form: Medical History (10)

Generated On: 11 Aug 2021 21:58:56

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:52:49
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 19:03:50
User entered 'Yes (Y)'	Shelby Pickle (b) (4) (b) (4)	10 Aug 2020 19:22:04

US3142034

Folder: Screening

Form: Medical History (10)

Generated On: 11 Aug 2021 21:58:56

If No, please specify the stop date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:52:49
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:03:50
User entered empty.	(b) (4) Shelby Pickle (b) (4)	10 Aug 2020 19:22:04

US3142034

Folder: Screening

Form: Medical History (10)

Generated On: 11 Aug 2021 21:58:56

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:52:49
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:03:50
User entered '0'	Shelby Pickle (b) (4)	10 Aug 2020 19:22:04

US3142034

Folder: Screening

Form: Medical History (10)

Generated On: 11 Aug 2021 21:58:56

Start Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:52:49
User entered 'Jan 2000'	System	10 Aug 2020 19:22:04

US3142034

Folder: Screening

Form: Medical History (10)

Generated On: 11 Aug 2021 21:58:56

Start Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:52:49
User entered '2000'	System	10 Aug 2020 19:22:04

US3142034

Folder: Screening

Form: Medical History (10)

Generated On: 11 Aug 2021 21:58:56

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:52:49
User entered empty.	System	10 Aug 2020 19:22:04

US3142034

Folder: Screening

Form: Medical History (10)

Generated On: 11 Aug 2021 21:58:56

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:52:49
User entered empty.	System	10 Aug 2020 19:22:04

US3142034

Folder: Screening

Form: Medical History (11)

Generated On: 11 Aug 2021 21:58:56

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:52:49
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:03:50
User closed query 'Per DM CLR: Please note that there is no Con Med listed for treatment of this condition and treatment would be expected for this condition. Please review and if applicable add a Con Med or provide an explanation for no medical treatment.' (Site from DM).	(b) (4) (b) (4), (b) (6)	07 Oct 2020 02:27:00
Query 'Per DM CLR: Please note that there is no Con Jill York Med listed for treatment of this condition and treatment would be expected for this condition. Please review and if applicable add a Con Med or provide an explanation for no medical treatment.' answered with 'no conmed in source' (Site from DM).	(b) (4)	05 Oct 2020 14:38:04
User opened query 'Per DM CLR: Please note that there is no Con Med listed for treatment of this condition and treatment would be expected for this condition. Please review and if applicable add a Con Med or provide an explanation for no medical treatment.' (Site from DM).	(b) (4), (b) (6)	01 Sep 2020 07:38:54
User coded data point as SOC: Vascular disorders, HLT: Vascular hypertensive disorders, HLT: Vascular hypertensive disorders NEC, PT: Hypertension, LLT: Hypertension - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	11 Aug 2020 22:29:05
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	11 Aug 2020 22:29:05
Data point term sent to Coder	System	10 Aug 2020 19:22:53
User entered 'Hypertension'	Shelby Pickle (b) (4) (b) (4)	10 Aug 2020 19:22:28

US3142034

Folder: Screening

Form: Medical History (11)

Generated On: 11 Aug 2021 21:58:56

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:52:49
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:03:50
User entered 'UN UNK 2000'	(b) (4) Shelby Pickle (b) (4) (b) (4)	10 Aug 2020 19:22:28

US3142034

Folder: Screening

Form: Medical History (11)

Generated On: 11 Aug 2021 21:58:56

Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:52:49
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:03:50
User entered '0'	(b) (4) Shelby Pickle (b) (4) (b) (4)	10 Aug 2020 19:22:28

US3142034

Folder: Screening

Form: Medical History (11)

Generated On: 11 Aug 2021 21:58:56

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:52:49
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 19:03:50
User entered 'Yes (Y)'	Shelby Pickle (b) (4) (b) (4)	10 Aug 2020 19:22:28

US3142034

Folder: Screening

Form: Medical History (11)

Generated On: 11 Aug 2021 21:58:56

If No, please specify the stop date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:52:49
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:03:50
User entered empty.	(b) (4) Shelby Pickle (b) (4)	10 Aug 2020 19:22:28

US3142034

Folder: Screening

Form: Medical History (11)

Generated On: 11 Aug 2021 21:58:56

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:52:49
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:03:50
User entered '0'	(b) (4) Shelby Pickle (b) (4)	10 Aug 2020 19:22:28

US3142034

Folder: Screening

Form: Medical History (11)

Generated On: 11 Aug 2021 21:58:56

Start Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:52:49
User entered 'Jan 2000'	System	10 Aug 2020 19:22:28

US3142034

Folder: Screening

Form: Medical History (11)

Generated On: 11 Aug 2021 21:58:56

Start Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:52:49
User entered '2000'	System	10 Aug 2020 19:22:28

US3142034

Folder: Screening

Form: Medical History (11)

Generated On: 11 Aug 2021 21:58:56

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:52:49
User entered empty.	System	10 Aug 2020 19:22:28

US3142034

Folder: Screening

Form: Medical History (11)

Generated On: 11 Aug 2021 21:58:56

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:52:49
User entered empty.	System	10 Aug 2020 19:22:28

US3142034

Folder: Screening

Form: Medical History (12)

Generated On: 11 Aug 2021 21:58:56

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:52:49
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:03:50
User coded data point as SOC: Vascular disorders, HLGT: Vascular infections and inflammations, HLT: Phlebitis NEC, PT: Phlebitis, LLT: Phlebitis - version MedDRA\23.0.	Coder Import (b) (4)	23 Nov 2020 15:00:05
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\23.0.	Coder Import (b) (4)	23 Nov 2020 15:00:05
User closed query 'Per DM CLR: Please specify the location of PHLEBITIS. Review and update Med History eCRF as appropriate. ' (Site from DM).	(b) (4), (b) (6)	07 Oct 2020 12:16:25
Data point term sent to Coder	System	05 Oct 2020 14:39:51
Query 'Per DM CLR: Please specify the location of PHLEBITIS. Review and update Med History eCRF as appropriate. ' answered with 'updated' (Site from DM).	Jill York (b) (4)	05 Oct 2020 14:39:22
Coding entries removed.	Jill York (b) (4)	05 Oct 2020 14:39:13
User entered 'PHLEBITIS - unknown location' reason for change: Data Entry Error	Jill York (b) (4)	05 Oct 2020 14:39:13
User opened query 'Per DM CLR: Please specify the location of PHLEBITIS. Review and update Med History eCRF as appropriate. ' (Site from DM).	(b) (4), (b) (6)	01 Sep 2020 07:39:12
User coded data point as SOC: Vascular disorders, HLGT: Vascular infections and inflammations, HLT: Phlebitis NEC, PT: Phlebitis, LLT: Phlebitis - version MedDRA\23.0.	Coder Import (b) (4)	11 Aug 2020 22:28:53
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4)	11 Aug 2020 22:28:53
Data point term sent to Coder	System	10 Aug 2020 19:23:56
User entered 'Phlebitis'	Shelby Pickle (b) (4)	10 Aug 2020 19:23:13
	(b) (4)	

US3142034

Folder: Screening

Form: Medical History (12)

Generated On: 11 Aug 2021 21:58:56

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:52:49
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 19:03:50
User entered 'UN UNK 1974'	Shelby Pickle (b) (4) (b) (4)	10 Aug 2020 19:23:13

US3142034

Folder: Screening

Form: Medical History (12)

Generated On: 11 Aug 2021 21:58:56

Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:52:49
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:03:50
User entered '0'	Shelby Pickle (b) (4)	10 Aug 2020 19:23:13

US3142034

Folder: Screening

Form: Medical History (12)

Generated On: 11 Aug 2021 21:58:56

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:52:49
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 19:03:50
User entered 'No (N)'	Shelby Pickle (b) (4) (b) (4)	10 Aug 2020 19:23:13

US3142034

Folder: Screening

Form: Medical History (12)

Generated On: 11 Aug 2021 21:58:56

If No, please specify the stop date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:52:49
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:03:50
User entered 'UN UNK 1974'	(b) (4) Shelby Pickle (b) (4)	10 Aug 2020 19:23:13

US3142034

Folder: Screening

Form: Medical History (12)

Generated On: 11 Aug 2021 21:58:56

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:52:49
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:03:50
User entered '0'	Shelby Pickle (b) (4)	10 Aug 2020 19:23:13

US3142034

Folder: Screening

Form: Medical History (12)

Generated On: 11 Aug 2021 21:58:56

Start Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:52:49
User entered 'Jan 1974'	System	10 Aug 2020 19:23:13

US3142034

Folder: Screening

Form: Medical History (12)

Generated On: 11 Aug 2021 21:58:56

Start Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:52:49
User entered '1974'	System	10 Aug 2020 19:23:13

US3142034

Folder: Screening

Form: Medical History (12)

Generated On: 11 Aug 2021 21:58:56

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:52:49
User entered 'Jan 1974'	System	10 Aug 2020 19:23:13

US3142034

Folder: Screening

Form: Medical History (12)

Generated On: 11 Aug 2021 21:58:56

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:52:49
User entered '1974'	System	10 Aug 2020 19:23:13

US3142034

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 21:58:56

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:52:49
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 19:03:50
User entered 'Yes (Y)'	Shelby Pickle (b) (4) (b) (4)	10 Aug 2020 19:24:16

US3142034

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 21:58:56

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:52:49
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:03:50
User entered '31 Jul 2020'	(b) (4) Shelby Pickle (b) (4)	10 Aug 2020 19:24:16

US3142034

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 21:58:56

Time of assessment (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:52:49
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:03:50
User entered '11:37'	(b) (4) Shelby Pickle (b) (4) (b) (4)	10 Aug 2020 19:24:16

US3142034

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 21:58:56

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:52:49
User entered '31 Jul 2020 11:37'	System	10 Aug 2020 19:24:16

US3142034

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 21:58:56

[Height \(xxx.x\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:52:49
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:03:50
User entered '64' in	(b) (4) Shelby Pickle (b) (4)	10 Aug 2020 19:24:16
DataPoint set to visible.	(b) (4) System	31 Jul 2020 17:32:01

US3142034

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 21:58:56

[Weight \(xxx.x\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:52:49
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:03:50
User entered '196.2' lb	(b) (4) Shelby Pickle (b) (4)	10 Aug 2020 19:24:16
DataPoint set to visible.	(b) (4) System	31 Jul 2020 17:32:01

US3142034

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 21:58:56

[BMI \(xxx.x\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:52:49
Amendment Manager: User entered '33.74807'	System	16 Sep 2020 23:39:48
User entered '33.7'	System	10 Aug 2020 19:24:16
DataPoint set to visible.	System	31 Jul 2020 17:32:01

US3142034

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 21:58:56

[BMI units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:52:49
User entered 'kg/m2'	System	10 Aug 2020 19:24:16
DataPoint set to visible.	System	31 Jul 2020 17:32:01

US3142034

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 21:58:56

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:52:49
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:03:50
User closed query 'Per CDM: Per CCGs pages 15-16, when Screening and Visit 1 are done on the same day, ND should be recorded for TEMPERATURE, PULSE, RESPIRATORY RATE, SYSTOLIC BP, and DIASTOLIC BP on Screening CRF. Please update accordingly. NOTE: Route is not required ' (Site from DM).	(b) (4) (b) (4), (b) (6)	28 Sep 2020 02:20:09
Query 'Per CDM: Per CCGs pages 15-16, when Screening and Visit 1 are done on the same day, ND should be recorded for TEMPERATURE, PULSE, RESPIRATORY RATE, SYSTOLIC BP, and DIASTOLIC BP on Screening CRF. Please update accordingly. NOTE: Route is not required ' answered with 'done' (Site from DM).	Meghan York (b) (4) (b) (4)	25 Sep 2020 17:00:12
User entered missing code ND - Not Done; reason for change Data Entry Error	Meghan York (b) (4) (b) (4)	25 Sep 2020 17:00:06
User opened query 'Per CDM: Per CCGs pages 15-16, when Screening and Visit 1 are done on the same day, ND should be recorded for TEMPERATURE, PULSE, RESPIRATORY RATE, SYSTOLIC BP, and DIASTOLIC BP on Screening CRF. Please update accordingly. NOTE: Route is not required ' (Site from DM).	(b) (4), (b) (6)	28 Aug 2020 14:14:39
User entered '97.1' F	Shelby Pickle (b) (4) (b) (4)	10 Aug 2020 19:24:16

US3142034

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 21:58:56

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:52:49
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:03:50
User entered empty; reason for change Data Entry Error	(b) (4) Meghan York (b) (4)	25 Sep 2020 17:00:06
User entered 'Other (Other)'	(b) (4) Shelby Pickle (b) (4)	10 Aug 2020 19:24:16

US3142034

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 21:58:56

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:52:49
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:03:50
User entered empty; reason for change Data Entry Error	(b) (4) Meghan York (b) (4)	25 Sep 2020 17:00:06
User entered 'Temporal'	(b) (4) Shelby Pickle (b) (4)	10 Aug 2020 19:24:16

US3142034

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 21:58:56

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:52:49
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:03:50
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4)	25 Sep 2020 17:00:06
User entered '61'	Meghan York (b) (4)	10 Aug 2020 19:24:16
	(b) (4)	

US3142034

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 21:58:56

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:52:49
User entered 'bpm'	System	10 Aug 2020 19:24:16

US3142034

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 21:58:56

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:52:49
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:03:50
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4)	25 Sep 2020 17:00:06
User entered '15'	Meghan York (b) (4)	
	(b) (4)	
	Shelby Pickle (b) (4)	10 Aug 2020 19:24:16
	(b) (4)	

US3142034

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 21:58:56

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:52:49
User entered 'breaths/min'	System	10 Aug 2020 19:24:16

US3142034

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 21:58:56

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:52:49
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:03:50
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4)	25 Sep 2020 17:00:06
User entered '141'	Meghan York (b) (4)	10 Aug 2020 19:24:16
	(b) (4)	

US3142034

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 21:58:56

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:52:49
User entered 'mmHg'	System	10 Aug 2020 19:24:16

US3142034

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 21:58:56

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:52:49
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:03:50
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4)	25 Sep 2020 17:00:06
User entered '84'	Meghan York (b) (4)	
	(b) (4)	
	Shelby Pickle (b) (4)	10 Aug 2020 19:24:16
	(b) (4)	

US3142034

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 21:58:56

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:52:49
User entered 'mmHg'	System	10 Aug 2020 19:24:16

US3142034

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 21:58:56

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:52:49

US3142034

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 21:58:56

[Weight \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:52:49

US3142034

Folder: Screening

Form: Physical Examination

Generated On: 11 Aug 2021 21:58:56

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:52:49
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:03:50
User entered 'Yes (Y)'	(b) (4) Shelby Pickle (b) (4)	10 Aug 2020 19:24:29

US3142034

Folder: Screening

Form: Physical Examination

Generated On: 11 Aug 2021 21:58:56

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:52:49
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:03:50
Query 'The Physical Examination Date is prior to the Screening Visit Date. Please review and reconcile.' canceled (Site from System).	(b) (4) (b) (4), (b) (6)	08 Sep 2020 04:40:50
User opened query 'The Physical Examination Date is prior to the Screening Visit Date. Please review and reconcile.' (Site from System).	System	28 Aug 2020 00:31:11
User entered '31 Jul 2020'	Shelby Pickle (b) (4) (b) (4)	10 Aug 2020 19:24:29

US3142034

Folder: Screening

Form: Childbearing Potential

Generated On: 11 Aug 2021 21:58:56

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:52:49
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:03:50
User entered '31 Jul 2020'	(b) (4) Shelby Pickle (b) (4)	10 Aug 2020 19:25:22

US3142034

Folder: Screening

Form: Childbearing Potential

Generated On: 11 Aug 2021 21:58:56

[Is the participant of childbearing potential?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:52:49
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:03:50
User entered 'No (N)'	(b) (4) Shelby Pickle (b) (4)	10 Aug 2020 19:25:22

US3142034

Folder: Screening

Form: Childbearing Potential

Generated On: 11 Aug 2021 21:58:56

[If No, what is the reason?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:52:49
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 19:03:50
User entered 'Post-menopausal (POST-MENOPAUSAL)'	Shelby Pickle (b) (4) (b) (4)	10 Aug 2020 19:25:22

US3142034

Folder: Screening

Form: Childbearing Potential

Generated On: 11 Aug 2021 21:58:56

If Partner medically sterile or Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:52:49
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:03:50
User entered empty.	(b) (4) Shelby Pickle (b) (4)	10 Aug 2020 19:25:22

US3142034

Folder: Screening

Form: Childbearing Potential

Generated On: 11 Aug 2021 21:58:56

If Surgically sterile, date of surgery (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:52:49
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 19:03:50
User entered empty.	Shelby Pickle (b) (4) (b) (4)	10 Aug 2020 19:25:22

US3142034

Folder: Screening

Form: Childbearing Potential

Generated On: 11 Aug 2021 21:58:56

Date of surgery unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:52:49
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:03:50
User entered '0'	(b) (4) Shelby Pickle (b) (4) (b) (4)	10 Aug 2020 19:25:22

US3142034

Folder: Screening

Form: Childbearing Potential

Generated On: 11 Aug 2021 21:58:56

If Post-menopausal, date of last menstruation (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:52:49
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 19:03:50
User entered 'UN Nov 1999'	Shelby Pickle (b) (4) (b) (4)	10 Aug 2020 19:25:22

US3142034

Folder: Screening

Form: Childbearing Potential

Generated On: 11 Aug 2021 21:58:56

Date of last menstruation unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:52:49
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:03:50
User entered '0'	(b) (4) Shelby Pickle (b) (4)	10 Aug 2020 19:25:22

US3142034

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 21:58:56

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 17:52:49
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 19:03:50
User entered 'Yes (Y)'	Shelby Pickle (b) (4) (b) (4)	31 Jul 2020 17:32:31

US3142034

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 21:58:56

[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 17:52:49
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:03:50
User entered 'No (N)'	(b) (4) Shelby Pickle (b) (4) (b) (4)	31 Jul 2020 17:32:31

US3142034

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 21:58:56

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 17:52:49
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:03:50
User entered 'No (N)'	Shelby Pickle (b) (4)	31 Jul 2020 17:32:31

US3142034

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 21:58:56

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 17:52:49
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:03:50
User entered 'No (N)'	Shelby Pickle (b) (4)	31 Jul 2020 17:32:31

US3142034

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 21:58:56

[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 17:52:49
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 19:03:50
User entered 'No (N)'	Shelby Pickle (b) (4) (b) (4)	31 Jul 2020 17:32:31

US3142034

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 21:58:56

[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 17:52:49
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:03:50
User entered 'No (N)'	Shelby Pickle (b) (4)	31 Jul 2020 17:32:31

US3142034

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 21:58:56

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 17:52:49
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:03:50
User entered 'No (N)'	Shelby Pickle (b) (4)	31 Jul 2020 17:32:31

US3142034

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 21:58:56

[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 17:52:49
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:03:50
User entered 'No (N)'	Shelby Pickle (b) (4)	31 Jul 2020 17:32:31

US3142034

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 21:58:56

[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 17:52:49
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 19:03:50
User entered 'No (N)'	Shelby Pickle (b) (4) (b) (4)	31 Jul 2020 17:32:31

US3142034

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 21:58:56

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 17:52:49
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:03:50
User entered 'No (N)'	Shelby Pickle (b) (4)	31 Jul 2020 17:32:31

US3142034

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 21:58:56

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 17:52:49
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:03:50
User entered 'No (N)'	Shelby Pickle (b) (4)	31 Jul 2020 17:32:31

US3142034

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 21:58:56

[Other](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:52:49
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:03:50
User entered 'No (N)'	Shelby Pickle (b) (4)	31 Jul 2020 17:32:31

US3142034

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 21:58:56

[Specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:52:49
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 19:03:50
User entered empty.	Shelby Pickle (b) (4) (b) (4)	31 Jul 2020 17:32:31

US3142034

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 21:58:56

No Risk Identified

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:52:49
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:03:50
User entered '0'	Shelby Pickle (b) (4)	31 Jul 2020 17:32:31

US3142034

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 21:58:56

[Resides in Nursing Home or Assisted Living Facility](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:52:49
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:03:50
User entered '0'	Shelby Pickle (b) (4)	31 Jul 2020 17:32:31

US3142034

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 21:58:56

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 17:52:49
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:03:50
User entered '0'	Shelby Pickle (b) (4)	31 Jul 2020 17:32:31

US3142034

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 21:58:56

[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 17:52:49
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:03:50
User entered '0'	Shelby Pickle (b) (4)	31 Jul 2020 17:32:31

US3142034

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 21:58:56

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 17:52:49
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:03:50
User entered '0'	Shelby Pickle (b) (4)	31 Jul 2020 17:32:31

US3142034

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 21:58:56

[Resides in a single family home](#) (i.e., detached housing)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:52:49
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:03:50
User entered '1'	Shelby Pickle (b) (4)	31 Jul 2020 17:32:31

US3142034

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 21:58:56

[Other](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:52:49
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:03:50
User entered '0'	Shelby Pickle (b) (4)	31 Jul 2020 17:32:31

US3142034

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 21:58:56

[Specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:52:49
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 19:03:50
User entered empty.	Shelby Pickle (b) (4) (b) (4)	31 Jul 2020 17:32:31

US3142034

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 11 Aug 2021 21:58:56

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 06:09:24
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 19:03:50
User entered 'Yes (Y)'	Shelby Pickle (b) (4) (b) (4)	10 Aug 2020 19:25:37

US3142034

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 11 Aug 2021 21:58:56

[Visit date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 06:09:24
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 19:03:50
User entered '31 Jul 2020'	Shelby Pickle (b) (4) (b) (4)	10 Aug 2020 19:25:37

US3142034

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 11 Aug 2021 21:58:56

[Was visit performed at the participant's home or at the clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 06:09:24
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:03:50
User entered 'Clinic (Clinic)'	(b) (4) Shelby Pickle (b) (4)	10 Aug 2020 19:25:37

US3142034

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 11 Aug 2021 21:58:56

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 06:09:24
User entered 'VISIT1'	System	10 Aug 2020 19:25:37

US3142034

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 11 Aug 2021 21:58:56

What was the date of randomization? (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 06:09:24
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:03:50
User entered '31 JUL 2020'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	31 Jul 2020 19:24:16

US3142034

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 11 Aug 2021 21:58:56

[What was the participant's randomization number?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 06:09:24
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:03:50
Amendment Manager: User closed query 'Data entered is non-conformant. Please correct.' (Site from System).	(b) (4)	21 Aug 2020 01:31:17
Amendment Manager: Data point set to conformant.	System	21 Aug 2020 01:31:17
User opened query 'Data entered is non-conformant. Please correct.' (Site from System).	System	31 Jul 2020 19:24:16
User entered '184364' (non-conformant).	RWS_ENDPOINT ENDPOINT (b) (4)	31 Jul 2020 19:24:16

US3142034

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 11 Aug 2021 21:58:56

[In what Cohort was the participant enrolled?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 06:09:24
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:03:50
User entered '>=65 years (3)'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	31 Jul 2020 19:24:16

US3142034

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 11 Aug 2021 21:58:56

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)	24 Apr 2021 06:09:24
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 19:03:50
User entered 'No (N)'	Shelby Pickle (b) (4) (b) (4)	10 Aug 2020 19:25:55

US3142034

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 11 Aug 2021 21:58:56

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)	24 Apr 2021 06:09:24
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 19:03:50
User entered 'No (N)'	Shelby Pickle (b) (4) (b) (4)	10 Aug 2020 19:25:55

US3142034

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 11 Aug 2021 21:58:56

Severe obesity (body mass index > or = 40kg/m2)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 06:09:24
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 19:03:50
User entered 'No (N)'	Shelby Pickle (b) (4) (b) (4)	10 Aug 2020 19:25:55

US3142034

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 11 Aug 2021 21:58:56

Diabetes (Type I, Type 2, or gestational)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 06:09:24
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 19:03:50
User entered 'No (N)'	Shelby Pickle (b) (4) (b) (4)	10 Aug 2020 19:25:55

US3142034

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 11 Aug 2021 21:58:56

[Liver Disease](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 06:09:24
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 19:03:50
User entered 'No (N)'	Shelby Pickle (b) (4) (b) (4)	10 Aug 2020 19:25:55

US3142034

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 11 Aug 2021 21:58:56

[Human Immunodeficiency Virus \(HIV\) infection](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 06:09:24
DataPoint set to visible.	System	09 Dec 2020 22:52:42
Amendment Manager inserted this DataPoint.	System	19 Sep 2020 03:09:28

US3142034

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 11 Aug 2021 21:58:56

Height

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 06:09:24
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:03:50
User closed query 'Per CDM: Per CCGs pages 15-16, when Screening and Visit 1 are done on the same day, ND should be recorded for HEIGHT and WEIGHT. Please update accordingly.' (Site from DM).	(b) (4) (b) (4), (b) (6)	28 Sep 2020 02:10:55
Query 'Per CDM: Per CCGs pages 15-16, when Screening and Visit 1 are done on the same day, ND should be recorded for HEIGHT and WEIGHT. Please update accordingly.' answered with 'done' (Site from DM).	Meghan York (b) (4) (b) (4)	25 Sep 2020 16:59:33
User entered missing code ND - Not Done; reason for change Data Entry Error	Meghan York (b) (4) (b) (4)	25 Sep 2020 16:59:25
User opened query 'Per CDM: Per CCGs pages 15-16, when Screening and Visit 1 are done on the same day, ND should be recorded for HEIGHT and WEIGHT. Please update accordingly.' (Site from DM).	(b) (4), (b) (6)	31 Aug 2020 06:31:56
User entered '64' in	Shelby Pickle (b) (4) (b) (4)	10 Aug 2020 19:27:42

US3142034

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 11 Aug 2021 21:58:56

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 06:09:24
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 19:03:50
User entered missing code ND - Not Done; reason for change Data Entry Error	Meghan York (b) (4) (b) (4)	25 Sep 2020 16:59:25
User entered '196.1' lb	Shelby Pickle (b) (4) (b) (4)	10 Aug 2020 19:27:42

US3142034

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 11 Aug 2021 21:58:56

Height

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 06:09:24
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:03:50
User closed query 'Per CDM: Per CCGs pages 15-16, when Screening and Visit 1 are done on the same day, ND should be recorded for HEIGHT and WEIGHT. Please update accordingly.' (Site from DM).	(b) (4) (b) (4), (b) (6)	28 Sep 2020 02:10:55
Query 'Per CDM: Per CCGs pages 15-16, when Screening and Visit 1 are done on the same day, ND should be recorded for HEIGHT and WEIGHT. Please update accordingly.' answered with 'done' (Site from DM).	Meghan York (b) (4) (b) (4)	25 Sep 2020 16:59:33
User entered missing code ND - Not Done; reason for change Data Entry Error	Meghan York (b) (4) (b) (4)	25 Sep 2020 16:59:25
User opened query 'Per CDM: Per CCGs pages 15-16, when Screening and Visit 1 are done on the same day, ND should be recorded for HEIGHT and WEIGHT. Please update accordingly.' (Site from DM).	(b) (4), (b) (6)	31 Aug 2020 06:31:56
User entered '64' in	Shelby Pickle (b) (4) (b) (4)	10 Aug 2020 19:27:42

US3142034

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 11 Aug 2021 21:58:56

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 06:09:24
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 19:03:50
User entered missing code ND - Not Done; reason for change Data Entry Error	Meghan York (b) (4) (b) (4)	25 Sep 2020 16:59:25
User entered '196.1' lb	Shelby Pickle (b) (4) (b) (4)	10 Aug 2020 19:27:42

US3142034

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 21:58:56

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 06:09:24
User accepted default value 'Pre-Dose (PREDOSE)'	Shelby Pickle (b) (4) (b) (4)	10 Aug 2020 19:27:42

US3142034

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 21:58:56

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 06:09:24
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 19:03:50
User entered 'Yes (Y)'	Shelby Pickle (b) (4) (b) (4)	10 Aug 2020 19:27:42

US3142034

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 21:58:56

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 06:09:24
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 19:03:50
User entered '31 Jul 2020'	Shelby Pickle (b) (4) (b) (4)	10 Aug 2020 19:27:42

US3142034

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 21:58:56

Time of assessment (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 06:09:24
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 19:03:50
User entered '11:37'	Shelby Pickle (b) (4) (b) (4)	10 Aug 2020 19:27:42

US3142034

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 21:58:56

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 06:09:24
User entered '31 Jul 2020 11:37'	System	10 Aug 2020 19:27:42

US3142034

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 21:58:56

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 06:09:24
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 19:03:50
User entered '97.1' F	Shelby Pickle (b) (4) (b) (4)	10 Aug 2020 19:27:42

US3142034

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 21:58:56

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 06:09:24
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 19:03:50
User entered 'Other (Other)'	Shelby Pickle (b) (4) (b) (4)	10 Aug 2020 19:27:42

US3142034

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 21:58:56

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 06:09:24
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 19:03:50
User entered 'Temporal'	Shelby Pickle (b) (4) (b) (4)	10 Aug 2020 19:27:42

US3142034

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 21:58:56

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 06:09:24
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 19:03:50
User entered '61'	Shelby Pickle (b) (4) (b) (4)	10 Aug 2020 19:27:42

US3142034

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 21:58:56

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 06:09:24
User entered 'bpm'	System	10 Aug 2020 19:27:42

US3142034

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 21:58:56

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 06:09:24
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 19:03:50
User entered '15'	Shelby Pickle (b) (4) (b) (4)	10 Aug 2020 19:27:42

US3142034

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 21:58:56

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 06:09:24
User entered 'breaths/min'	System	10 Aug 2020 19:27:42

US3142034

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 21:58:56

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 06:09:24
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 19:03:50
User entered '141'	Shelby Pickle (b) (4) (b) (4)	10 Aug 2020 19:27:42

US3142034

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 21:58:56

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 06:09:24
User entered 'mmHg'	System	10 Aug 2020 19:27:42

US3142034

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 21:58:56

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 06:09:24
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 19:03:50
User entered '84'	Shelby Pickle (b) (4) (b) (4)	10 Aug 2020 19:27:42

US3142034

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 21:58:56

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 06:09:24
User entered 'mmHg'	System	10 Aug 2020 19:27:42

US3142034

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 11 Aug 2021 21:58:56

Height

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 06:09:24
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:03:50
User closed query 'Per CDM: Per CCGs pages 15-16, when Screening and Visit 1 are done on the same day, ND should be recorded for HEIGHT and WEIGHT. Please update accordingly.' (Site from DM).	(b) (4) (b) (4), (b) (6)	28 Sep 2020 02:10:55
Query 'Per CDM: Per CCGs pages 15-16, when Screening and Visit 1 are done on the same day, ND should be recorded for HEIGHT and WEIGHT. Please update accordingly.' answered with 'done' (Site from DM).	Meghan York (b) (4) (b) (4)	25 Sep 2020 16:59:33
User entered missing code ND - Not Done; reason for change Data Entry Error	Meghan York (b) (4) (b) (4)	25 Sep 2020 16:59:25
User opened query 'Per CDM: Per CCGs pages 15-16, when Screening and Visit 1 are done on the same day, ND should be recorded for HEIGHT and WEIGHT. Please update accordingly.' (Site from DM).	(b) (4), (b) (6)	31 Aug 2020 06:31:56
User entered '64' in	Shelby Pickle (b) (4) (b) (4)	10 Aug 2020 19:27:42

US3142034

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 11 Aug 2021 21:58:56

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 06:09:24
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 19:03:50
User entered missing code ND - Not Done; reason for change Data Entry Error	Meghan York (b) (4) (b) (4)	25 Sep 2020 16:59:25
User entered '196.1' lb	Shelby Pickle (b) (4) (b) (4)	10 Aug 2020 19:27:42

US3142034

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 21:58:56

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 06:09:24
User accepted default value 'Post-Dose (POSTDOSE)'	Shelby Pickle (b) (4) (b) (4)	10 Aug 2020 19:27:42

US3142034

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 21:58:56

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 06:09:24
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 19:03:50
User entered 'Yes (Y)'	Shelby Pickle (b) (4) (b) (4)	10 Aug 2020 19:27:42

US3142034

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 21:58:56

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 06:09:24
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 19:03:50
User entered '31 Jul 2020'	Shelby Pickle (b) (4) (b) (4)	10 Aug 2020 19:27:42

US3142034

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 21:58:56

Time of assessment (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 06:09:24
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:03:50
User closed query 'Post-dose vital signs time is prior to or less than 60 minutes after the Dose Time. Please review and reconcile.' (Site from System).	(b) (4) (b) (4), (b) (6)	12 Aug 2020 04:54:14
Query 'Post-dose vital signs time is prior to or less than 60 minutes after the Dose Time. Please review and reconcile.' answered with '30 minute observation period required' (Site from System).	Shelby Pickle (b) (4) (b) (4)	10 Aug 2020 19:27:54
User opened query 'Post-dose vital signs time is prior System to or less than 60 minutes after the Dose Time. Please review and reconcile.' (Site from System).		10 Aug 2020 19:27:42
User entered '14:21'	Shelby Pickle (b) (4) (b) (4)	10 Aug 2020 19:27:42

US3142034

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 21:58:56

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 06:09:24
User entered '31 Jul 2020 14:21'	System	10 Aug 2020 19:27:42

US3142034

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 21:58:56

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 06:09:24
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:03:50
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) (4), (b) (6)	07 Oct 2020 03:23:01
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 'temporal scanners read low - not an AE' (Site from System).	Jill York (b) (4)	05 Oct 2020 14:40:16
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	16 Sep 2020 23:39:48
User entered '96.6' F	Shelby Pickle (b) (4) (b) (4)	10 Aug 2020 19:27:42

US3142034

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 21:58:56

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 06:09:24
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 19:03:50
User entered 'Other (Other)'	Shelby Pickle (b) (4) (b) (4)	10 Aug 2020 19:27:42

US3142034

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 21:58:56

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 06:09:24
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 19:03:50
User entered 'Temporal'	Shelby Pickle (b) (4) (b) (4)	10 Aug 2020 19:27:42

US3142034

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 21:58:56

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 06:09:24
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 19:03:50
User entered '60'	Shelby Pickle (b) (4) (b) (4)	10 Aug 2020 19:27:42

US3142034

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 21:58:56

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 06:09:24
User entered 'bpm'	System	10 Aug 2020 19:27:42

US3142034

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 21:58:56

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 06:09:24
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 19:03:50
User entered '20'	Shelby Pickle (b) (4) (b) (4)	10 Aug 2020 19:27:42

US3142034

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 21:58:56

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 06:09:24
User entered 'breaths/min'	System	10 Aug 2020 19:27:42

US3142034

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 21:58:56

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 06:09:24
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 19:03:50
User entered '134'	Shelby Pickle (b) (4) (b) (4)	10 Aug 2020 19:27:42

US3142034

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 21:58:56

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 06:09:24
User entered 'mmHg'	System	10 Aug 2020 19:27:42

US3142034

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 21:58:56

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 06:09:24
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 19:03:50
Amendment Manager: Query closed during migrationSystem process because the edit check no longer exists in target version.		16 Sep 2020 23:39:47
User opened query 'Diastolic Blood Pressure reportedSystem is out of range > 100 per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' (Site from System).		10 Aug 2020 19:27:42
User entered '102'	Shelby Pickle (b) (4) (b) (4)	10 Aug 2020 19:27:42

US3142034

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 21:58:56

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 06:09:24
User entered 'mmHg'	System	10 Aug 2020 19:27:42

US3142034

Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 11 Aug 2021 21:58:56

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 06:09:24
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 19:03:50
User entered 'No (N)' reason for change: Data Entry Error	Meghan York (b) (4) (b) (4)	25 Sep 2020 16:58:48
User entered 'Yes (Y)'	Shelby Pickle (b) (4) (b) (4)	10 Aug 2020 19:29:14

US3142034

Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 11 Aug 2021 21:58:56

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 06:09:24
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 19:03:50
User closed query 'Data entered is non-conformant. Please correct.' (Site from System).	System	25 Sep 2020 16:58:54
User entered empty; reason for change Data Entry Error	Meghan York (b) (4) (b) (4)	25 Sep 2020 16:58:54
User opened query 'Data entered is non-conformant. Please correct.' (Site from System).	System	25 Sep 2020 16:58:48
User entered ' 2020' (non-conformant).	Meghan York (b) (4) (b) (4)	25 Sep 2020 16:58:48
User entered '31 Jul 2020'	Shelby Pickle (b) (4) (b) (4)	10 Aug 2020 19:29:14

US3142034

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 11 Aug 2021 21:58:56

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 06:09:24
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 19:03:50
User entered 'Yes (Y)'	Meghan York (b) (4) (b) (4)	31 Jul 2020 20:02:05

US3142034

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 11 Aug 2021 21:58:56

If No, reason not given

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 06:09:24
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 19:03:50
User entered empty.	Meghan York (b) (4) (b) (4)	31 Jul 2020 20:02:05

US3142034

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 11 Aug 2021 21:58:56

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)	24 Apr 2021 06:09:24
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 19:03:50
User entered empty.	Meghan York (b) (4) (b) (4)	31 Jul 2020 20:02:05

US3142034

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 11 Aug 2021 21:58:56

[What was the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 06:09:24
User entered 'MRNA-1273 OR PLACEBO'	System	31 Jul 2020 20:02:05

US3142034

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 11 Aug 2021 21:58:56

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 06:09:24
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:03:50
User entered '31 Jul 2020'	(b) (4) Meghan York (b) (4)	31 Jul 2020 20:02:05

US3142034

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 11 Aug 2021 21:58:56

[What was the treatment time? \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 06:09:24
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 19:03:50
User entered '13:50'	Meghan York (b) (4) (b) (4)	31 Jul 2020 20:02:05

US3142034

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 11 Aug 2021 21:58:56

[Treatment Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 06:09:24
User entered '31 Jul 2020 13:50'	System	31 Jul 2020 20:02:05

US3142034

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 11 Aug 2021 21:58:56

[Which arm was used to give treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 06:09:24
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 19:03:50
User entered 'Left Arm (LEFT ARM)'	Meghan York (b) (4) (b) (4)	31 Jul 2020 20:02:05

US3142034

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 11 Aug 2021 21:58:56

[What was the frequency of the study treatment dosing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 06:09:24
User entered 'ONCE'	System	31 Jul 2020 20:02:05

US3142034

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 11 Aug 2021 21:58:56

[What was the route of administration for the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 06:09:24
User entered 'INTRAMUSCULAR'	System	31 Jul 2020 20:02:05

US3142034

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 21:58:56

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 06:09:24
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:03:50
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	05 Aug 2020 20:47:51

US3142034

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 21:58:56

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 06:09:24
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:03:50
User entered '31 Jul 2020'	(b) (4) (b) (4), (b) (6)	05 Aug 2020 20:47:51

US3142034

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 21:58:56

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 06:09:24
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:03:50
User entered '13:10'	(b) (4) (b) (4), (b) (6)	05 Aug 2020 20:47:51

US3142034

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 21:58:56

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 06:09:24
User entered '31 Jul 2020 13:10'	System	05 Aug 2020 20:47:51

US3142034

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 11 Aug 2021 21:58:56

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 06:09:24
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 19:03:50
User entered '31 Jul 2020'	Shelby Pickle (b) (4) (b) (4)	10 Aug 2020 19:29:34

US3142034

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 11 Aug 2021 21:58:56

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 06:09:24
User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)'	Shelby Pickle (b) (4) (b) (4)	10 Aug 2020 19:29:34

US3142034

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 11 Aug 2021 21:58:56

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 06:09:24
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 19:03:50
User entered 'Yes (Y)'	Shelby Pickle (b) (4) (b) (4)	10 Aug 2020 19:29:34

US3142034

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 11 Aug 2021 21:58:56

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 06:09:24
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 19:03:50
User entered '13:10'	Shelby Pickle (b) (4) (b) (4)	10 Aug 2020 19:29:34

US3142034

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 11 Aug 2021 21:58:56

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 06:09:24
User entered '31 Jul 2020 13:10'	System	10 Aug 2020 19:29:34

US3142034

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 11 Aug 2021 21:58:56

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 06:09:24
User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)'	Shelby Pickle (b) (4) (b) (4)	10 Aug 2020 19:29:34

US3142034

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 11 Aug 2021 21:58:56

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 06:09:24
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 19:03:50
User entered 'Yes (Y)'	Shelby Pickle (b) (4) (b) (4)	10 Aug 2020 19:29:34

US3142034

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 11 Aug 2021 21:58:56

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 06:09:24
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 19:03:50
User entered '13:10'	Shelby Pickle (b) (4) (b) (4)	10 Aug 2020 19:29:34

US3142034

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 11 Aug 2021 21:58:56

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 06:09:24
User entered '31 Jul 2020 13:10'	System	10 Aug 2020 19:29:34

US3142034

Folder: Visit 1 Day 1

Form: Continuing

Generated On: 11 Aug 2021 21:58:56

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 06:09:24
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 19:03:50
User entered 'Yes (Y)'	Shelby Pickle (b) (4) (b) (4)	10 Aug 2020 19:29:40

US3142034

Folder: Visit 1 Day 1

Form: Continuing

Generated On: 11 Aug 2021 21:58:56

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 06:09:24
User entered '1'	System	10 Aug 2020 19:29:40

US3142034

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 11 Aug 2021 21:58:56

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:25:25
Data entry locked.	System	31 Jul 2020 20:02:05
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	31 Jul 2020 20:02:05

US3142034

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 11 Aug 2021 21:58:56

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:25:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8F5B9B48-1138-4DBF-A9AC-B36F0A557EB4)', Time: '2020-07-31T14:40:29', User OID: 'PatientReportedOutcome (US3142034)', ODM File OID: '78bffcf3-777c-42cf-9c59-d1210ab33b89'	System	31 Jul 2020 20:41:02
User entered 'Yes (Y)'	System	31 Jul 2020 20:41:02

US3142034

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 11 Aug 2021 21:58:56

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:25:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8F5B9B48-1138-4DBF-A9AC-B36F0A557EB4)', Time: '2020-07-31T14:40:43', User OID: 'PatientReportedOutcome (US3142034)', ODM File OID: '78bffc3-777c-42cf-9c59-d1210ab33b89'	System	31 Jul 2020 20:41:02
User entered '96.6'	System	31 Jul 2020 20:41:02

US3142034

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 11 Aug 2021 21:58:56

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:25:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8F5B9B48-1138-4DBF-A9AC-B36F0A557EB4)', Time: '2020-07-31T14:40:47', User OID: 'PatientReportedOutcome (US3142034)', ODM File OID: '78bffc3-777c-42cf-9c59-d1210ab33b89'	System	31 Jul 2020 20:41:02
User entered 'No (N)'	System	31 Jul 2020 20:41:02

US3142034

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 11 Aug 2021 21:58:56

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:25:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8F5B9B48-1138-4DBF-A9AC-B36F0A557EB4)', Time: '2020-07-31T14:40:59', User OID: 'PatientReportedOutcome (US3142034)', ODM File OID: '78bffc3-777c-42cf-9c59-d1210ab33b89' User entered '31 Jul 2020 14:40'	System	31 Jul 2020 20:41:02
	System	31 Jul 2020 20:41:02

US3142034

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 11 Aug 2021 21:58:56

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:25:25
User entered '31 Jul 2020 14:10'	System	31 Jul 2020 20:02:05

US3142034

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 11 Aug 2021 21:58:56

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:25:25
User entered '31 Jul 2020 16:40'	System	31 Jul 2020 20:02:05

US3142034

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 11 Aug 2021 21:58:56

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:25:25
Data entry locked.	System	31 Jul 2020 20:02:05
User entered 'Day 1, after vaccination (at home)'	System	31 Jul 2020 20:02:05

US3142034

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 11 Aug 2021 21:58:56

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:25:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8F5B9B48-1138-4DBF-A9AC-B36F0A557EB4)', Time: '2020-08-01T07:44:32', User OID: 'PatientReportedOutcome (US3142034)', ODM File OID: 'd26edfda-3c4d-4849-9d39-d1425d44c04d' User entered 'Yes (Y)'	System	01 Aug 2020 13:44:55
	System	01 Aug 2020 13:44:55

US3142034

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 11 Aug 2021 21:58:56

Please record your **TEMPERATURE in °F**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:25:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8F5B9B48-1138-4DBF-A9AC-B36F0A557EB4)', Time: '2020-08-01T07:44:38', User OID: 'PatientReportedOutcome (US3142034)', ODM File OID: 'd26edfda-3c4d-4849-9d39-d1425d44c04d' User entered '95.5'	System	01 Aug 2020 13:44:55
	System	01 Aug 2020 13:44:55

US3142034

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 11 Aug 2021 21:58:56

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:25:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8F5B9B48-1138-4DBF-A9AC-B36F0A557EB4)', Time: '2020-08-01T07:44:42', User OID: 'PatientReportedOutcome (US3142034)', ODM File OID: 'd26edfda-3c4d-4849-9d39-d1425d44c04d' User entered 'No (N)'	System	01 Aug 2020 13:44:55
	System	01 Aug 2020 13:44:55

US3142034

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 11 Aug 2021 21:58:56

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:25:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8F5B9B48-1138-4DBF-A9AC-B36F0A557EB4)', Time: '2020-08-01T07:44:50', User OID: 'PatientReportedOutcome (US3142034)', ODM File OID: 'd26edfda-3c4d-4849-9d39-d1425d44c04d' User entered '01 Aug 2020 07:44'	System	01 Aug 2020 13:44:55
	System	01 Aug 2020 13:44:55

US3142034

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 11 Aug 2021 21:58:56

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:25:25
User entered '31 Jul 2020 17:35'	System	31 Jul 2020 20:02:05

US3142034

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 11 Aug 2021 21:58:56

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:25:25
User entered '01 Aug 2020 11:59'	System	31 Jul 2020 20:02:05

US3142034

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 11 Aug 2021 21:58:56

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:25:25
Data entry locked.	System	31 Jul 2020 20:02:05
User entered 'Day 2'	System	31 Jul 2020 20:02:05

US3142034

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 11 Aug 2021 21:58:56

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:25:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8F5B9B48-1138-4DBF-A9AC-B36F0A557EB4)', Time: '2020-08-01T18:25:45', User OID: 'PatientReportedOutcome (US3142034)', ODM File OID: '21d01b70-6785-461f-bb51-f02aa90c666a' User entered 'Yes (Y)'	System	02 Aug 2020 00:26:08
	System	02 Aug 2020 00:26:08

US3142034

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 11 Aug 2021 21:58:56

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:25:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8F5B9B48-1138-4DBF-A9AC-B36F0A557EB4)', Time: '2020-08-01T18:25:55', User OID: 'PatientReportedOutcome (US3142034)', ODM File OID: '21d01b70-6785-461f-bb51-f02aa90c666a' User entered '97.8'	System	02 Aug 2020 00:26:08
	System	02 Aug 2020 00:26:08

US3142034

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 11 Aug 2021 21:58:56

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:25:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8F5B9B48-1138-4DBF-A9AC-B36F0A557EB4)', Time: '2020-08-01T18:25:58', User OID: 'PatientReportedOutcome (US3142034)', ODM File OID: '21d01b70-6785-461f-bb51-f02aa90c666a' User entered 'No (N)'	System	02 Aug 2020 00:26:08
	System	02 Aug 2020 00:26:08

US3142034

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 11 Aug 2021 21:58:56

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:25:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8F5B9B48-1138-4DBF-A9AC-B36F0A557EB4)', Time: '2020-08-01T18:26:05', User OID: 'PatientReportedOutcome (US3142034)', ODM File OID: '21d01b70-6785-461f-bb51-f02aa90c666a' User entered '01 Aug 2020 18:26'	System	02 Aug 2020 00:26:08
	System	02 Aug 2020 00:26:08

US3142034

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 11 Aug 2021 21:58:56

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:25:25
User entered '01 Aug 2020 12:00'	System	31 Jul 2020 20:02:05

US3142034

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 11 Aug 2021 21:58:56

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:25:25
User entered '02 Aug 2020 11:59'	System	31 Jul 2020 20:02:05

US3142034

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 11 Aug 2021 21:58:56

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:25:25
Data entry locked.	System	31 Jul 2020 20:02:05
User entered 'Day 3'	System	31 Jul 2020 20:02:05

US3142034

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 11 Aug 2021 21:58:56

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:25:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8F5B9B48-1138-4DBF-A9AC-B36F0A557EB4)', Time: '2020-08-02T17:49:16', User OID: 'PatientReportedOutcome (US3142034)', ODM File OID: 'd2e97913-2d6d-4561-9f27-fbd2c4648f59'	System	02 Aug 2020 23:49:43
User entered 'Yes (Y)'	System	02 Aug 2020 23:49:43

US3142034

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 11 Aug 2021 21:58:56

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:25:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8F5B9B48-1138-4DBF-A9AC-B36F0A557EB4)', Time: '2020-08-02T17:49:22', User OID: 'PatientReportedOutcome (US3142034)', ODM File OID: 'd2e97913-2d6d-4561-9f27-fbd2c4648f59' User entered '98.1'	System	02 Aug 2020 23:49:43
	System	02 Aug 2020 23:49:43

US3142034

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 11 Aug 2021 21:58:56

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:25:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8F5B9B48-1138-4DBF-A9AC-B36F0A557EB4)', Time: '2020-08-02T17:49:27', User OID: 'PatientReportedOutcome (US3142034)', ODM File OID: 'd2e97913-2d6d-4561-9f27-fbd2c4648f59'	System	02 Aug 2020 23:49:43
User entered 'No (N)'	System	02 Aug 2020 23:49:43

US3142034

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 11 Aug 2021 21:58:56

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:25:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8F5B9B48-1138-4DBF-A9AC-B36F0A557EB4)', Time: '2020-08-02T17:49:41', User OID: 'PatientReportedOutcome (US3142034)', ODM File OID: 'd2e97913-2d6d-4561-9f27-fbd2c4648f59'	System	02 Aug 2020 23:49:43
User entered '02 Aug 2020 17:49'	System	02 Aug 2020 23:49:43

US3142034

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 11 Aug 2021 21:58:56

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:25:25
User entered '02 Aug 2020 12:00'	System	31 Jul 2020 20:02:05

US3142034

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 11 Aug 2021 21:58:56

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:25:25
User entered '03 Aug 2020 11:59'	System	31 Jul 2020 20:02:05

US3142034

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 11 Aug 2021 21:58:56

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:25:25
Data entry locked.	System	31 Jul 2020 20:02:05
User entered 'Day 4'	System	31 Jul 2020 20:02:05

US3142034

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 11 Aug 2021 21:58:56

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:25:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8F5B9B48-1138-4DBF-A9AC-B36F0A557EB4)', Time: '2020-08-03T19:26:53', User OID: 'PatientReportedOutcome (US3142034)', ODM File OID: '798e8f86-e3da-4f3c-baeb-03669d8d37a5' User entered 'Yes (Y)'	System	04 Aug 2020 01:27:22
	System	04 Aug 2020 01:27:22

US3142034

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 11 Aug 2021 21:58:56

Please record your **TEMPERATURE in °F**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:25:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8F5B9B48-1138-4DBF-A9AC-B36F0A557EB4)', Time: '2020-08-03T19:27:01', User OID: 'PatientReportedOutcome (US3142034)', ODM File OID: '798e8f86-e3da-4f3c-baeb-03669d8d37a5' User entered '96.1'	System	04 Aug 2020 01:27:22
	System	04 Aug 2020 01:27:22

US3142034

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 11 Aug 2021 21:58:56

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:25:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8F5B9B48-1138-4DBF-A9AC-B36F0A557EB4)', Time: '2020-08-03T19:27:15', User OID: 'PatientReportedOutcome (US3142034)', ODM File OID: '798e8f86-e3da-4f3c-baeb-03669d8d37a5'	System	04 Aug 2020 01:27:22
User entered 'No (N)'	System	04 Aug 2020 01:27:22

US3142034

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 11 Aug 2021 21:58:56

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:25:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8F5B9B48-1138-4DBF-A9AC-B36F0A557EB4)', Time: '2020-08-03T19:27:19', User OID: 'PatientReportedOutcome (US3142034)', ODM File OID: '798e8f86-e3da-4f3c-baeb-03669d8d37a5' User entered '03 Aug 2020 19:27'	System	04 Aug 2020 01:27:22
	System	04 Aug 2020 01:27:22

US3142034

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 11 Aug 2021 21:58:56

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:25:25
User entered '03 Aug 2020 12:00'	System	31 Jul 2020 20:02:05

US3142034

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 11 Aug 2021 21:58:56

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:25:25
User entered '04 Aug 2020 11:59'	System	31 Jul 2020 20:02:05

US3142034

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 11 Aug 2021 21:58:56

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:25:25
Data entry locked.	System	31 Jul 2020 20:02:05
User entered 'Day 5'	System	31 Jul 2020 20:02:05

US3142034

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 11 Aug 2021 21:58:56

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:25:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8F5B9B48-1138-4DBF-A9AC-B36F0A557EB4)', Time: '2020-08-04T20:15:15', User OID: 'PatientReportedOutcome (US3142034)', ODM File OID: '9c07fc71-bbba-4f4c-8402-ab831d4f8d0a' User entered 'Yes (Y)'	System	05 Aug 2020 02:15:31
	System	05 Aug 2020 02:15:31

US3142034

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 11 Aug 2021 21:58:56

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:25:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8F5B9B48-1138-4DBF-A9AC-B36F0A557EB4)', Time: '2020-08-04T20:15:22', User OID: 'PatientReportedOutcome (US3142034)', ODM File OID: '9c07fc71-bbba-4f4c-8402-ab831d4f8d0a' User entered '97.6'	System	05 Aug 2020 02:15:31
	System	05 Aug 2020 02:15:31

US3142034

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 11 Aug 2021 21:58:56

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:25:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8F5B9B48-1138-4DBF-A9AC-B36F0A557EB4)', Time: '2020-08-04T20:15:26', User OID: 'PatientReportedOutcome (US3142034)', ODM File OID: '9c07fc71-bbba-4f4c-8402-ab831d4f8d0a'	System	05 Aug 2020 02:15:31
User entered 'No (N)'	System	05 Aug 2020 02:15:31

US3142034

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 11 Aug 2021 21:58:56

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:25:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8F5B9B48-1138-4DBF-A9AC-B36F0A557EB4)', Time: '2020-08-04T20:15:29', User OID: 'PatientReportedOutcome (US3142034)', ODM File OID: '9c07fc71-bbba-4f4c-8402-ab831d4f8d0a'	System	05 Aug 2020 02:15:31
User entered '04 Aug 2020 20:15'	System	05 Aug 2020 02:15:31

US3142034

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 11 Aug 2021 21:58:56

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:25:25
User entered '04 Aug 2020 12:00'	System	31 Jul 2020 20:02:05

US3142034

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 11 Aug 2021 21:58:56

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:25:25
User entered '05 Aug 2020 11:59'	System	31 Jul 2020 20:02:05

US3142034

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 11 Aug 2021 21:58:56

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:25:25
Data entry locked.	System	31 Jul 2020 20:02:05
User entered 'Day 6'	System	31 Jul 2020 20:02:05

US3142034

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 11 Aug 2021 21:58:56

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:25:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8F5B9B48-1138-4DBF-A9AC-B36F0A557EB4)', Time: '2020-08-05T16:50:08', User OID: 'PatientReportedOutcome (US3142034)', ODM File OID: '508e5c49-3130-4e5e-a2b0-550dd8bb312f' User entered 'Yes (Y)'	System	05 Aug 2020 22:50:24
	System	05 Aug 2020 22:50:24

US3142034

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 11 Aug 2021 21:58:56

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:25:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8F5B9B48-1138-4DBF-A9AC-B36F0A557EB4)', Time: '2020-08-05T16:50:14', User OID: 'PatientReportedOutcome (US3142034)', ODM File OID: '508e5c49-3130-4e5e-a2b0-550dd8bb312f' User entered '98.1'	System	05 Aug 2020 22:50:24
	System	05 Aug 2020 22:50:24

US3142034

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 11 Aug 2021 21:58:56

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:25:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8F5B9B48-1138-4DBF-A9AC-B36F0A557EB4)', Time: '2020-08-05T16:50:18', User OID: 'PatientReportedOutcome (US3142034)', ODM File OID: '508e5c49-3130-4e5e-a2b0-550dd8bb312f' User entered 'No (N)'	System	05 Aug 2020 22:50:24
	System	05 Aug 2020 22:50:24

US3142034

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 11 Aug 2021 21:58:56

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:25:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8F5B9B48-1138-4DBF-A9AC-B36F0A557EB4)', Time: '2020-08-05T16:50:22', User OID: 'PatientReportedOutcome (US3142034)', ODM File OID: '508e5c49-3130-4e5e-a2b0-550dd8bb312f' User entered '05 Aug 2020 16:50'	System	05 Aug 2020 22:50:24
	System	05 Aug 2020 22:50:24

US3142034

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 11 Aug 2021 21:58:56

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:25:25
User entered '05 Aug 2020 12:00'	System	31 Jul 2020 20:02:05

US3142034

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 11 Aug 2021 21:58:56

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:25:25
User entered '06 Aug 2020 11:59'	System	31 Jul 2020 20:02:05

US3142034

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 11 Aug 2021 21:58:56

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:25:25
Data entry locked.	System	31 Jul 2020 20:02:05
User entered 'Day 7'	System	31 Jul 2020 20:02:05

US3142034

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 11 Aug 2021 21:58:56

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:25:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8F5B9B48-1138-4DBF-A9AC-B36F0A557EB4)', Time: '2020-08-06T18:35:46', User OID: 'PatientReportedOutcome (US3142034)', ODM File OID: '162e4386-5990-4b92-8de9-664a5575b4f5' User entered 'Yes (Y)'	System	07 Aug 2020 00:36:01
	System	07 Aug 2020 00:36:01

US3142034

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 11 Aug 2021 21:58:56

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:25:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8F5B9B48-1138-4DBF-A9AC-B36F0A557EB4)', Time: '2020-08-06T18:35:51', User OID: 'PatientReportedOutcome (US3142034)', ODM File OID: '162e4386-5990-4b92-8de9-664a5575b4f5' User entered '98.3'	System	07 Aug 2020 00:36:01
	System	07 Aug 2020 00:36:01

US3142034

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 11 Aug 2021 21:58:56

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:25:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8F5B9B48-1138-4DBF-A9AC-B36F0A557EB4)', Time: '2020-08-06T18:35:54', User OID: 'PatientReportedOutcome (US3142034)', ODM File OID: '162e4386-5990-4b92-8de9-664a5575b4f5'	System	07 Aug 2020 00:36:01
User entered 'No (N)'	System	07 Aug 2020 00:36:01

US3142034

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 11 Aug 2021 21:58:56

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:25:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8F5B9B48-1138-4DBF-A9AC-B36F0A557EB4)', Time: '2020-08-06T18:35:59', User OID: 'PatientReportedOutcome (US3142034)', ODM File OID: '162e4386-5990-4b92-8de9-664a5575b4f5' User entered '06 Aug 2020 18:35'	System	07 Aug 2020 00:36:01
	System	07 Aug 2020 00:36:01

US3142034

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 11 Aug 2021 21:58:56

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:25:25
User entered '06 Aug 2020 12:00'	System	31 Jul 2020 20:02:05

US3142034

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 11 Aug 2021 21:58:56

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:25:25
User entered '07 Aug 2020 11:59'	System	31 Jul 2020 20:02:05

US3142034

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 11 Aug 2021 21:58:56

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:25:25
Data entry locked.	System	31 Jul 2020 20:02:05
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	31 Jul 2020 20:02:05

US3142034

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 11 Aug 2021 21:58:56

Please record - **PAIN AT INJECTION SITE.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:25:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8F5B9B48-1138-4DBF-A9AC-B36F0A557EB4)', Time: '2020-07-31T14:41:11', User OID: 'PatientReportedOutcome (US3142034)', ODM File OID: 'b5bb1005-e868-4ed1-8474-5e10d24bb3a0'	System	31 Jul 2020 20:41:40
User entered 'None (1)'	System	31 Jul 2020 20:41:40

US3142034

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 11 Aug 2021 21:58:56

Is there any **REDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:25:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8F5B9B48-1138-4DBF-A9AC-B36F0A557EB4)', Time: '2020-07-31T14:41:23', User OID: 'PatientReportedOutcome (US3142034)', ODM File OID: 'b5bb1005-e868-4ed1-8474-5e10d24bb3a0'	System	31 Jul 2020 20:41:40
User entered 'No (N)'	System	31 Jul 2020 20:41:40

US3142034

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 11 Aug 2021 21:58:56

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:25:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8F5B9B48-1138-4DBF-A9AC-B36F0A557EB4)', Time: '2020-07-31T14:41:27', User OID: 'PatientReportedOutcome (US3142034)', ODM File OID: 'b5bb1005-e868-4ed1-8474-5e10d24bb3a0'	System	31 Jul 2020 20:41:40
User entered 'No (N)'	System	31 Jul 2020 20:41:40

US3142034

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 11 Aug 2021 21:58:56

Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:25:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8F5B9B48-1138-4DBF-A9AC-B36F0A557EB4)', Time: '2020-07-31T14:41:31', User OID: 'PatientReportedOutcome (US3142034)', ODM File OID: 'b5bb1005-e868-4ed1-8474-5e10d24bb3a0'	System	31 Jul 2020 20:41:40
User entered 'None (1)'	System	31 Jul 2020 20:41:40

US3142034

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 11 Aug 2021 21:58:56

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:25:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8F5B9B48-1138-4DBF-A9AC-B36F0A557EB4)', Time: '2020-07-31T14:41:38', User OID: 'PatientReportedOutcome (US3142034)', ODM File OID: 'b5bb1005-e868-4ed1-8474-5e10d24bb3a0' User entered '31 Jul 2020 14:41'	System	31 Jul 2020 20:41:40
	System	31 Jul 2020 20:41:40

US3142034

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 11 Aug 2021 21:58:56

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:25:25
User entered '31 Jul 2020 14:10'	System	31 Jul 2020 20:02:05

US3142034

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 11 Aug 2021 21:58:56

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:25:25
User entered '31 Jul 2020 16:40'	System	31 Jul 2020 20:02:05

US3142034

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 11 Aug 2021 21:58:56

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:25:25
Data entry locked.	System	31 Jul 2020 20:02:05
User entered 'Day 1, after vaccination (at home)'	System	31 Jul 2020 20:02:05

US3142034

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 11 Aug 2021 21:58:56

Please record - **PAIN AT INJECTION SITE.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:25:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8F5B9B48-1138-4DBF-A9AC-B36F0A557EB4)', Time: '2020-08-01T07:45:35', User OID: 'PatientReportedOutcome (US3142034)', ODM File OID: '44208be4-c278-460a-ab98-674abab9db37'	System	01 Aug 2020 13:46:22
User entered 'None (1)'	System	01 Aug 2020 13:46:22

US3142034

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 11 Aug 2021 21:58:56

Is there any **REDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:25:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8F5B9B48-1138-4DBF-A9AC-B36F0A557EB4)', Time: '2020-08-01T07:46:02', User OID: 'PatientReportedOutcome (US3142034)', ODM File OID: '44208be4-c278-460a-ab98-674abab9db37'	System	01 Aug 2020 13:46:22
User entered 'No (N)'	System	01 Aug 2020 13:46:22

US3142034

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 11 Aug 2021 21:58:56

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:25:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8F5B9B48-1138-4DBF-A9AC-B36F0A557EB4)', Time: '2020-08-01T07:46:06', User OID: 'PatientReportedOutcome (US3142034)', ODM File OID: '44208be4-c278-460a-ab98-674abab9db37'	System	01 Aug 2020 13:46:22
User entered 'No (N)'	System	01 Aug 2020 13:46:22

US3142034

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 11 Aug 2021 21:58:56

Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:25:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8F5B9B48-1138-4DBF-A9AC-B36F0A557EB4)', Time: '2020-08-01T07:46:10', User OID: 'PatientReportedOutcome (US3142034)', ODM File OID: '44208be4-c278-460a-ab98-674abab9db37'	System	01 Aug 2020 13:46:22
User entered 'None (1)'	System	01 Aug 2020 13:46:22

US3142034

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 11 Aug 2021 21:58:56

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:25:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8F5B9B48-1138-4DBF-A9AC-B36F0A557EB4)', Time: '2020-08-01T07:46:18', User OID: 'PatientReportedOutcome (US3142034)', ODM File OID: '44208be4-c278-460a-ab98-674abab9db37' User entered '01 Aug 2020 07:46'	System	01 Aug 2020 13:46:22
	System	01 Aug 2020 13:46:22

US3142034

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 11 Aug 2021 21:58:56

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:25:25
User entered '31 Jul 2020 17:35'	System	31 Jul 2020 20:02:05

US3142034

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 11 Aug 2021 21:58:56

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:25:25
User entered '01 Aug 2020 11:59'	System	31 Jul 2020 20:02:05

US3142034

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 11 Aug 2021 21:58:56

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:25:25
Data entry locked.	System	31 Jul 2020 20:02:05
User entered 'Day 2'	System	31 Jul 2020 20:02:05

US3142034

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 11 Aug 2021 21:58:56

Please record - **PAIN AT INJECTION SITE.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:25:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8F5B9B48-1138-4DBF-A9AC-B36F0A557EB4)', Time: '2020-08-01T18:26:44', User OID: 'PatientReportedOutcome (US3142034)', ODM File OID: '06ce876f-c72e-4a94-bcdc-84b6fa5e34a7'	System	02 Aug 2020 00:27:02
User entered 'None (1)'	System	02 Aug 2020 00:27:02

US3142034

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 11 Aug 2021 21:58:56

Is there any **REDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:25:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8F5B9B48-1138-4DBF-A9AC-B36F0A557EB4)', Time: '2020-08-01T18:26:49', User OID: 'PatientReportedOutcome (US3142034)', ODM File OID: '06ce876f-c72e-4a94-bcdc-84b6fa5e34a7'	System	02 Aug 2020 00:27:02
User entered 'No (N)'	System	02 Aug 2020 00:27:02

US3142034

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 11 Aug 2021 21:58:56

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:25:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8F5B9B48-1138-4DBF-A9AC-B36F0A557EB4)', Time: '2020-08-01T18:26:53', User OID: 'PatientReportedOutcome (US3142034)', ODM File OID: '06ce876f-c72e-4a94-bcdc-84b6fa5e34a7'	System	02 Aug 2020 00:27:02
User entered 'No (N)'	System	02 Aug 2020 00:27:02

US3142034

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 11 Aug 2021 21:58:56

Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:25:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8F5B9B48-1138-4DBF-A9AC-B36F0A557EB4)', Time: '2020-08-01T18:26:56', User OID: 'PatientReportedOutcome (US3142034)', ODM File OID: '06ce876f-c72e-4a94-bcdc-84b6fa5e34a7'	System	02 Aug 2020 00:27:02
User entered 'None (1)'	System	02 Aug 2020 00:27:02

US3142034

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 11 Aug 2021 21:58:56

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:25:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8F5B9B48-1138-4DBF-A9AC-B36F0A557EB4)', Time: '2020-08-01T18:27:01', User OID: 'PatientReportedOutcome (US3142034)', ODM File OID: '06ce876f-c72e-4a94-bcdc-84b6fa5e34a7'	System	02 Aug 2020 00:27:02
User entered '01 Aug 2020 18:27'	System	02 Aug 2020 00:27:02

US3142034

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 11 Aug 2021 21:58:56

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:25:25
User entered '01 Aug 2020 12:00'	System	31 Jul 2020 20:02:05

US3142034

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 11 Aug 2021 21:58:56

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:25:25
User entered '02 Aug 2020 11:59'	System	31 Jul 2020 20:02:05

US3142034

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 11 Aug 2021 21:58:56

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:25:25
Data entry locked.	System	31 Jul 2020 20:02:05
User entered 'Day 3'	System	31 Jul 2020 20:02:05

US3142034

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 11 Aug 2021 21:58:56

Please record - **PAIN AT INJECTION SITE.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:25:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8F5B9B48-1138-4DBF-A9AC-B36F0A557EB4)', Time: '2020-08-02T17:49:46', User OID: 'PatientReportedOutcome (US3142034)', ODM File OID: '190f8425-fddb-4ca6-9842-a5562d0b43d2'	System	02 Aug 2020 23:50:10
User entered 'None (1)'	System	02 Aug 2020 23:50:10

US3142034

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 11 Aug 2021 21:58:56

Is there any **REDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:25:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8F5B9B48-1138-4DBF-A9AC-B36F0A557EB4)', Time: '2020-08-02T17:49:49', User OID: 'PatientReportedOutcome (US3142034)', ODM File OID: '190f8425-fddb-4ca6-9842-a5562d0b43d2'	System	02 Aug 2020 23:50:10
User entered 'No (N)'	System	02 Aug 2020 23:50:10

US3142034

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 11 Aug 2021 21:58:56

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:25:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8F5B9B48-1138-4DBF-A9AC-B36F0A557EB4)', Time: '2020-08-02T17:49:51', User OID: 'PatientReportedOutcome (US3142034)', ODM File OID: '190f8425-fddb-4ca6-9842-a5562d0b43d2'	System	02 Aug 2020 23:50:10
User entered 'No (N)'	System	02 Aug 2020 23:50:10

US3142034

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 11 Aug 2021 21:58:56

Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:25:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8F5B9B48-1138-4DBF-A9AC-B36F0A557EB4)', Time: '2020-08-02T17:49:54', User OID: 'PatientReportedOutcome (US3142034)', ODM File OID: '190f8425-fddb-4ca6-9842-a5562d0b43d2'	System	02 Aug 2020 23:50:10
User entered 'None (1)'	System	02 Aug 2020 23:50:10

US3142034

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 11 Aug 2021 21:58:56

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:25:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8F5B9B48-1138-4DBF-A9AC-B36F0A557EB4)', Time: '2020-08-02T17:50:07', User OID: 'PatientReportedOutcome (US3142034)', ODM File OID: '190f8425-fddb-4ca6-9842-a5562d0b43d2'	System	02 Aug 2020 23:50:10
User entered '02 Aug 2020 17:50'	System	02 Aug 2020 23:50:10

US3142034

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 11 Aug 2021 21:58:56

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:25:25
User entered '02 Aug 2020 12:00'	System	31 Jul 2020 20:02:05

US3142034

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 11 Aug 2021 21:58:56

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:25:25
User entered '03 Aug 2020 11:59'	System	31 Jul 2020 20:02:05

US3142034

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 11 Aug 2021 21:58:56

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:25:25
Data entry locked.	System	31 Jul 2020 20:02:05
User entered 'Day 4'	System	31 Jul 2020 20:02:05

US3142034

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 11 Aug 2021 21:58:56

Please record - **PAIN AT INJECTION SITE.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:25:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8F5B9B48-1138-4DBF-A9AC-B36F0A557EB4)', Time: '2020-08-03T19:27:25', User OID: 'PatientReportedOutcome (US3142034)', ODM File OID: 'a4b15277-aaa1-4766-ad15-9bc100d2039e' User entered 'None (1)'	System	04 Aug 2020 01:27:46
	System	04 Aug 2020 01:27:46

US3142034

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 11 Aug 2021 21:58:56

Is there any **REDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:25:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8F5B9B48-1138-4DBF-A9AC-B36F0A557EB4)', Time: '2020-08-03T19:27:28', User OID: 'PatientReportedOutcome (US3142034)', ODM File OID: 'a4b15277-aaa1-4766-ad15-9bc100d2039e' User entered 'No (N)'	System	04 Aug 2020 01:27:46
	System	04 Aug 2020 01:27:46

US3142034

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 11 Aug 2021 21:58:56

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:25:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8F5B9B48-1138-4DBF-A9AC-B36F0A557EB4)', Time: '2020-08-03T19:27:30', User OID: 'PatientReportedOutcome (US3142034)', ODM File OID: 'a4b15277-aaa1-4766-ad15-9bc100d2039e' User entered 'No (N)'	System	04 Aug 2020 01:27:46
	System	04 Aug 2020 01:27:46

US3142034

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 11 Aug 2021 21:58:56

Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:25:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8F5B9B48-1138-4DBF-A9AC-B36F0A557EB4)', Time: '2020-08-03T19:27:39', User OID: 'PatientReportedOutcome (US3142034)', ODM File OID: 'a4b15277-aaa1-4766-ad15-9bc100d2039e'	System	04 Aug 2020 01:27:46
User entered 'None (1)'	System	04 Aug 2020 01:27:46

US3142034

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 11 Aug 2021 21:58:56

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:25:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8F5B9B48-1138-4DBF-A9AC-B36F0A557EB4)', Time: '2020-08-03T19:27:44', User OID: 'PatientReportedOutcome (US3142034)', ODM File OID: 'a4b15277-aaa1-4766-ad15-9bc100d2039e' User entered '03 Aug 2020 19:27'	System	04 Aug 2020 01:27:46
	System	04 Aug 2020 01:27:46

US3142034

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 11 Aug 2021 21:58:56

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:25:25
User entered '03 Aug 2020 12:00'	System	31 Jul 2020 20:02:05

US3142034

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 11 Aug 2021 21:58:56

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:25:25
User entered '04 Aug 2020 11:59'	System	31 Jul 2020 20:02:05

US3142034

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 11 Aug 2021 21:58:56

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:25:25
Data entry locked.	System	31 Jul 2020 20:02:05
User entered 'Day 5'	System	31 Jul 2020 20:02:05

US3142034

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 11 Aug 2021 21:58:56

Please record - **PAIN AT INJECTION SITE.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:25:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8F5B9B48-1138-4DBF-A9AC-B36F0A557EB4)', Time: '2020-08-04T20:15:34', User OID: 'PatientReportedOutcome (US3142034)', ODM File OID: 'd8f0f26e-09ab-4d31-9fe2-cf3a2bd0d1cb'	System	05 Aug 2020 02:15:54
User entered 'None (1)'	System	05 Aug 2020 02:15:54

US3142034

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 11 Aug 2021 21:58:56

Is there any **REDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:25:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8F5B9B48-1138-4DBF-A9AC-B36F0A557EB4)', Time: '2020-08-04T20:15:37', User OID: 'PatientReportedOutcome (US3142034)', ODM File OID: 'd8f0f26e-09ab-4d31-9fe2-cf3a2bd0d1cb'	System	05 Aug 2020 02:15:54
User entered 'No (N)'	System	05 Aug 2020 02:15:54

US3142034

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 11 Aug 2021 21:58:56

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:25:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8F5B9B48-1138-4DBF-A9AC-B36F0A557EB4)', Time: '2020-08-04T20:15:39', User OID: 'PatientReportedOutcome (US3142034)', ODM File OID: 'd8f0f26e-09ab-4d31-9fe2-cf3a2bd0d1cb'	System	05 Aug 2020 02:15:54
User entered 'No (N)'	System	05 Aug 2020 02:15:54

US3142034

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 11 Aug 2021 21:58:56

Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:25:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8F5B9B48-1138-4DBF-A9AC-B36F0A557EB4)', Time: '2020-08-04T20:15:42', User OID: 'PatientReportedOutcome (US3142034)', ODM File OID: 'd8f0f26e-09ab-4d31-9fe2-cf3a2bd0d1cb'	System	05 Aug 2020 02:15:54
User entered 'None (1)'	System	05 Aug 2020 02:15:54

US3142034

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 11 Aug 2021 21:58:56

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:25:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8F5B9B48-1138-4DBF-A9AC-B36F0A557EB4)', Time: '2020-08-04T20:15:51', User OID: 'PatientReportedOutcome (US3142034)', ODM File OID: 'd8f0f26e-09ab-4d31-9fe2-cf3a2bd0d1cb' User entered '04 Aug 2020 20:15'	System	05 Aug 2020 02:15:54
	System	05 Aug 2020 02:15:54

US3142034

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 11 Aug 2021 21:58:56

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:25:25
User entered '04 Aug 2020 12:00'	System	31 Jul 2020 20:02:05

US3142034

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 11 Aug 2021 21:58:56

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:25:25
User entered '05 Aug 2020 11:59'	System	31 Jul 2020 20:02:05

US3142034

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 11 Aug 2021 21:58:56

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:25:25
Data entry locked.	System	31 Jul 2020 20:02:05
User entered 'Day 6'	System	31 Jul 2020 20:02:05

US3142034

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 11 Aug 2021 21:58:56

Please record - **PAIN AT INJECTION SITE.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:25:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8F5B9B48-1138-4DBF-A9AC-B36F0A557EB4)', Time: '2020-08-05T16:50:27', User OID: 'PatientReportedOutcome (US3142034)', ODM File OID: '4bde5304-1be7-4390-93ca-c99b499d8418'	System	05 Aug 2020 22:50:42
User entered 'None (1)'	System	05 Aug 2020 22:50:42

US3142034

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 11 Aug 2021 21:58:56

Is there any **REDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:25:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8F5B9B48-1138-4DBF-A9AC-B36F0A557EB4)', Time: '2020-08-05T16:50:30', User OID: 'PatientReportedOutcome (US3142034)', ODM File OID: '4bde5304-1be7-4390-93ca-c99b499d8418'	System	05 Aug 2020 22:50:42
User entered 'No (N)'	System	05 Aug 2020 22:50:42

US3142034

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 11 Aug 2021 21:58:56

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:25:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8F5B9B48-1138-4DBF-A9AC-B36F0A557EB4)', Time: '2020-08-05T16:50:33', User OID: 'PatientReportedOutcome (US3142034)', ODM File OID: '4bde5304-1be7-4390-93ca-c99b499d8418'	System	05 Aug 2020 22:50:42
User entered 'No (N)'	System	05 Aug 2020 22:50:42

US3142034

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 11 Aug 2021 21:58:56

Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:25:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8F5B9B48-1138-4DBF-A9AC-B36F0A557EB4)', Time: '2020-08-05T16:50:35', User OID: 'PatientReportedOutcome (US3142034)', ODM File OID: '4bde5304-1be7-4390-93ca-c99b499d8418'	System	05 Aug 2020 22:50:42
User entered 'None (1)'	System	05 Aug 2020 22:50:42

US3142034

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 11 Aug 2021 21:58:56

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:25:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8F5B9B48-1138-4DBF-A9AC-B36F0A557EB4)', Time: '2020-08-05T16:50:40', User OID: 'PatientReportedOutcome (US3142034)', ODM File OID: '4bde5304-1be7-4390-93ca-c99b499d8418'	System	05 Aug 2020 22:50:42
User entered '05 Aug 2020 16:50'	System	05 Aug 2020 22:50:42

US3142034

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 11 Aug 2021 21:58:56

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:25:25
User entered '05 Aug 2020 12:00'	System	31 Jul 2020 20:02:05

US3142034

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 11 Aug 2021 21:58:56

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:25:25
User entered '06 Aug 2020 11:59'	System	31 Jul 2020 20:02:05

US3142034

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 11 Aug 2021 21:58:56

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:25:25
Data entry locked.	System	31 Jul 2020 20:02:05
User entered 'Day 7'	System	31 Jul 2020 20:02:05

US3142034

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 11 Aug 2021 21:58:56

Please record - **PAIN AT INJECTION SITE.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:25:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8F5B9B48-1138-4DBF-A9AC-B36F0A557EB4)', Time: '2020-08-06T18:36:04', User OID: 'PatientReportedOutcome (US3142034)', ODM File OID: '9f1641c1-72d4-4ca5-97c0-589549fe781c' User entered 'None (1)'	System	07 Aug 2020 00:36:20
	System	07 Aug 2020 00:36:20

US3142034

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 11 Aug 2021 21:58:56

Is there any **REDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:25:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8F5B9B48-1138-4DBF-A9AC-B36F0A557EB4)', Time: '2020-08-06T18:36:07', User OID: 'PatientReportedOutcome (US3142034)', ODM File OID: '9f1641c1-72d4-4ca5-97c0-589549fe781c' User entered 'No (N)'	System	07 Aug 2020 00:36:20
	System	07 Aug 2020 00:36:20

US3142034

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 11 Aug 2021 21:58:56

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:25:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8F5B9B48-1138-4DBF-A9AC-B36F0A557EB4)', Time: '2020-08-06T18:36:10', User OID: 'PatientReportedOutcome (US3142034)', ODM File OID: '9f1641c1-72d4-4ca5-97c0-589549fe781c' User entered 'No (N)'	System	07 Aug 2020 00:36:20
	System	07 Aug 2020 00:36:20

US3142034

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 11 Aug 2021 21:58:56

Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:25:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8F5B9B48-1138-4DBF-A9AC-B36F0A557EB4)', Time: '2020-08-06T18:36:13', User OID: 'PatientReportedOutcome (US3142034)', ODM File OID: '9f1641c1-72d4-4ca5-97c0-589549fe781c' User entered 'None (1)'	System	07 Aug 2020 00:36:20
	System	07 Aug 2020 00:36:20

US3142034

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 11 Aug 2021 21:58:56

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:25:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8F5B9B48-1138-4DBF-A9AC-B36F0A557EB4)', Time: '2020-08-06T18:36:17', User OID: 'PatientReportedOutcome (US3142034)', ODM File OID: '9f1641c1-72d4-4ca5-97c0-589549fe781c' User entered '06 Aug 2020 18:36'	System	07 Aug 2020 00:36:20
	System	07 Aug 2020 00:36:20

US3142034

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 11 Aug 2021 21:58:56

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:25:25
User entered '06 Aug 2020 12:00'	System	31 Jul 2020 20:02:05

US3142034

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 11 Aug 2021 21:58:56

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:25:25
User entered '07 Aug 2020 11:59'	System	31 Jul 2020 20:02:05

US3142034

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 11 Aug 2021 21:58:56

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:25:25
Data entry locked.	System	31 Jul 2020 20:02:05
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	31 Jul 2020 20:02:05

US3142034

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 11 Aug 2021 21:58:56

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:25:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8F5B9B48-1138-4DBF-A9AC-B36F0A557EB4)', Time: '2020-07-31T14:41:45', User OID: 'PatientReportedOutcome (US3142034)', ODM File OID: 'e0c68560-5841-475b-a766-d1bc9498892a' User entered 'None (0)'	System	31 Jul 2020 20:42:19
	System	31 Jul 2020 20:42:19

US3142034

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 11 Aug 2021 21:58:56

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:25:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8F5B9B48-1138-4DBF-A9AC-B36F0A557EB4)', Time: '2020-07-31T14:41:48', User OID: 'PatientReportedOutcome (US3142034)', ODM File OID: 'e0c68560-5841-475b-a766-d1bc9498892a' User entered 'None (0)'	System	31 Jul 2020 20:42:19
	System	31 Jul 2020 20:42:19

US3142034

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 11 Aug 2021 21:58:56

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:25:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8F5B9B48-1138-4DBF-A9AC-B36F0A557EB4)', Time: '2020-07-31T14:41:52', User OID: 'PatientReportedOutcome (US3142034)', ODM File OID: 'e0c68560-5841-475b-a766-d1bc9498892a' User entered 'None (0)'	System	31 Jul 2020 20:42:19
	System	31 Jul 2020 20:42:19

US3142034

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 11 Aug 2021 21:58:56

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:25:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8F5B9B48-1138-4DBF-A9AC-B36F0A557EB4)', Time: '2020-07-31T14:41:57', User OID: 'PatientReportedOutcome (US3142034)', ODM File OID: 'e0c68560-5841-475b-a766-d1bc9498892a' User entered 'None (0)'	System	31 Jul 2020 20:42:19
	System	31 Jul 2020 20:42:19

US3142034

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 11 Aug 2021 21:58:56

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:25:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8F5B9B48-1138-4DBF-A9AC-B36F0A557EB4)', Time: '2020-07-31T14:42:00', User OID: 'PatientReportedOutcome (US3142034)', ODM File OID: 'e0c68560-5841-475b-a766-d1bc9498892a' User entered 'None (0)'	System	31 Jul 2020 20:42:19
	System	31 Jul 2020 20:42:19

US3142034

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 11 Aug 2021 21:58:56

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:25:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8F5B9B48-1138-4DBF-A9AC-B36F0A557EB4)', Time: '2020-07-31T14:42:02', User OID: 'PatientReportedOutcome (US3142034)', ODM File OID: 'e0c68560-5841-475b-a766-d1bc9498892a' User entered 'None (0)'	System	31 Jul 2020 20:42:19
	System	31 Jul 2020 20:42:19

US3142034

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 11 Aug 2021 21:58:56

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)	05 Mar 2021 01:25:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8F5B9B48-1138-4DBF-A9AC-B36F0A557EB4)', Time: '2020-07-31T14:42:10', User OID: 'PatientReportedOutcome (US3142034)', ODM File OID: 'e0c68560-5841-475b-a766-d1bc9498892a' User entered 'No (N)'	System	31 Jul 2020 20:42:19
	System	31 Jul 2020 20:42:19

US3142034

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 11 Aug 2021 21:58:56

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:25:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8F5B9B48-1138-4DBF-A9AC-B36F0A557EB4)', Time: '2020-07-31T14:42:18', User OID: 'PatientReportedOutcome (US3142034)', ODM File OID: 'e0c68560-5841-475b-a766-d1bc9498892a' User entered '31 Jul 2020 14:42'	System	31 Jul 2020 20:42:19
	System	31 Jul 2020 20:42:19

US3142034

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 11 Aug 2021 21:58:56

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:25:25
User entered '31 Jul 2020 14:10'	System	31 Jul 2020 20:02:05

US3142034

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 11 Aug 2021 21:58:56

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:25:25
User entered '31 Jul 2020 16:40'	System	31 Jul 2020 20:02:05

US3142034

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 11 Aug 2021 21:58:56

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:25:25
Data entry locked.	System	31 Jul 2020 20:02:05
User entered 'Day 1, after vaccination (at home)'	System	31 Jul 2020 20:02:05

US3142034

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 11 Aug 2021 21:58:56

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:25:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8F5B9B48-1138-4DBF-A9AC-B36F0A557EB4)', Time: '2020-08-01T07:44:58', User OID: 'PatientReportedOutcome (US3142034)', ODM File OID: 'f6108fc6-b7ea-4a12-82ae-c10a83d5bef5' User entered 'None (0)'	System	01 Aug 2020 13:45:32
	System	01 Aug 2020 13:45:32

US3142034

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 11 Aug 2021 21:58:56

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:25:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8F5B9B48-1138-4DBF-A9AC-B36F0A557EB4)', Time: '2020-08-01T07:45:05', User OID: 'PatientReportedOutcome (US3142034)', ODM File OID: 'f6108fc6-b7ea-4a12-82ae-c10a83d5bef5' User entered 'None (0)'	System	01 Aug 2020 13:45:32
	System	01 Aug 2020 13:45:32

US3142034

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 11 Aug 2021 21:58:56

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:25:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8F5B9B48-1138-4DBF-A9AC-B36F0A557EB4)', Time: '2020-08-01T07:45:08', User OID: 'PatientReportedOutcome (US3142034)', ODM File OID: 'f6108fc6-b7ea-4a12-82ae-c10a83d5bef5' User entered 'None (0)'	System	01 Aug 2020 13:45:32
	System	01 Aug 2020 13:45:32

US3142034

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 11 Aug 2021 21:58:56

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:25:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8F5B9B48-1138-4DBF-A9AC-B36F0A557EB4)', Time: '2020-08-01T07:45:10', User OID: 'PatientReportedOutcome (US3142034)', ODM File OID: 'f6108fc6-b7ea-4a12-82ae-c10a83d5bef5' User entered 'None (0)'	System	01 Aug 2020 13:45:32
	System	01 Aug 2020 13:45:32

US3142034

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 11 Aug 2021 21:58:56

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:25:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8F5B9B48-1138-4DBF-A9AC-B36F0A557EB4)', Time: '2020-08-01T07:45:14', User OID: 'PatientReportedOutcome (US3142034)', ODM File OID: 'f6108fc6-b7ea-4a12-82ae-c10a83d5bef5' User entered 'None (0)'	System	01 Aug 2020 13:45:32
	System	01 Aug 2020 13:45:32

US3142034

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 11 Aug 2021 21:58:56

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:25:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8F5B9B48-1138-4DBF-A9AC-B36F0A557EB4)', Time: '2020-08-01T07:45:16', User OID: 'PatientReportedOutcome (US3142034)', ODM File OID: 'f6108fc6-b7ea-4a12-82ae-c10a83d5bef5' User entered 'None (0)'	System	01 Aug 2020 13:45:32
	System	01 Aug 2020 13:45:32

US3142034

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 11 Aug 2021 21:58:56

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)	05 Mar 2021 01:25:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8F5B9B48-1138-4DBF-A9AC-B36F0A557EB4)', Time: '2020-08-01T07:45:22', User OID: 'PatientReportedOutcome (US3142034)', ODM File OID: 'f6108fc6-b7ea-4a12-82ae-c10a83d5bef5' User entered 'No (N)'	System	01 Aug 2020 13:45:32
	System	01 Aug 2020 13:45:32

US3142034

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 11 Aug 2021 21:58:56

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:25:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8F5B9B48-1138-4DBF-A9AC-B36F0A557EB4)', Time: '2020-08-01T07:45:30', User OID: 'PatientReportedOutcome (US3142034)', ODM File OID: 'f6108fc6-b7ea-4a12-82ae-c10a83d5bef5' User entered '01 Aug 2020 07:45'	System	01 Aug 2020 13:45:32
	System	01 Aug 2020 13:45:32

US3142034

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 11 Aug 2021 21:58:56

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:25:25
User entered '31 Jul 2020 17:35'	System	31 Jul 2020 20:02:05

US3142034

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 11 Aug 2021 21:58:56

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:25:25
User entered '01 Aug 2020 11:59'	System	31 Jul 2020 20:02:05

US3142034

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 11 Aug 2021 21:58:56

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:25:25
Data entry locked.	System	31 Jul 2020 20:02:05
User entered 'Day 2'	System	31 Jul 2020 20:02:05

US3142034

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 11 Aug 2021 21:58:56

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:25:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8F5B9B48-1138-4DBF-A9AC-B36F0A557EB4)', Time: '2020-08-01T18:26:09', User OID: 'PatientReportedOutcome (US3142034)', ODM File OID: '94b8a8cc-6191-4d6c-bdc9-265eabbe0dd8' User entered 'None (0)'	System	02 Aug 2020 00:26:37
	System	02 Aug 2020 00:26:37

US3142034

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 11 Aug 2021 21:58:56

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:25:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8F5B9B48-1138-4DBF-A9AC-B36F0A557EB4)', Time: '2020-08-01T18:26:12', User OID: 'PatientReportedOutcome (US3142034)', ODM File OID: '94b8a8cc-6191-4d6c-bdc9-265eabbe0dd8' User entered 'None (0)'	System	02 Aug 2020 00:26:37
	System	02 Aug 2020 00:26:37

US3142034

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 11 Aug 2021 21:58:56

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:25:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8F5B9B48-1138-4DBF-A9AC-B36F0A557EB4)', Time: '2020-08-01T18:26:15', User OID: 'PatientReportedOutcome (US3142034)', ODM File OID: '94b8a8cc-6191-4d6c-bdc9-265eabbe0dd8' User entered 'None (0)'	System	02 Aug 2020 00:26:37
	System	02 Aug 2020 00:26:37

US3142034

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 11 Aug 2021 21:58:56

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:25:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8F5B9B48-1138-4DBF-A9AC-B36F0A557EB4)', Time: '2020-08-01T18:26:19', User OID: 'PatientReportedOutcome (US3142034)', ODM File OID: '94b8a8cc-6191-4d6c-bdc9-265eabbe0dd8' User entered 'None (0)'	System	02 Aug 2020 00:26:37
	System	02 Aug 2020 00:26:37

US3142034

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 11 Aug 2021 21:58:56

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:25:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8F5B9B48-1138-4DBF-A9AC-B36F0A557EB4)', Time: '2020-08-01T18:26:22', User OID: 'PatientReportedOutcome (US3142034)', ODM File OID: '94b8a8cc-6191-4d6c-bdc9-265eabbe0dd8' User entered 'None (0)'	System	02 Aug 2020 00:26:37
	System	02 Aug 2020 00:26:37

US3142034

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 11 Aug 2021 21:58:56

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:25:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8F5B9B48-1138-4DBF-A9AC-B36F0A557EB4)', Time: '2020-08-01T18:26:24', User OID: 'PatientReportedOutcome (US3142034)', ODM File OID: '94b8a8cc-6191-4d6c-bdc9-265eabbe0dd8' User entered 'None (0)'	System	02 Aug 2020 00:26:37
	System	02 Aug 2020 00:26:37

US3142034

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 11 Aug 2021 21:58:56

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)	05 Mar 2021 01:25:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8F5B9B48-1138-4DBF-A9AC-B36F0A557EB4)', Time: '2020-08-01T18:26:29', User OID: 'PatientReportedOutcome (US3142034)', ODM File OID: '94b8a8cc-6191-4d6c-bdc9-265eabbe0dd8' User entered 'No (N)'	System	02 Aug 2020 00:26:37
	System	02 Aug 2020 00:26:37

US3142034

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 11 Aug 2021 21:58:56

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:25:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8F5B9B48-1138-4DBF-A9AC-B36F0A557EB4)', Time: '2020-08-01T18:26:36', User OID: 'PatientReportedOutcome (US3142034)', ODM File OID: '94b8a8cc-6191-4d6c-bdc9-265eabbe0dd8' User entered '01 Aug 2020 18:26'	System	02 Aug 2020 00:26:37
	System	02 Aug 2020 00:26:37

US3142034

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 11 Aug 2021 21:58:56

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:25:25
User entered '01 Aug 2020 12:00'	System	31 Jul 2020 20:02:05

US3142034

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 11 Aug 2021 21:58:56

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:25:25
User entered '02 Aug 2020 11:59'	System	31 Jul 2020 20:02:05

US3142034

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 11 Aug 2021 21:58:56

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:25:25
Data entry locked.	System	31 Jul 2020 20:02:05
User entered 'Day 3'	System	31 Jul 2020 20:02:05

US3142034

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 11 Aug 2021 21:58:56

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:25:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8F5B9B48-1138-4DBF-A9AC-B36F0A557EB4)', Time: '2020-08-02T17:50:11', User OID: 'PatientReportedOutcome (US3142034)', ODM File OID: '92afef6a-6023-45f9-b1e9-c92ae07fd35e' User entered 'None (0)'	System	02 Aug 2020 23:50:38
	System	02 Aug 2020 23:50:38

US3142034

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 11 Aug 2021 21:58:56

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:25:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8F5B9B48-1138-4DBF-A9AC-B36F0A557EB4)', Time: '2020-08-02T17:50:14', User OID: 'PatientReportedOutcome (US3142034)', ODM File OID: '92afef6a-6023-45f9-b1e9-c92ae07fd35e' User entered 'None (0)'	System	02 Aug 2020 23:50:38
	System	02 Aug 2020 23:50:38

US3142034

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 11 Aug 2021 21:58:56

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:25:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8F5B9B48-1138-4DBF-A9AC-B36F0A557EB4)', Time: '2020-08-02T17:50:16', User OID: 'PatientReportedOutcome (US3142034)', ODM File OID: '92afef6a-6023-45f9-b1e9-c92ae07fd35e' User entered 'None (0)'	System	02 Aug 2020 23:50:38
	System	02 Aug 2020 23:50:38

US3142034

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 11 Aug 2021 21:58:56

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:25:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8F5B9B48-1138-4DBF-A9AC-B36F0A557EB4)', Time: '2020-08-02T17:50:20', User OID: 'PatientReportedOutcome (US3142034)', ODM File OID: '92afef6a-6023-45f9-b1e9-c92ae07fd35e' User entered 'None (0)'	System	02 Aug 2020 23:50:38
	System	02 Aug 2020 23:50:38

US3142034

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 11 Aug 2021 21:58:56

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:25:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8F5B9B48-1138-4DBF-A9AC-B36F0A557EB4)', Time: '2020-08-02T17:50:22', User OID: 'PatientReportedOutcome (US3142034)', ODM File OID: '92afef6a-6023-45f9-b1e9-c92ae07fd35e' User entered 'None (0)'	System	02 Aug 2020 23:50:38
	System	02 Aug 2020 23:50:38

US3142034

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 11 Aug 2021 21:58:56

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:25:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8F5B9B48-1138-4DBF-A9AC-B36F0A557EB4)', Time: '2020-08-02T17:50:25', User OID: 'PatientReportedOutcome (US3142034)', ODM File OID: '92afef6a-6023-45f9-b1e9-c92ae07fd35e' User entered 'None (0)'	System	02 Aug 2020 23:50:38
	System	02 Aug 2020 23:50:38

US3142034

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 11 Aug 2021 21:58:56

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)	05 Mar 2021 01:25:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8F5B9B48-1138-4DBF-A9AC-B36F0A557EB4)', Time: '2020-08-02T17:50:28', User OID: 'PatientReportedOutcome (US3142034)', ODM File OID: '92afef6a-6023-45f9-b1e9-c92ae07fd35e' User entered 'No (N)'	System	02 Aug 2020 23:50:38
	System	02 Aug 2020 23:50:38

US3142034

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 11 Aug 2021 21:58:56

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:25:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8F5B9B48-1138-4DBF-A9AC-B36F0A557EB4)', Time: '2020-08-02T17:50:36', User OID: 'PatientReportedOutcome (US3142034)', ODM File OID: '92afef6a-6023-45f9-b1e9-c92ae07fd35e' User entered '02 Aug 2020 17:50'	System	02 Aug 2020 23:50:38
	System	02 Aug 2020 23:50:38

US3142034

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 11 Aug 2021 21:58:56

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:25:25
User entered '02 Aug 2020 12:00'	System	31 Jul 2020 20:02:05

US3142034

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 11 Aug 2021 21:58:56

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:25:25
User entered '03 Aug 2020 11:59'	System	31 Jul 2020 20:02:05

US3142034

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 11 Aug 2021 21:58:56

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:25:25
Data entry locked.	System	31 Jul 2020 20:02:05
User entered 'Day 4'	System	31 Jul 2020 20:02:05

US3142034

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 11 Aug 2021 21:58:56

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:25:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8F5B9B48-1138-4DBF-A9AC-B36F0A557EB4)', Time: '2020-08-03T19:27:48', User OID: 'PatientReportedOutcome (US3142034)', ODM File OID: 'e1a950cd-256d-48b1-b213-5eedb4376881' User entered 'None (0)'	System	04 Aug 2020 01:28:19
	System	04 Aug 2020 01:28:19

US3142034

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 11 Aug 2021 21:58:56

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:25:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8F5B9B48-1138-4DBF-A9AC-B36F0A557EB4)', Time: '2020-08-03T19:27:50', User OID: 'PatientReportedOutcome (US3142034)', ODM File OID: 'e1a950cd-256d-48b1-b213-5eedb4376881' User entered 'None (0)'	System	04 Aug 2020 01:28:19
	System	04 Aug 2020 01:28:19

US3142034

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 11 Aug 2021 21:58:56

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:25:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8F5B9B48-1138-4DBF-A9AC-B36F0A557EB4)', Time: '2020-08-03T19:27:53', User OID: 'PatientReportedOutcome (US3142034)', ODM File OID: 'e1a950cd-256d-48b1-b213-5eedb4376881' User entered 'None (0)'	System	04 Aug 2020 01:28:19
	System	04 Aug 2020 01:28:19

US3142034

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 11 Aug 2021 21:58:56

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:25:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8F5B9B48-1138-4DBF-A9AC-B36F0A557EB4)', Time: '2020-08-03T19:27:55', User OID: 'PatientReportedOutcome (US3142034)', ODM File OID: 'e1a950cd-256d-48b1-b213-5eedb4376881' User entered 'None (0)'	System	04 Aug 2020 01:28:19
	System	04 Aug 2020 01:28:19

US3142034

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 11 Aug 2021 21:58:56

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:25:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8F5B9B48-1138-4DBF-A9AC-B36F0A557EB4)', Time: '2020-08-03T19:28:12', User OID: 'PatientReportedOutcome (US3142034)', ODM File OID: 'e1a950cd-256d-48b1-b213-5eedb4376881' User entered 'None (0)'	System	04 Aug 2020 01:28:19
	System	04 Aug 2020 01:28:19

US3142034

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 11 Aug 2021 21:58:56

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:25:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8F5B9B48-1138-4DBF-A9AC-B36F0A557EB4)', Time: '2020-08-03T19:28:00', User OID: 'PatientReportedOutcome (US3142034)', ODM File OID: 'e1a950cd-256d-48b1-b213-5eedb4376881' User entered 'None (0)'	System	04 Aug 2020 01:28:19
	System	04 Aug 2020 01:28:19

US3142034

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 11 Aug 2021 21:58:56

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)	05 Mar 2021 01:25:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8F5B9B48-1138-4DBF-A9AC-B36F0A557EB4)', Time: '2020-08-03T19:28:03', User OID: 'PatientReportedOutcome (US3142034)', ODM File OID: 'e1a950cd-256d-48b1-b213-5eedb4376881' User entered 'No (N)'	System	04 Aug 2020 01:28:19
	System	04 Aug 2020 01:28:19

US3142034

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 11 Aug 2021 21:58:56

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:25:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8F5B9B48-1138-4DBF-A9AC-B36F0A557EB4)', Time: '2020-08-03T19:28:18', User OID: 'PatientReportedOutcome (US3142034)', ODM File OID: 'e1a950cd-256d-48b1-b213-5eedb4376881' User entered '03 Aug 2020 19:28'	System	04 Aug 2020 01:28:19
	System	04 Aug 2020 01:28:19

US3142034

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 11 Aug 2021 21:58:56

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:25:25
User entered '03 Aug 2020 12:00'	System	31 Jul 2020 20:02:05

US3142034

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 11 Aug 2021 21:58:56

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:25:25
User entered '04 Aug 2020 11:59'	System	31 Jul 2020 20:02:05

US3142034

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 11 Aug 2021 21:58:56

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:25:25
Data entry locked.	System	31 Jul 2020 20:02:05
User entered 'Day 5'	System	31 Jul 2020 20:02:05

US3142034

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 11 Aug 2021 21:58:56

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:25:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8F5B9B48-1138-4DBF-A9AC-B36F0A557EB4)', Time: '2020-08-04T20:15:55', User OID: 'PatientReportedOutcome (US3142034)', ODM File OID: '9077970f-e5cc-4231-a1e6-f9fed7edc349' User entered 'None (0)'	System	05 Aug 2020 02:16:25
	System	05 Aug 2020 02:16:25

US3142034

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 11 Aug 2021 21:58:56

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:25:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8F5B9B48-1138-4DBF-A9AC-B36F0A557EB4)', Time: '2020-08-04T20:15:57', User OID: 'PatientReportedOutcome (US3142034)', ODM File OID: '9077970f-e5cc-4231-a1e6-f9fed7edc349' User entered 'None (0)'	System	05 Aug 2020 02:16:25
	System	05 Aug 2020 02:16:25

US3142034

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 11 Aug 2021 21:58:56

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:25:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8F5B9B48-1138-4DBF-A9AC-B36F0A557EB4)', Time: '2020-08-04T20:16:00', User OID: 'PatientReportedOutcome (US3142034)', ODM File OID: '9077970f-e5cc-4231-a1e6-f9fed7edc349' User entered 'None (0)'	System	05 Aug 2020 02:16:25
	System	05 Aug 2020 02:16:25

US3142034

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 11 Aug 2021 21:58:56

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:25:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8F5B9B48-1138-4DBF-A9AC-B36F0A557EB4)', Time: '2020-08-04T20:16:03', User OID: 'PatientReportedOutcome (US3142034)', ODM File OID: '9077970f-e5cc-4231-a1e6-f9fed7edc349' User entered 'None (0)'	System	05 Aug 2020 02:16:25
	System	05 Aug 2020 02:16:25

US3142034

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 11 Aug 2021 21:58:56

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:25:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8F5B9B48-1138-4DBF-A9AC-B36F0A557EB4)', Time: '2020-08-04T20:16:06', User OID: 'PatientReportedOutcome (US3142034)', ODM File OID: '9077970f-e5cc-4231-a1e6-f9fed7edc349' User entered 'None (0)'	System	05 Aug 2020 02:16:25
	System	05 Aug 2020 02:16:25

US3142034

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 11 Aug 2021 21:58:56

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:25:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8F5B9B48-1138-4DBF-A9AC-B36F0A557EB4)', Time: '2020-08-04T20:16:08', User OID: 'PatientReportedOutcome (US3142034)', ODM File OID: '9077970f-e5cc-4231-a1e6-f9fed7edc349' User entered 'None (0)'	System	05 Aug 2020 02:16:25
	System	05 Aug 2020 02:16:25

US3142034

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 11 Aug 2021 21:58:56

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)	05 Mar 2021 01:25:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8F5B9B48-1138-4DBF-A9AC-B36F0A557EB4)', Time: '2020-08-04T20:16:11', User OID: 'PatientReportedOutcome (US3142034)', ODM File OID: '9077970f-e5cc-4231-a1e6-f9fed7edc349'	System	05 Aug 2020 02:16:25
User entered 'No (N)'	System	05 Aug 2020 02:16:25

US3142034

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 11 Aug 2021 21:58:56

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:25:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8F5B9B48-1138-4DBF-A9AC-B36F0A557EB4)', Time: '2020-08-04T20:16:21', User OID: 'PatientReportedOutcome (US3142034)', ODM File OID: '9077970f-e5cc-4231-a1e6-f9fed7edc349'	System	05 Aug 2020 02:16:25
User entered '04 Aug 2020 20:16'	System	05 Aug 2020 02:16:25

US3142034

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 11 Aug 2021 21:58:56

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:25:25
User entered '04 Aug 2020 12:00'	System	31 Jul 2020 20:02:05

US3142034

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 11 Aug 2021 21:58:56

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:25:25
User entered '05 Aug 2020 11:59'	System	31 Jul 2020 20:02:05

US3142034

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 11 Aug 2021 21:58:56

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:25:25
Data entry locked.	System	31 Jul 2020 20:02:05
User entered 'Day 6'	System	31 Jul 2020 20:02:05

US3142034

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 11 Aug 2021 21:58:56

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:25:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8F5B9B48-1138-4DBF-A9AC-B36F0A557EB4)', Time: '2020-08-05T16:50:45', User OID: 'PatientReportedOutcome (US3142034)', ODM File OID: '98e25be5-21d2-408b-bee3-cf16fac71e30' User entered 'None (0)'	System	05 Aug 2020 22:51:12
	System	05 Aug 2020 22:51:12

US3142034

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 11 Aug 2021 21:58:56

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:25:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8F5B9B48-1138-4DBF-A9AC-B36F0A557EB4)', Time: '2020-08-05T16:50:48', User OID: 'PatientReportedOutcome (US3142034)', ODM File OID: '98e25be5-21d2-408b-bee3-cf16fac71e30' User entered 'None (0)'	System	05 Aug 2020 22:51:12
	System	05 Aug 2020 22:51:12

US3142034

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 11 Aug 2021 21:58:56

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:25:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8F5B9B48-1138-4DBF-A9AC-B36F0A557EB4)', Time: '2020-08-05T16:50:50', User OID: 'PatientReportedOutcome (US3142034)', ODM File OID: '98e25be5-21d2-408b-bee3-cf16fac71e30' User entered 'None (0)'	System	05 Aug 2020 22:51:12
	System	05 Aug 2020 22:51:12

US3142034

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 11 Aug 2021 21:58:56

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:25:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8F5B9B48-1138-4DBF-A9AC-B36F0A557EB4)', Time: '2020-08-05T16:50:53', User OID: 'PatientReportedOutcome (US3142034)', ODM File OID: '98e25be5-21d2-408b-bee3-cf16fac71e30' User entered 'None (0)'	System	05 Aug 2020 22:51:12
	System	05 Aug 2020 22:51:12

US3142034

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 11 Aug 2021 21:58:56

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:25:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8F5B9B48-1138-4DBF-A9AC-B36F0A557EB4)', Time: '2020-08-05T16:50:55', User OID: 'PatientReportedOutcome (US3142034)', ODM File OID: '98e25be5-21d2-408b-bee3-cf16fac71e30' User entered 'None (0)'	System	05 Aug 2020 22:51:12
	System	05 Aug 2020 22:51:12

US3142034

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 11 Aug 2021 21:58:56

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:25:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8F5B9B48-1138-4DBF-A9AC-B36F0A557EB4)', Time: '2020-08-05T16:50:57', User OID: 'PatientReportedOutcome (US3142034)', ODM File OID: '98e25be5-21d2-408b-bee3-cf16fac71e30' User entered 'None (0)'	System	05 Aug 2020 22:51:12
	System	05 Aug 2020 22:51:12

US3142034

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 11 Aug 2021 21:58:56

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)	05 Mar 2021 01:25:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8F5B9B48-1138-4DBF-A9AC-B36F0A557EB4)', Time: '2020-08-05T16:51:00', User OID: 'PatientReportedOutcome (US3142034)', ODM File OID: '98e25be5-21d2-408b-bee3-cf16fac71e30'	System	05 Aug 2020 22:51:12
User entered 'No (N)'	System	05 Aug 2020 22:51:12

US3142034

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 11 Aug 2021 21:58:56

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:25:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8F5B9B48-1138-4DBF-A9AC-B36F0A557EB4)', Time: '2020-08-05T16:51:08', User OID: 'PatientReportedOutcome (US3142034)', ODM File OID: '98e25be5-21d2-408b-bee3-cf16fac71e30' User entered '05 Aug 2020 16:51'	System	05 Aug 2020 22:51:12
	System	05 Aug 2020 22:51:12

US3142034

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 11 Aug 2021 21:58:56

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:25:25
User entered '05 Aug 2020 12:00'	System	31 Jul 2020 20:02:05

US3142034

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 11 Aug 2021 21:58:56

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:25:25
User entered '06 Aug 2020 11:59'	System	31 Jul 2020 20:02:05

US3142034

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 11 Aug 2021 21:58:56

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:25:25
Data entry locked.	System	31 Jul 2020 20:02:05
User entered 'Day 7'	System	31 Jul 2020 20:02:05

US3142034

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 11 Aug 2021 21:58:56

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:25:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8F5B9B48-1138-4DBF-A9AC-B36F0A557EB4)', Time: '2020-08-06T18:36:21', User OID: 'PatientReportedOutcome (US3142034)', ODM File OID: '9c3e6342-be33-4985-b673-09648af249cc' User entered 'None (0)'	System	07 Aug 2020 00:36:59
	System	07 Aug 2020 00:36:59

US3142034

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 11 Aug 2021 21:58:56

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:25:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8F5B9B48-1138-4DBF-A9AC-B36F0A557EB4)', Time: '2020-08-06T18:36:24', User OID: 'PatientReportedOutcome (US3142034)', ODM File OID: '9c3e6342-be33-4985-b673-09648af249cc' User entered 'None (0)'	System	07 Aug 2020 00:36:59
	System	07 Aug 2020 00:36:59

US3142034

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 11 Aug 2021 21:58:56

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:25:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8F5B9B48-1138-4DBF-A9AC-B36F0A557EB4)', Time: '2020-08-06T18:36:26', User OID: 'PatientReportedOutcome (US3142034)', ODM File OID: '9c3e6342-be33-4985-b673-09648af249cc' User entered 'None (0)'	System	07 Aug 2020 00:36:59
	System	07 Aug 2020 00:36:59

US3142034

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 11 Aug 2021 21:58:56

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:25:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8F5B9B48-1138-4DBF-A9AC-B36F0A557EB4)', Time: '2020-08-06T18:36:46', User OID: 'PatientReportedOutcome (US3142034)', ODM File OID: '9c3e6342-be33-4985-b673-09648af249cc' User entered 'None (0)'	System	07 Aug 2020 00:36:59
	System	07 Aug 2020 00:36:59

US3142034

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 11 Aug 2021 21:58:56

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:25:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8F5B9B48-1138-4DBF-A9AC-B36F0A557EB4)', Time: '2020-08-06T18:36:29', User OID: 'PatientReportedOutcome (US3142034)', ODM File OID: '9c3e6342-be33-4985-b673-09648af249cc' User entered 'None (0)'	System	07 Aug 2020 00:36:59
	System	07 Aug 2020 00:36:59

US3142034

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 11 Aug 2021 21:58:56

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:25:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8F5B9B48-1138-4DBF-A9AC-B36F0A557EB4)', Time: '2020-08-06T18:36:31', User OID: 'PatientReportedOutcome (US3142034)', ODM File OID: '9c3e6342-be33-4985-b673-09648af249cc' User entered 'None (0)'	System	07 Aug 2020 00:36:59
	System	07 Aug 2020 00:36:59

US3142034

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 11 Aug 2021 21:58:56

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)	05 Mar 2021 01:25:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8F5B9B48-1138-4DBF-A9AC-B36F0A557EB4)', Time: '2020-08-06T18:36:36', User OID: 'PatientReportedOutcome (US3142034)', ODM File OID: '9c3e6342-be33-4985-b673-09648af249cc' User entered 'No (N)'	System	07 Aug 2020 00:36:59
	System	07 Aug 2020 00:36:59

US3142034

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 11 Aug 2021 21:58:56

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:25:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8F5B9B48-1138-4DBF-A9AC-B36F0A557EB4)', Time: '2020-08-06T18:36:54', User OID: 'PatientReportedOutcome (US3142034)', ODM File OID: '9c3e6342-be33-4985-b673-09648af249cc' User entered '06 Aug 2020 18:36'	System	07 Aug 2020 00:36:59
	System	07 Aug 2020 00:36:59

US3142034

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 11 Aug 2021 21:58:56

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:25:25
User entered '06 Aug 2020 12:00'	System	31 Jul 2020 20:02:05

US3142034

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 11 Aug 2021 21:58:56

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:25:25
User entered '07 Aug 2020 11:59'	System	31 Jul 2020 20:02:05

US3142034

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 11 Aug 2021 21:58:56

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 06:09:24
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 19:03:50
User entered 'Yes (Y)'	Dalia Jeronimo (b) (4) (b) (4)	20 Aug 2020 19:59:09

US3142034

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 11 Aug 2021 21:58:56

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 06:09:24
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 19:03:50
User entered '9 Aug 2020'	Dalia Jeronimo (b) (4) (b) (4)	20 Aug 2020 19:59:09

US3142034

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 11 Aug 2021 21:58:56

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 06:09:24
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 19:03:50
User entered 'Contact Made (CONTACT MADE)'	Dalia Jeronimo (b) (4) (b) (4)	20 Aug 2020 19:59:09

US3142034

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 11 Aug 2021 21:58:56

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 06:09:24
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 19:03:50
User entered empty.	Dalia Jeronimo (b) (4) (b) (4)	20 Aug 2020 19:59:09

US3142034

Folder: Safety Call Day 8 (1)

Form: Continuing

Generated On: 11 Aug 2021 21:58:56

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 06:09:24
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 19:03:50
User entered 'Yes (Y)'	Dalia Jeronimo (b) (4) (b) (4)	20 Aug 2020 19:58:40

US3142034

Folder: Safety Call Day 8 (1)

Form: Continuing

Generated On: 11 Aug 2021 21:58:56

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 06:09:24
User entered '1'	System	20 Aug 2020 19:58:40

US3142034

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 11 Aug 2021 21:58:56

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 06:09:24
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 19:03:50
User entered 'Yes (Y)'	Dalia Jeronimo (b) (4) (b) (4)	24 Aug 2020 15:11:43

US3142034

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 11 Aug 2021 21:58:56

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 06:09:24
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 19:03:50
User closed query 'Safety Call Day 15 'Date of Contact or Contact Attempt' is less than 14 days or greater than 17 days after Visit 1 Treatment Date on the Exposure Form. Please review and reconcile, or clarify.' (Site from System).	(b) (4), (b) (6)	05 Oct 2020 15:39:08
Query 'Safety Call Day 15 'Date of Contact or Contact Attempt' is less than 14 days or greater than 17 days after Visit 1 Treatment Date on the Exposure Form. Please review and reconcile, or clarify.' answered with 'information is correct' (Site from System).	Meghan York (b) (4) (b) (4)	01 Oct 2020 15:13:04
User opened query 'Safety Call Day 15 'Date of Contact or Contact Attempt' is less than 14 days or greater than 17 days after Visit 1 Treatment Date on the Exposure Form. Please review and reconcile, or clarify.' (Site from System).	System	24 Aug 2020 15:11:43
User entered '18 Aug 2020'	Dalia Jeronimo (b) (4) (b) (4)	24 Aug 2020 15:11:43

US3142034

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 11 Aug 2021 21:58:56

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 06:09:24
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 19:03:50
User entered 'Contact Made (CONTACT MADE)'	Dalia Jeronimo (b) (4) (b) (4)	24 Aug 2020 15:11:43

US3142034

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 11 Aug 2021 21:58:56

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 06:09:24
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 19:03:50
User entered empty.	Dalia Jeronimo (b) (4) (b) (4)	24 Aug 2020 15:11:43

US3142034

Folder: Safety Call Day 15 (1)

Form: Continuing

Generated On: 11 Aug 2021 21:58:56

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 06:09:24
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 19:03:50
User entered 'Yes (Y)'	Dalia Jeronimo (b) (4) (b) (4)	24 Aug 2020 15:11:52

US3142034

Folder: Safety Call Day 15 (1)

Form: Continuing

Generated On: 11 Aug 2021 21:58:56

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 06:09:24
User entered 'I'	System	24 Aug 2020 15:11:52

US3142034

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 11 Aug 2021 21:58:56

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 06:09:24
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 19:03:50
User entered 'Yes (Y)'	Jami Wagner (b) (4) (b) (4)	31 Aug 2020 02:26:28

US3142034

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 11 Aug 2021 21:58:56

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 06:09:24
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:03:50
User entered '24 Aug 2020'	Jami Wagner (b) (4)	31 Aug 2020 02:26:28

US3142034

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 11 Aug 2021 21:58:56

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 06:09:24
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 19:03:50
User entered 'Contact Made (CONTACT MADE)'	Jami Wagner (b) (4) (b) (4)	31 Aug 2020 02:26:28

US3142034

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 11 Aug 2021 21:58:56

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 06:09:24
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 19:03:50
User entered empty.	Jami Wagner (b) (4) (b) (4)	31 Aug 2020 02:26:28

US3142034

Folder: Safety Call Day 22 (1)

Form: Continuing

Generated On: 11 Aug 2021 21:58:56

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 06:09:24
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 19:03:50
User entered 'Yes (Y)'	Shelby Pickle (b) (4) (b) (4)	27 Aug 2020 21:06:00

US3142034

Folder: Safety Call Day 22 (1)

Form: Continuing

Generated On: 11 Aug 2021 21:58:56

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 06:09:24
User entered '1'	System	27 Aug 2020 21:06:00

US3142034

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 11 Aug 2021 21:58:56

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 06:09:24
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 19:03:50
User entered 'Yes (Y)'	Shelby Pickle (b) (4) (b) (4)	28 Aug 2020 00:31:11

US3142034

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 11 Aug 2021 21:58:56

Visit date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 06:09:24
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:03:50
User closed query 'Visit 2 Date is < 28 days or > 35 days after Visit 1 vaccination. Please reconcile or confirm dates.' (Site from System).	(b) (4) (b) (4), (b) (6)	31 Aug 2020 12:51:07
Query 'Visit 2 Date is < 28 days or > 35 days after Visit 1 vaccination. Please reconcile or confirm dates.' answered with 'Information provided is correct' (Site from System).	Shelby Pickle (b) (4) (b) (4)	28 Aug 2020 00:31:19
User opened query 'Visit 2 Date is < 28 days or > 35 days after Visit 1 vaccination. Please reconcile or confirm dates.' (Site from System).	System	28 Aug 2020 00:31:11
User entered '27 Aug 2020'	Shelby Pickle (b) (4) (b) (4)	28 Aug 2020 00:31:11

US3142034

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 11 Aug 2021 21:58:56

[Was visit performed at the participant's home or at the clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 06:09:24
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 19:03:50
User entered 'Clinic (Clinic)'	Shelby Pickle (b) (4) (b) (4)	28 Aug 2020 00:31:11

US3142034

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 11 Aug 2021 21:58:56

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 06:09:24
User entered 'VISIT2'	System	28 Aug 2020 00:31:11

US3142034

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 21:58:56

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 06:09:24
User accepted default value 'Pre-Dose (PREDOSE)'	Shelby Pickle (b) (4) (b) (4)	28 Aug 2020 00:32:55

US3142034

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 21:58:56

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 06:09:24
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 19:03:50
User entered 'Yes (Y)'	Shelby Pickle (b) (4) (b) (4)	28 Aug 2020 00:32:55

US3142034

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 21:58:56

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 06:09:24
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 19:03:50
User entered '27 Aug 2020'	Shelby Pickle (b) (4) (b) (4)	28 Aug 2020 00:32:55

US3142034

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 21:58:56

Time of assessment (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 06:09:24
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 19:03:50
User entered '14:10'	Shelby Pickle (b) (4) (b) (4)	28 Aug 2020 00:32:55

US3142034

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 21:58:56

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 06:09:24
User entered '27 Aug 2020 14:10'	System	28 Aug 2020 00:32:55

US3142034

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 21:58:56

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 06:09:24
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 19:03:50
User entered '97.1' F	Shelby Pickle (b) (4) (b) (4)	28 Aug 2020 00:32:55

US3142034

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 21:58:56

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 06:09:24
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 19:03:50
User entered 'Other (Other)'	Shelby Pickle (b) (4) (b) (4)	28 Aug 2020 00:32:55

US3142034

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 21:58:56

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 06:09:24
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 19:03:50
User entered 'Temporal'	Shelby Pickle (b) (4) (b) (4)	28 Aug 2020 00:32:55

US3142034

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 21:58:56

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 06:09:24
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 19:03:50
User entered '67'	Shelby Pickle (b) (4) (b) (4)	28 Aug 2020 00:32:55

US3142034

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 21:58:56

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 06:09:24
User entered 'bpm'	System	28 Aug 2020 00:32:55

US3142034

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 21:58:56

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 06:09:24
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 19:03:50
User entered '14'	Shelby Pickle (b) (4) (b) (4)	28 Aug 2020 00:32:55

US3142034

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 21:58:56

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 06:09:24
User entered 'breaths/min'	System	28 Aug 2020 00:32:55

US3142034

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 21:58:56

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 06:09:24
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 19:03:50
User entered '100' reason for change: Data Entry Error	Meghan York (b) (4) (b) (4)	05 Oct 2020 15:56:09
User entered '141' reason for change: Data Entry Error	Meghan York (b) (4) (b) (4)	05 Oct 2020 15:55:08
User entered '100'	Shelby Pickle (b) (4) (b) (4)	28 Aug 2020 00:32:55

US3142034

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 21:58:56

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 06:09:24
User entered 'mmHg'	System	28 Aug 2020 00:32:55

US3142034

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 21:58:56

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 06:09:24
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 19:03:50
User entered '60' reason for change: Data Entry Error	Meghan York (b) (4) (b) (4)	05 Oct 2020 15:56:09
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).	System	05 Oct 2020 15:55:08
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 by data change (Site from System).	System	05 Oct 2020 15:55:08
User entered '84' reason for change: Data Entry Error	Meghan York (b) (4) (b) (4)	05 Oct 2020 15:55:08
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	16 Sep 2020 23:39:48
User entered '58'	Shelby Pickle (b) (4) (b) (4)	28 Aug 2020 00:32:55

US3142034

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 21:58:56

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 06:09:24
User entered 'mmHg'	System	28 Aug 2020 00:32:55

US3142034

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 21:58:56

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 06:09:24
User accepted default value 'Post-Dose (POSTDOSE)'	Shelby Pickle (b) (4) (b) (4)	28 Aug 2020 00:32:55

US3142034

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 21:58:56

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 06:09:24
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 19:03:50
User entered 'Yes (Y)'	Shelby Pickle (b) (4) (b) (4)	28 Aug 2020 00:32:55

US3142034

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 21:58:56

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 06:09:24
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 19:03:50
User entered '27 Aug 2020'	Shelby Pickle (b) (4) (b) (4)	28 Aug 2020 00:32:55

US3142034

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 21:58:56

Time of assessment (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 06:09:24
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 19:03:50
User entered '15:25'	Shelby Pickle (b) (4) (b) (4)	28 Aug 2020 00:32:55

US3142034

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 21:58:56

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 06:09:24
User entered '27 Aug 2020 15:25'	System	28 Aug 2020 00:32:55

US3142034

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 21:58:56

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 06:09:24
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 19:03:50
User entered '97.5' F	Shelby Pickle (b) (4) (b) (4)	28 Aug 2020 00:32:55

US3142034

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 21:58:56

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 06:09:24
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 19:03:50
User entered 'Other (Other)'	Shelby Pickle (b) (4) (b) (4)	28 Aug 2020 00:32:55

US3142034

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 21:58:56

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 06:09:24
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 19:03:50
User entered 'Temporal'	Shelby Pickle (b) (4) (b) (4)	28 Aug 2020 00:32:55

US3142034

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 21:58:56

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 06:09:24
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 19:03:50
User entered '61'	Shelby Pickle (b) (4) (b) (4)	28 Aug 2020 00:32:55

US3142034

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 21:58:56

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 06:09:24
User entered 'bpm'	System	28 Aug 2020 00:32:55

US3142034

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 21:58:56

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 06:09:24
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 19:03:50
User entered '12'	Shelby Pickle (b) (4) (b) (4)	28 Aug 2020 00:32:55

US3142034

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 21:58:56

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 06:09:24
User entered 'breaths/min'	System	28 Aug 2020 00:32:55

US3142034

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 21:58:56

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 06:09:24
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 19:03:50
User entered '132'	Shelby Pickle (b) (4) (b) (4)	28 Aug 2020 00:32:55

US3142034

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 21:58:56

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 06:09:24
User entered 'mmHg'	System	28 Aug 2020 00:32:55

US3142034

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 21:58:56

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 06:09:24
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 19:03:50
User entered '72'	Shelby Pickle (b) (4) (b) (4)	28 Aug 2020 00:32:55

US3142034

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 21:58:56

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 06:09:24
User entered 'mmHg'	System	28 Aug 2020 00:32:55

US3142034

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Generated On: 11 Aug 2021 21:58:56

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 06:09:24
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 19:03:50
User entered 'Yes (Y)'	Shelby Pickle (b) (4) (b) (4)	28 Aug 2020 00:33:31

US3142034

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Generated On: 11 Aug 2021 21:58:56

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 06:09:24
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 19:03:50
User entered '27 Aug 2020'	Shelby Pickle (b) (4) (b) (4)	28 Aug 2020 00:33:31

US3142034

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 11 Aug 2021 21:58:56

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 06:09:24
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 19:03:50
User entered 'Yes (Y)'	Shelby Pickle (b) (4) (b) (4)	27 Aug 2020 21:06:21

US3142034

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 11 Aug 2021 21:58:56

If No, reason not given

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 06:09:24
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 19:03:50
User entered empty.	Shelby Pickle (b) (4) (b) (4)	27 Aug 2020 21:06:21

US3142034

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 11 Aug 2021 21:58:56

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)	24 Apr 2021 06:09:24
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 19:03:50
User entered empty.	Shelby Pickle (b) (4) (b) (4)	27 Aug 2020 21:06:21

US3142034

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 11 Aug 2021 21:58:56

[What was the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 06:09:24
User entered 'MRNA-1273 OR PLACEBO'	System	27 Aug 2020 21:06:21

US3142034

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 11 Aug 2021 21:58:56

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 06:09:24
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 19:03:50
User entered '27 Aug 2020'	Shelby Pickle (b) (4) (b) (4)	27 Aug 2020 21:06:21

US3142034

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 11 Aug 2021 21:58:56

[What was the treatment time? \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 06:09:24
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 19:03:50
User entered '14:55'	Shelby Pickle (b) (4) (b) (4)	27 Aug 2020 21:06:21

US3142034

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 11 Aug 2021 21:58:56

[Treatment Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 06:09:24
User entered '27 Aug 2020 14:55'	System	27 Aug 2020 21:06:21

US3142034

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 11 Aug 2021 21:58:56

[Which arm was used to give treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 06:09:24
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 19:03:50
User entered 'Left Arm (LEFT ARM)'	Shelby Pickle (b) (4) (b) (4)	27 Aug 2020 21:06:21

US3142034

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 11 Aug 2021 21:58:56

[What was the frequency of the study treatment dosing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 06:09:24
User entered 'ONCE'	System	27 Aug 2020 21:06:21

US3142034

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 11 Aug 2021 21:58:56

[What was the route of administration for the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 06:09:24
User entered 'INTRAMUSCULAR'	System	27 Aug 2020 21:06:21

US3142034

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 21:58:56

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 06:09:24
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 19:03:50
User entered 'Yes (Y)'	Shelby Pickle (b) (4) (b) (4)	28 Aug 2020 00:33:51

US3142034

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 21:58:56

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 06:09:24
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 19:03:50
User entered '27 Aug 2020'	Shelby Pickle (b) (4) (b) (4)	28 Aug 2020 00:33:51

US3142034

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 21:58:56

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 06:09:24
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 19:03:50
User entered '14:24'	Shelby Pickle (b) (4) (b) (4)	28 Aug 2020 00:33:51

US3142034

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 21:58:56

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 06:09:24
User entered '27 Aug 2020 14:24'	System	28 Aug 2020 00:33:51

US3142034

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 11 Aug 2021 21:58:56

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 06:09:24
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:03:50
User entered '27 Aug 2020'	(b) (4) Shelby Pickle (b) (4)	28 Aug 2020 00:34:07

US3142034

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 11 Aug 2021 21:58:56

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 06:09:24
User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)'	Shelby Pickle (b) (4) (b) (4)	28 Aug 2020 00:34:07

US3142034

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 11 Aug 2021 21:58:56

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 06:09:24
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 19:03:50
User entered 'Yes (Y)'	Shelby Pickle (b) (4) (b) (4)	28 Aug 2020 00:34:07

US3142034

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 11 Aug 2021 21:58:56

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 06:09:24
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 19:03:50
User entered '14:19'	Shelby Pickle (b) (4) (b) (4)	28 Aug 2020 00:34:07

US3142034

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 11 Aug 2021 21:58:56

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 06:09:24
User entered '27 Aug 2020 14:19'	System	28 Aug 2020 00:34:07

US3142034

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 11 Aug 2021 21:58:56

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 06:09:24
User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)'	Shelby Pickle (b) (4) (b) (4)	28 Aug 2020 00:34:07

US3142034

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 11 Aug 2021 21:58:56

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 06:09:24
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 19:03:50
User entered 'Yes (Y)'	Shelby Pickle (b) (4) (b) (4)	28 Aug 2020 00:34:07

US3142034

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 11 Aug 2021 21:58:56

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 06:09:24
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 19:03:50
User entered '14:19'	Shelby Pickle (b) (4) (b) (4)	28 Aug 2020 00:34:07

US3142034

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 11 Aug 2021 21:58:56

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 06:09:24
User entered '27 Aug 2020 14:19'	System	28 Aug 2020 00:34:07

US3142034

Folder: Visit 2 Day 29 (1)

Form: Continuing

Generated On: 11 Aug 2021 21:58:56

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 06:09:24
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 19:03:50
User entered 'Yes (Y)'	Shelby Pickle (b) (4) (b) (4)	28 Aug 2020 00:34:13

US3142034

Folder: Visit 2 Day 29 (1)

Form: Continuing

Generated On: 11 Aug 2021 21:58:56

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 06:09:24
User entered '1'	System	28 Aug 2020 00:34:13

US3142034

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 11 Aug 2021 21:58:56

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:25:25
Data entry locked.	System	27 Aug 2020 21:06:21
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	27 Aug 2020 21:06:21

US3142034

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 11 Aug 2021 21:58:56

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:25:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8F5B9B48-1138-4DBF-A9AC-B36F0A557EB4)', Time: '2020-08-27T15:21:41', User OID: 'PatientReportedOutcome (US3142034)', ODM File OID: 'ec722b1d-98fc-4f82-a672-34a8f052482b' User entered 'Yes (Y)'	System	27 Aug 2020 21:22:05
	System	27 Aug 2020 21:22:05

US3142034

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 11 Aug 2021 21:58:56

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:25:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8F5B9B48-1138-4DBF-A9AC-B36F0A557EB4)', Time: '2020-08-27T15:21:49', User OID: 'PatientReportedOutcome (US3142034)', ODM File OID: 'ec722b1d-98fc-4f82-a672-34a8f052482b' User entered '97.5'	System	27 Aug 2020 21:22:05
	System	27 Aug 2020 21:22:05

US3142034

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 11 Aug 2021 21:58:56

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:25:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8F5B9B48-1138-4DBF-A9AC-B36F0A557EB4)', Time: '2020-08-27T15:21:56', User OID: 'PatientReportedOutcome (US3142034)', ODM File OID: 'ec722b1d-98fc-4f82-a672-34a8f052482b' User entered 'No (N)'	System	27 Aug 2020 21:22:05
	System	27 Aug 2020 21:22:05

US3142034

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 11 Aug 2021 21:58:56

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:25:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8F5B9B48-1138-4DBF-A9AC-B36F0A557EB4)', Time: '2020-08-27T15:22:02', User OID: 'PatientReportedOutcome (US3142034)', ODM File OID: 'ec722b1d-98fc-4f82-a672-34a8f052482b' User entered '27 Aug 2020 15:22'	System	27 Aug 2020 21:22:05
	System	27 Aug 2020 21:22:05

US3142034

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 11 Aug 2021 21:58:56

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:25:25
User entered '27 Aug 2020 15:15'	System	27 Aug 2020 21:06:21

US3142034

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 11 Aug 2021 21:58:56

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:25:25
User entered '27 Aug 2020 17:45'	System	27 Aug 2020 21:06:21

US3142034

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 11 Aug 2021 21:58:56

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:25:25
Data entry locked.	System	27 Aug 2020 21:06:21
User entered 'Day 1, after vaccination (at home)'	System	27 Aug 2020 21:06:21

US3142034

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 11 Aug 2021 21:58:56

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:25:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8F5B9B48-1138-4DBF-A9AC-B36F0A557EB4)', Time: '2020-08-27T19:39:07', User OID: 'PatientReportedOutcome (US3142034)', ODM File OID: 'a59f794e-c91f-42c9-b1de-e709f8fd8e09'	System	28 Aug 2020 01:39:29
User entered 'Yes (Y)'	System	28 Aug 2020 01:39:29

US3142034

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 11 Aug 2021 21:58:56

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:25:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8F5B9B48-1138-4DBF-A9AC-B36F0A557EB4)', Time: '2020-08-27T19:39:15', User OID: 'PatientReportedOutcome (US3142034)', ODM File OID: 'a59f794e-c91f-42c9-b1de-e709f8fd8e09' User entered '97.6'	System	28 Aug 2020 01:39:29
	System	28 Aug 2020 01:39:29

US3142034

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 11 Aug 2021 21:58:56

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:25:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8F5B9B48-1138-4DBF-A9AC-B36F0A557EB4)', Time: '2020-08-27T19:39:19', User OID: 'PatientReportedOutcome (US3142034)', ODM File OID: 'a59f794e-c91f-42c9-b1de-e709f8fd8e09'	System	28 Aug 2020 01:39:29
User entered 'No (N)'	System	28 Aug 2020 01:39:29

US3142034

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 11 Aug 2021 21:58:56

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:25:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8F5B9B48-1138-4DBF-A9AC-B36F0A557EB4)', Time: '2020-08-27T19:39:24', User OID: 'PatientReportedOutcome (US3142034)', ODM File OID: 'a59f794e-c91f-42c9-b1de-e709f8fd8e09' User entered '27 Aug 2020 19:39'	System	28 Aug 2020 01:39:29
	System	28 Aug 2020 01:39:29

US3142034

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 11 Aug 2021 21:58:56

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:25:25
User entered '27 Aug 2020 18:40'	System	27 Aug 2020 21:06:21

US3142034

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 11 Aug 2021 21:58:56

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:25:25
User entered '28 Aug 2020 11:59'	System	27 Aug 2020 21:06:21

US3142034

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 11 Aug 2021 21:58:56

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:25:25
Data entry locked.	System	27 Aug 2020 21:06:21
User entered 'Day 2'	System	27 Aug 2020 21:06:21

US3142034

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 11 Aug 2021 21:58:56

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:25:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8F5B9B48-1138-4DBF-A9AC-B36F0A557EB4)', Time: '2020-08-28T16:29:33', User OID: 'PatientReportedOutcome (US3142034)', ODM File OID: 'cb047ef6-b4b7-4d49-bb75-14e2811181de' User entered 'Yes (Y)'	System	28 Aug 2020 22:29:58
	System	28 Aug 2020 22:29:58

US3142034

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 11 Aug 2021 21:58:56

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:25:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8F5B9B48-1138-4DBF-A9AC-B36F0A557EB4)', Time: '2020-08-28T16:29:47', User OID: 'PatientReportedOutcome (US3142034)', ODM File OID: 'cb047ef6-b4b7-4d49-bb75-14e2811181de' User entered '97.4'	System	28 Aug 2020 22:29:58
	System	28 Aug 2020 22:29:58

US3142034

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 11 Aug 2021 21:58:56

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:25:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8F5B9B48-1138-4DBF-A9AC-B36F0A557EB4)', Time: '2020-08-28T16:29:50', User OID: 'PatientReportedOutcome (US3142034)', ODM File OID: 'cb047ef6-b4b7-4d49-bb75-14e2811181de' User entered 'No (N)'	System	28 Aug 2020 22:29:58
	System	28 Aug 2020 22:29:58

US3142034

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 11 Aug 2021 21:58:56

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:25:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8F5B9B48-1138-4DBF-A9AC-B36F0A557EB4)', Time: '2020-08-28T16:29:55', User OID: 'PatientReportedOutcome (US3142034)', ODM File OID: 'cb047ef6-b4b7-4d49-bb75-14e2811181de' User entered '28 Aug 2020 16:29'	System	28 Aug 2020 22:29:58
	System	28 Aug 2020 22:29:58

US3142034

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 11 Aug 2021 21:58:56

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:25:25
User entered '28 Aug 2020 12:00'	System	27 Aug 2020 21:06:21

US3142034

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 11 Aug 2021 21:58:56

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:25:25
User entered '29 Aug 2020 11:59'	System	27 Aug 2020 21:06:21

US3142034

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 11 Aug 2021 21:58:56

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:25:25
Data entry locked.	System	27 Aug 2020 21:06:21
User entered 'Day 3'	System	27 Aug 2020 21:06:21

US3142034

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 11 Aug 2021 21:58:56

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:25:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8F5B9B48-1138-4DBF-A9AC-B36F0A557EB4)', Time: '2020-08-29T18:16:32', User OID: 'PatientReportedOutcome (US3142034)', ODM File OID: '305498af-bb6c-44cf-9918-a4b9e981660c' User entered 'Yes (Y)'	System	30 Aug 2020 00:16:56
	System	30 Aug 2020 00:16:56

US3142034

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 11 Aug 2021 21:58:56

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:25:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8F5B9B48-1138-4DBF-A9AC-B36F0A557EB4)', Time: '2020-08-29T18:16:40', User OID: 'PatientReportedOutcome (US3142034)', ODM File OID: '305498af-bb6c-44cf-9918-a4b9e981660c' User entered '97.0'	System	30 Aug 2020 00:16:56
	System	30 Aug 2020 00:16:56

US3142034

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 11 Aug 2021 21:58:56

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:25:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8F5B9B48-1138-4DBF-A9AC-B36F0A557EB4)', Time: '2020-08-29T18:16:45', User OID: 'PatientReportedOutcome (US3142034)', ODM File OID: '305498af-bb6c-44cf-9918-a4b9e981660c' User entered 'No (N)'	System	30 Aug 2020 00:16:56
	System	30 Aug 2020 00:16:56

US3142034

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 11 Aug 2021 21:58:56

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:25:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8F5B9B48-1138-4DBF-A9AC-B36F0A557EB4)', Time: '2020-08-29T18:16:52', User OID: 'PatientReportedOutcome (US3142034)', ODM File OID: '305498af-bb6c-44cf-9918-a4b9e981660c' User entered '29 Aug 2020 18:16'	System	30 Aug 2020 00:16:56
	System	30 Aug 2020 00:16:56

US3142034

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 11 Aug 2021 21:58:56

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:25:25
User entered '29 Aug 2020 12:00'	System	27 Aug 2020 21:06:21

US3142034

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 11 Aug 2021 21:58:56

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:25:25
User entered '30 Aug 2020 11:59'	System	27 Aug 2020 21:06:21

US3142034

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 11 Aug 2021 21:58:56

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:25:25
Data entry locked.	System	27 Aug 2020 21:06:21
User entered 'Day 4'	System	27 Aug 2020 21:06:21

US3142034

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 11 Aug 2021 21:58:56

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:25:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8F5B9B48-1138-4DBF-A9AC-B36F0A557EB4)', Time: '2020-08-30T16:50:31', User OID: 'PatientReportedOutcome (US3142034)', ODM File OID: '8fd04dd1-641a-46b4-a1cf-216c78b47486' User entered 'Yes (Y)'	System	30 Aug 2020 22:50:49
	System	30 Aug 2020 22:50:49

US3142034

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 11 Aug 2021 21:58:56

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:25:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8F5B9B48-1138-4DBF-A9AC-B36F0A557EB4)', Time: '2020-08-30T16:50:37', User OID: 'PatientReportedOutcome (US3142034)', ODM File OID: '8fd04dd1-641a-46b4-a1cf-216c78b47486' User entered '96.9'	System	30 Aug 2020 22:50:49
	System	30 Aug 2020 22:50:49

US3142034

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 11 Aug 2021 21:58:56

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:25:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8F5B9B48-1138-4DBF-A9AC-B36F0A557EB4)', Time: '2020-08-30T16:50:41', User OID: 'PatientReportedOutcome (US3142034)', ODM File OID: '8fd04dd1-641a-46b4-a1cf-216c78b47486'	System	30 Aug 2020 22:50:49
User entered 'No (N)'	System	30 Aug 2020 22:50:49

US3142034

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 11 Aug 2021 21:58:56

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:25:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8F5B9B48-1138-4DBF-A9AC-B36F0A557EB4)', Time: '2020-08-30T16:50:44', User OID: 'PatientReportedOutcome (US3142034)', ODM File OID: '8fd04dd1-641a-46b4-a1cf-216c78b47486'	System	30 Aug 2020 22:50:49
User entered '30 Aug 2020 16:50'	System	30 Aug 2020 22:50:49

US3142034

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 11 Aug 2021 21:58:56

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:25:25
User entered '30 Aug 2020 12:00'	System	27 Aug 2020 21:06:21

US3142034

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 11 Aug 2021 21:58:56

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:25:25
User entered '31 Aug 2020 11:59'	System	27 Aug 2020 21:06:21

US3142034

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 11 Aug 2021 21:58:56

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:25:25
Data entry locked.	System	27 Aug 2020 21:06:21
User entered 'Day 5'	System	27 Aug 2020 21:06:21

US3142034

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 11 Aug 2021 21:58:56

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:25:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8F5B9B48-1138-4DBF-A9AC-B36F0A557EB4)', Time: '2020-08-31T17:35:24', User OID: 'PatientReportedOutcome (US3142034)', ODM File OID: '4a3bd23f-22d2-48df-b02a-c792796a68b5' User entered 'Yes (Y)'	System	31 Aug 2020 23:35:52
	System	31 Aug 2020 23:35:52

US3142034

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 11 Aug 2021 21:58:56

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:25:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8F5B9B48-1138-4DBF-A9AC-B36F0A557EB4)', Time: '2020-08-31T17:35:34', User OID: 'PatientReportedOutcome (US3142034)', ODM File OID: '4a3bd23f-22d2-48df-b02a-c792796a68b5' User entered '96.9'	System	31 Aug 2020 23:35:52
	System	31 Aug 2020 23:35:52

US3142034

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 11 Aug 2021 21:58:56

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:25:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8F5B9B48-1138-4DBF-A9AC-B36F0A557EB4)', Time: '2020-08-31T17:35:38', User OID: 'PatientReportedOutcome (US3142034)', ODM File OID: '4a3bd23f-22d2-48df-b02a-c792796a68b5' User entered 'No (N)'	System	31 Aug 2020 23:35:52
	System	31 Aug 2020 23:35:52

US3142034

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 11 Aug 2021 21:58:56

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:25:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8F5B9B48-1138-4DBF-A9AC-B36F0A557EB4)', Time: '2020-08-31T17:35:46', User OID: 'PatientReportedOutcome (US3142034)', ODM File OID: '4a3bd23f-22d2-48df-b02a-c792796a68b5' User entered '31 Aug 2020 17:35'	System	31 Aug 2020 23:35:52
	System	31 Aug 2020 23:35:52

US3142034

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 11 Aug 2021 21:58:56

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:25:25
User entered '31 Aug 2020 12:00'	System	27 Aug 2020 21:06:21

US3142034

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 11 Aug 2021 21:58:56

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:25:25
User entered '01 Sep 2020 11:59'	System	27 Aug 2020 21:06:21

US3142034

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 11 Aug 2021 21:58:56

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:25:25
Data entry locked.	System	27 Aug 2020 21:06:21
User entered 'Day 6'	System	27 Aug 2020 21:06:21

US3142034

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 11 Aug 2021 21:58:56

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:25:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8F5B9B48-1138-4DBF-A9AC-B36F0A557EB4)', Time: '2020-09-01T17:20:15', User OID: 'PatientReportedOutcome (US3142034)', ODM File OID: 'e0a5eb42-5e57-4b6e-9da8-e72486f943c7' User entered 'Yes (Y)'	System	01 Sep 2020 23:20:29
	System	01 Sep 2020 23:20:29

US3142034

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 11 Aug 2021 21:58:56

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:25:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8F5B9B48-1138-4DBF-A9AC-B36F0A557EB4)', Time: '2020-09-01T17:20:20', User OID: 'PatientReportedOutcome (US3142034)', ODM File OID: 'e0a5eb42-5e57-4b6e-9da8-e72486f943c7' User entered '98.4'	System	01 Sep 2020 23:20:29
	System	01 Sep 2020 23:20:29

US3142034

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 11 Aug 2021 21:58:56

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:25:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8F5B9B48-1138-4DBF-A9AC-B36F0A557EB4)', Time: '2020-09-01T17:20:23', User OID: 'PatientReportedOutcome (US3142034)', ODM File OID: 'e0a5eb42-5e57-4b6e-9da8-e72486f943c7'	System	01 Sep 2020 23:20:29
User entered 'No (N)'	System	01 Sep 2020 23:20:29

US3142034

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 11 Aug 2021 21:58:56

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:25:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8F5B9B48-1138-4DBF-A9AC-B36F0A557EB4)', Time: '2020-09-01T17:20:27', User OID: 'PatientReportedOutcome (US3142034)', ODM File OID: 'e0a5eb42-5e57-4b6e-9da8-e72486f943c7' User entered '01 Sep 2020 17:20'	System	01 Sep 2020 23:20:29
	System	01 Sep 2020 23:20:29

US3142034

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 11 Aug 2021 21:58:56

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:25:25
User entered '01 Sep 2020 12:00'	System	27 Aug 2020 21:06:21

US3142034

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 11 Aug 2021 21:58:56

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:25:25
User entered '02 Sep 2020 11:59'	System	27 Aug 2020 21:06:21

US3142034

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 11 Aug 2021 21:58:56

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:25:25
Data entry locked.	System	27 Aug 2020 21:06:21
User entered 'Day 7'	System	27 Aug 2020 21:06:21

US3142034

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 11 Aug 2021 21:58:56

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:25:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8F5B9B48-1138-4DBF-A9AC-B36F0A557EB4)', Time: '2020-09-02T16:39:02', User OID: 'PatientReportedOutcome (US3142034)', ODM File OID: '1da064a9-db7b-4911-b03a-aa8d3e029b2d' User entered 'Yes (Y)'	System	02 Sep 2020 22:39:30
	System	02 Sep 2020 22:39:30

US3142034

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 11 Aug 2021 21:58:56

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:25:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8F5B9B48-1138-4DBF-A9AC-B36F0A557EB4)', Time: '2020-09-02T16:39:18', User OID: 'PatientReportedOutcome (US3142034)', ODM File OID: '1da064a9-db7b-4911-b03a-aa8d3e029b2d' User entered '96.3'	System	02 Sep 2020 22:39:30
	System	02 Sep 2020 22:39:30

US3142034

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 11 Aug 2021 21:58:56

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:25:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8F5B9B48-1138-4DBF-A9AC-B36F0A557EB4)', Time: '2020-09-02T16:39:21', User OID: 'PatientReportedOutcome (US3142034)', ODM File OID: '1da064a9-db7b-4911-b03a-aa8d3e029b2d'	System	02 Sep 2020 22:39:30
User entered 'No (N)'	System	02 Sep 2020 22:39:30

US3142034

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 11 Aug 2021 21:58:56

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:25:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8F5B9B48-1138-4DBF-A9AC-B36F0A557EB4)', Time: '2020-09-02T16:39:25', User OID: 'PatientReportedOutcome (US3142034)', ODM File OID: '1da064a9-db7b-4911-b03a-aa8d3e029b2d' User entered '02 Sep 2020 16:39'	System	02 Sep 2020 22:39:30
	System	02 Sep 2020 22:39:30

US3142034

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 11 Aug 2021 21:58:56

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:25:25
User entered '02 Sep 2020 12:00'	System	27 Aug 2020 21:06:21

US3142034

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 11 Aug 2021 21:58:56

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:25:25
User entered '03 Sep 2020 11:59'	System	27 Aug 2020 21:06:21

US3142034

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 11 Aug 2021 21:58:56

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:25:25
Data entry locked.	System	27 Aug 2020 21:06:21
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	27 Aug 2020 21:06:21

US3142034

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 11 Aug 2021 21:58:56

Please record - **PAIN AT INJECTION SITE.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:25:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8F5B9B48-1138-4DBF-A9AC-B36F0A557EB4)', Time: '2020-08-27T15:22:11', User OID: 'PatientReportedOutcome (US3142034)', ODM File OID: 'dff11703-ddfc-471f-82be-bd0db4c914b5'	System	27 Aug 2020 21:22:34
User entered 'None (1)'	System	27 Aug 2020 21:22:34

US3142034

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 11 Aug 2021 21:58:56

Is there any **REDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:25:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8F5B9B48-1138-4DBF-A9AC-B36F0A557EB4)', Time: '2020-08-27T15:22:19', User OID: 'PatientReportedOutcome (US3142034)', ODM File OID: 'dff11703-ddfc-471f-82be-bd0db4c914b5'	System	27 Aug 2020 21:22:34
User entered 'No (N)'	System	27 Aug 2020 21:22:34

US3142034

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 11 Aug 2021 21:58:56

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:25:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8F5B9B48-1138-4DBF-A9AC-B36F0A557EB4)', Time: '2020-08-27T15:22:22', User OID: 'PatientReportedOutcome (US3142034)', ODM File OID: 'dff11703-ddfc-471f-82be-bd0db4c914b5'	System	27 Aug 2020 21:22:34
User entered 'No (N)'	System	27 Aug 2020 21:22:34

US3142034

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 11 Aug 2021 21:58:56

Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:25:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8F5B9B48-1138-4DBF-A9AC-B36F0A557EB4)', Time: '2020-08-27T15:22:25', User OID: 'PatientReportedOutcome (US3142034)', ODM File OID: 'dff11703-ddfc-471f-82be-bd0db4c914b5'	System	27 Aug 2020 21:22:34
User entered 'None (1)'	System	27 Aug 2020 21:22:34

US3142034

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 11 Aug 2021 21:58:56

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:25:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8F5B9B48-1138-4DBF-A9AC-B36F0A557EB4)', Time: '2020-08-27T15:22:31', User OID: 'PatientReportedOutcome (US3142034)', ODM File OID: 'dff11703-ddfc-471f-82be-bd0db4c914b5' User entered '27 Aug 2020 15:22'	System	27 Aug 2020 21:22:34
	System	27 Aug 2020 21:22:34

US3142034

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 11 Aug 2021 21:58:56

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:25:25
User entered '27 Aug 2020 15:15'	System	27 Aug 2020 21:06:21

US3142034

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 11 Aug 2021 21:58:56

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:25:25
User entered '27 Aug 2020 17:45'	System	27 Aug 2020 21:06:21

US3142034

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 11 Aug 2021 21:58:56

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:25:25
Data entry locked.	System	27 Aug 2020 21:06:21
User entered 'Day 1, after vaccination (at home)'	System	27 Aug 2020 21:06:21

US3142034

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 11 Aug 2021 21:58:56

Please record - **PAIN AT INJECTION SITE.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:25:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8F5B9B48-1138-4DBF-A9AC-B36F0A557EB4)', Time: '2020-08-27T19:39:36', User OID: 'PatientReportedOutcome (US3142034)', ODM File OID: '961f5838-ba9b-4b87-8d24-21078b54cb2e' User entered 'None (1)'	System	28 Aug 2020 01:39:53
	System	28 Aug 2020 01:39:53

US3142034

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 11 Aug 2021 21:58:56

Is there any **REDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:25:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8F5B9B48-1138-4DBF-A9AC-B36F0A557EB4)', Time: '2020-08-27T19:39:39', User OID: 'PatientReportedOutcome (US3142034)', ODM File OID: '961f5838-ba9b-4b87-8d24-21078b54cb2e'	System	28 Aug 2020 01:39:53
User entered 'No (N)'	System	28 Aug 2020 01:39:53

US3142034

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 11 Aug 2021 21:58:56

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:25:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8F5B9B48-1138-4DBF-A9AC-B36F0A557EB4)', Time: '2020-08-27T19:39:41', User OID: 'PatientReportedOutcome (US3142034)', ODM File OID: '961f5838-ba9b-4b87-8d24-21078b54cb2e'	System	28 Aug 2020 01:39:53
User entered 'No (N)'	System	28 Aug 2020 01:39:53

US3142034

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 11 Aug 2021 21:58:56

Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:25:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8F5B9B48-1138-4DBF-A9AC-B36F0A557EB4)', Time: '2020-08-27T19:39:46', User OID: 'PatientReportedOutcome (US3142034)', ODM File OID: '961f5838-ba9b-4b87-8d24-21078b54cb2e' User entered 'None (1)'	System	28 Aug 2020 01:39:53
	System	28 Aug 2020 01:39:53

US3142034

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 11 Aug 2021 21:58:56

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:25:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8F5B9B48-1138-4DBF-A9AC-B36F0A557EB4)', Time: '2020-08-27T19:39:51', User OID: 'PatientReportedOutcome (US3142034)', ODM File OID: '961f5838-ba9b-4b87-8d24-21078b54cb2e' User entered '27 Aug 2020 19:39'	System	28 Aug 2020 01:39:53
	System	28 Aug 2020 01:39:53

US3142034

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 11 Aug 2021 21:58:56

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:25:25
User entered '27 Aug 2020 18:40'	System	27 Aug 2020 21:06:21

US3142034

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 11 Aug 2021 21:58:56

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:25:25
User entered '28 Aug 2020 11:59'	System	27 Aug 2020 21:06:21

US3142034

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 11 Aug 2021 21:58:56

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:25:25
Data entry locked.	System	27 Aug 2020 21:06:21
User entered 'Day 2'	System	27 Aug 2020 21:06:21

US3142034

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 11 Aug 2021 21:58:56

Please record - **PAIN AT INJECTION SITE.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:25:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8F5B9B48-1138-4DBF-A9AC-B36F0A557EB4)', Time: '2020-08-28T16:30:00', User OID: 'PatientReportedOutcome (US3142034)', ODM File OID: 'cba96d20-a5da-4508-b7d5-8a2353481ea0' User entered 'None (1)'	System	28 Aug 2020 22:30:25
	System	28 Aug 2020 22:30:25

US3142034

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 11 Aug 2021 21:58:56

Is there any **REDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:25:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8F5B9B48-1138-4DBF-A9AC-B36F0A557EB4)', Time: '2020-08-28T16:30:11', User OID: 'PatientReportedOutcome (US3142034)', ODM File OID: 'cba96d20-a5da-4508-b7d5-8a2353481ea0' User entered 'No (N)'	System	28 Aug 2020 22:30:25
	System	28 Aug 2020 22:30:25

US3142034

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 11 Aug 2021 21:58:56

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:25:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8F5B9B48-1138-4DBF-A9AC-B36F0A557EB4)', Time: '2020-08-28T16:30:15', User OID: 'PatientReportedOutcome (US3142034)', ODM File OID: 'cba96d20-a5da-4508-b7d5-8a2353481ea0' User entered 'No (N)'	System	28 Aug 2020 22:30:25
	System	28 Aug 2020 22:30:25

US3142034

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 11 Aug 2021 21:58:56

Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:25:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8F5B9B48-1138-4DBF-A9AC-B36F0A557EB4)', Time: '2020-08-28T16:30:18', User OID: 'PatientReportedOutcome (US3142034)', ODM File OID: 'cba96d20-a5da-4508-b7d5-8a2353481ea0'	System	28 Aug 2020 22:30:25
User entered 'None (1)'	System	28 Aug 2020 22:30:25

US3142034

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 11 Aug 2021 21:58:56

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:25:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8F5B9B48-1138-4DBF-A9AC-B36F0A557EB4)', Time: '2020-08-28T16:30:23', User OID: 'PatientReportedOutcome (US3142034)', ODM File OID: 'cba96d20-a5da-4508-b7d5-8a2353481ea0' User entered '28 Aug 2020 16:30'	System	28 Aug 2020 22:30:25
	System	28 Aug 2020 22:30:25

US3142034

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 11 Aug 2021 21:58:56

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:25:25
User entered '28 Aug 2020 12:00'	System	27 Aug 2020 21:06:21

US3142034

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 11 Aug 2021 21:58:56

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:25:25
User entered '29 Aug 2020 11:59'	System	27 Aug 2020 21:06:21

US3142034

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 11 Aug 2021 21:58:56

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:25:25
Data entry locked.	System	27 Aug 2020 21:06:21
User entered 'Day 3'	System	27 Aug 2020 21:06:21

US3142034

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 11 Aug 2021 21:58:56

Please record - **PAIN AT INJECTION SITE.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:25:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8F5B9B48-1138-4DBF-A9AC-B36F0A557EB4)', Time: '2020-08-29T18:17:11', User OID: 'PatientReportedOutcome (US3142034)', ODM File OID: '2340b097-0be3-4e00-b127-4016d671f5f5'	System	30 Aug 2020 00:17:42
User entered 'None (1)'	System	30 Aug 2020 00:17:42

US3142034

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 11 Aug 2021 21:58:56

Is there any **REDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:25:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8F5B9B48-1138-4DBF-A9AC-B36F0A557EB4)', Time: '2020-08-29T18:17:16', User OID: 'PatientReportedOutcome (US3142034)', ODM File OID: '2340b097-0be3-4e00-b127-4016d671f5f5'	System	30 Aug 2020 00:17:42
User entered 'No (N)'	System	30 Aug 2020 00:17:42

US3142034

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 11 Aug 2021 21:58:56

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:25:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8F5B9B48-1138-4DBF-A9AC-B36F0A557EB4)', Time: '2020-08-29T18:17:20', User OID: 'PatientReportedOutcome (US3142034)', ODM File OID: '2340b097-0be3-4e00-b127-4016d671f5f5'	System	30 Aug 2020 00:17:42
User entered 'No (N)'	System	30 Aug 2020 00:17:42

US3142034

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 11 Aug 2021 21:58:56

Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:25:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8F5B9B48-1138-4DBF-A9AC-B36F0A557EB4)', Time: '2020-08-29T18:17:31', User OID: 'PatientReportedOutcome (US3142034)', ODM File OID: '2340b097-0be3-4e00-b127-4016d671f5f5'	System	30 Aug 2020 00:17:42
User entered 'None (1)'	System	30 Aug 2020 00:17:42

US3142034

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 11 Aug 2021 21:58:56

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:25:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8F5B9B48-1138-4DBF-A9AC-B36F0A557EB4)', Time: '2020-08-29T18:17:38', User OID: 'PatientReportedOutcome (US3142034)', ODM File OID: '2340b097-0be3-4e00-b127-4016d671f5f5' User entered '29 Aug 2020 18:17'	System	30 Aug 2020 00:17:42
	System	30 Aug 2020 00:17:42

US3142034

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 11 Aug 2021 21:58:56

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:25:25
User entered '29 Aug 2020 12:00'	System	27 Aug 2020 21:06:21

US3142034

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 11 Aug 2021 21:58:56

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:25:25
User entered '30 Aug 2020 11:59'	System	27 Aug 2020 21:06:21

US3142034

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 11 Aug 2021 21:58:56

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:25:25
Data entry locked.	System	27 Aug 2020 21:06:21
User entered 'Day 4'	System	27 Aug 2020 21:06:21

US3142034

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 11 Aug 2021 21:58:56

Please record - **PAIN AT INJECTION SITE.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:25:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8F5B9B48-1138-4DBF-A9AC-B36F0A557EB4)', Time: '2020-08-30T16:50:49', User OID: 'PatientReportedOutcome (US3142034)', ODM File OID: '748f10fa-007e-4a55-909e-23f73955563c'	System	30 Aug 2020 22:51:06
User entered 'None (1)'	System	30 Aug 2020 22:51:06

US3142034

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 11 Aug 2021 21:58:56

Is there any **REDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:25:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8F5B9B48-1138-4DBF-A9AC-B36F0A557EB4)', Time: '2020-08-30T16:50:52', User OID: 'PatientReportedOutcome (US3142034)', ODM File OID: '748f10fa-007e-4a55-909e-23f73955563c' User entered 'No (N)'	System	30 Aug 2020 22:51:06
	System	30 Aug 2020 22:51:06

US3142034

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 11 Aug 2021 21:58:56

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:25:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8F5B9B48-1138-4DBF-A9AC-B36F0A557EB4)', Time: '2020-08-30T16:50:54', User OID: 'PatientReportedOutcome (US3142034)', ODM File OID: '748f10fa-007e-4a55-909e-23f73955563c' User entered 'No (N)'	System	30 Aug 2020 22:51:06
	System	30 Aug 2020 22:51:06

US3142034

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 11 Aug 2021 21:58:56

Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:25:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8F5B9B48-1138-4DBF-A9AC-B36F0A557EB4)', Time: '2020-08-30T16:50:57', User OID: 'PatientReportedOutcome (US3142034)', ODM File OID: '748f10fa-007e-4a55-909e-23f73955563c'	System	30 Aug 2020 22:51:06
User entered 'None (1)'	System	30 Aug 2020 22:51:06

US3142034

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 11 Aug 2021 21:58:56

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:25:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8F5B9B48-1138-4DBF-A9AC-B36F0A557EB4)', Time: '2020-08-30T16:51:01', User OID: 'PatientReportedOutcome (US3142034)', ODM File OID: '748f10fa-007e-4a55-909e-23f73955563c' User entered '30 Aug 2020 16:51'	System	30 Aug 2020 22:51:06
	System	30 Aug 2020 22:51:06

US3142034

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 11 Aug 2021 21:58:56

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:25:25
User entered '30 Aug 2020 12:00'	System	27 Aug 2020 21:06:21

US3142034

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 11 Aug 2021 21:58:56

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:25:25
User entered '31 Aug 2020 11:59'	System	27 Aug 2020 21:06:21

US3142034

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 11 Aug 2021 21:58:56

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:25:25
Data entry locked.	System	27 Aug 2020 21:06:21
User entered 'Day 5'	System	27 Aug 2020 21:06:21

US3142034

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 11 Aug 2021 21:58:56

Please record - **PAIN AT INJECTION SITE.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:25:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8F5B9B48-1138-4DBF-A9AC-B36F0A557EB4)', Time: '2020-08-31T17:35:51', User OID: 'PatientReportedOutcome (US3142034)', ODM File OID: '67f1a0d0-ebf3-4115-8879-f1bebe9cde80'	System	31 Aug 2020 23:36:08
User entered 'None (1)'	System	31 Aug 2020 23:36:08

US3142034

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 11 Aug 2021 21:58:56

Is there any **REDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:25:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8F5B9B48-1138-4DBF-A9AC-B36F0A557EB4)', Time: '2020-08-31T17:35:53', User OID: 'PatientReportedOutcome (US3142034)', ODM File OID: '67f1a0d0-ebf3-4115-8879-f1bebe9cde80' User entered 'No (N)'	System	31 Aug 2020 23:36:08
	System	31 Aug 2020 23:36:08

US3142034

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 11 Aug 2021 21:58:56

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:25:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8F5B9B48-1138-4DBF-A9AC-B36F0A557EB4)', Time: '2020-08-31T17:35:56', User OID: 'PatientReportedOutcome (US3142034)', ODM File OID: '67f1a0d0-ebf3-4115-8879-f1bebe9cde80' User entered 'No (N)'	System	31 Aug 2020 23:36:08
	System	31 Aug 2020 23:36:08

US3142034

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 11 Aug 2021 21:58:56

Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:25:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8F5B9B48-1138-4DBF-A9AC-B36F0A557EB4)', Time: '2020-08-31T17:35:58', User OID: 'PatientReportedOutcome (US3142034)', ODM File OID: '67f1a0d0-ebf3-4115-8879-f1bebe9cde80'	System	31 Aug 2020 23:36:08
User entered 'None (1)'	System	31 Aug 2020 23:36:08

US3142034

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 11 Aug 2021 21:58:56

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:25:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8F5B9B48-1138-4DBF-A9AC-B36F0A557EB4)', Time: '2020-08-31T17:36:05', User OID: 'PatientReportedOutcome (US3142034)', ODM File OID: '67f1a0d0-ebf3-4115-8879-f1bebe9cde80' User entered '31 Aug 2020 17:36'	System	31 Aug 2020 23:36:08
	System	31 Aug 2020 23:36:08

US3142034

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 11 Aug 2021 21:58:56

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:25:25
User entered '31 Aug 2020 12:00'	System	27 Aug 2020 21:06:21

US3142034

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 11 Aug 2021 21:58:56

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:25:25
User entered '01 Sep 2020 11:59'	System	27 Aug 2020 21:06:21

US3142034

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 11 Aug 2021 21:58:56

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:25:25
Data entry locked.	System	27 Aug 2020 21:06:21
User entered 'Day 6'	System	27 Aug 2020 21:06:21

US3142034

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 11 Aug 2021 21:58:56

Please record - **PAIN AT INJECTION SITE.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:25:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8F5B9B48-1138-4DBF-A9AC-B36F0A557EB4)', Time: '2020-09-01T17:20:30', User OID: 'PatientReportedOutcome (US3142034)', ODM File OID: 'd7de83f5-a5cd-4cb6-9d04-cf819136fe06'	System	01 Sep 2020 23:20:43
User entered 'None (1)'	System	01 Sep 2020 23:20:43

US3142034

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 11 Aug 2021 21:58:56

Is there any **REDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:25:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8F5B9B48-1138-4DBF-A9AC-B36F0A557EB4)', Time: '2020-09-01T17:20:33', User OID: 'PatientReportedOutcome (US3142034)', ODM File OID: 'd7de83f5-a5cd-4cb6-9d04-cf819136fe06'	System	01 Sep 2020 23:20:43
User entered 'No (N)'	System	01 Sep 2020 23:20:43

US3142034

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 11 Aug 2021 21:58:56

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:25:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8F5B9B48-1138-4DBF-A9AC-B36F0A557EB4)', Time: '2020-09-01T17:20:35', User OID: 'PatientReportedOutcome (US3142034)', ODM File OID: 'd7de83f5-a5cd-4cb6-9d04-cf819136fe06'	System	01 Sep 2020 23:20:43
User entered 'No (N)'	System	01 Sep 2020 23:20:43

US3142034

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 11 Aug 2021 21:58:56

Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:25:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8F5B9B48-1138-4DBF-A9AC-B36F0A557EB4)', Time: '2020-09-01T17:20:38', User OID: 'PatientReportedOutcome (US3142034)', ODM File OID: 'd7de83f5-a5cd-4cb6-9d04-cf819136fe06'	System	01 Sep 2020 23:20:43
User entered 'None (1)'	System	01 Sep 2020 23:20:43

US3142034

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 11 Aug 2021 21:58:56

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:25:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8F5B9B48-1138-4DBF-A9AC-B36F0A557EB4)', Time: '2020-09-01T17:20:42', User OID: 'PatientReportedOutcome (US3142034)', ODM File OID: 'd7de83f5-a5cd-4cb6-9d04-cf819136fe06' User entered '01 Sep 2020 17:20'	System	01 Sep 2020 23:20:43
	System	01 Sep 2020 23:20:43

US3142034

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 11 Aug 2021 21:58:56

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:25:25
User entered '01 Sep 2020 12:00'	System	27 Aug 2020 21:06:21

US3142034

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 11 Aug 2021 21:58:56

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:25:25
User entered '02 Sep 2020 11:59'	System	27 Aug 2020 21:06:21

US3142034

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 11 Aug 2021 21:58:56

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:25:25
Data entry locked.	System	27 Aug 2020 21:06:21
User entered 'Day 7'	System	27 Aug 2020 21:06:21

US3142034

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 11 Aug 2021 21:58:56

Please record - **PAIN AT INJECTION SITE.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:25:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8F5B9B48-1138-4DBF-A9AC-B36F0A557EB4)', Time: '2020-09-02T16:39:31', User OID: 'PatientReportedOutcome (US3142034)', ODM File OID: '953f79d9-ba80-4787-a736-a8f0eebc0d48'	System	02 Sep 2020 22:40:16
User entered 'None (1)'	System	02 Sep 2020 22:40:16

US3142034

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 11 Aug 2021 21:58:56

Is there any **REDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:25:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8F5B9B48-1138-4DBF-A9AC-B36F0A557EB4)', Time: '2020-09-02T16:39:35', User OID: 'PatientReportedOutcome (US3142034)', ODM File OID: '953f79d9-ba80-4787-a736-a8f0eebc0d48'	System	02 Sep 2020 22:40:16
User entered 'No (N)'	System	02 Sep 2020 22:40:16

US3142034

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 11 Aug 2021 21:58:56

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:25:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8F5B9B48-1138-4DBF-A9AC-B36F0A557EB4)', Time: '2020-09-02T16:39:37', User OID: 'PatientReportedOutcome (US3142034)', ODM File OID: '953f79d9-ba80-4787-a736-a8f0eebc0d48'	System	02 Sep 2020 22:40:16
User entered 'No (N)'	System	02 Sep 2020 22:40:16

US3142034

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 11 Aug 2021 21:58:56

Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:25:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8F5B9B48-1138-4DBF-A9AC-B36F0A557EB4)', Time: '2020-09-02T16:39:41', User OID: 'PatientReportedOutcome (US3142034)', ODM File OID: '953f79d9-ba80-4787-a736-a8f0eebc0d48'	System	02 Sep 2020 22:40:16
User entered 'None (1)'	System	02 Sep 2020 22:40:16

US3142034

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 11 Aug 2021 21:58:56

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:25:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8F5B9B48-1138-4DBF-A9AC-B36F0A557EB4)', Time: '2020-09-02T16:39:46', User OID: 'PatientReportedOutcome (US3142034)', ODM File OID: '953f79d9-ba80-4787-a736-a8f0eebc0d48' User entered '02 Sep 2020 16:39'	System	02 Sep 2020 22:40:16
	System	02 Sep 2020 22:40:16

US3142034

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 11 Aug 2021 21:58:56

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:25:25
User entered '02 Sep 2020 12:00'	System	27 Aug 2020 21:06:21

US3142034

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 11 Aug 2021 21:58:56

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:25:25
User entered '03 Sep 2020 11:59'	System	27 Aug 2020 21:06:21

US3142034

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 11 Aug 2021 21:58:56

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:25:25
Data entry locked.	System	27 Aug 2020 21:06:21
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	27 Aug 2020 21:06:21

US3142034

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 11 Aug 2021 21:58:56

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:25:25

US3142034

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 11 Aug 2021 21:58:56

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:25:25

US3142034

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 11 Aug 2021 21:58:56

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:25:25

US3142034

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 11 Aug 2021 21:58:56

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:25:25

US3142034

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 11 Aug 2021 21:58:56

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:25:25

US3142034

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 11 Aug 2021 21:58:56

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:25:25

US3142034

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 11 Aug 2021 21:58:56

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)	05 Mar 2021 01:25:25

US3142034

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 11 Aug 2021 21:58:56

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:25:25

US3142034

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 11 Aug 2021 21:58:56

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:25:25
User entered '27 Aug 2020 15:15'	System	27 Aug 2020 21:06:21

US3142034

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 11 Aug 2021 21:58:56

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:25:25
User entered '27 Aug 2020 17:45'	System	27 Aug 2020 21:06:21

US3142034

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 11 Aug 2021 21:58:56

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:25:25
Data entry locked.	System	27 Aug 2020 21:06:21
User entered 'Day 1, after vaccination (at home)'	System	27 Aug 2020 21:06:21

US3142034

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 11 Aug 2021 21:58:56

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:25:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8F5B9B48-1138-4DBF-A9AC-B36F0A557EB4)', Time: '2020-08-27T19:39:55', User OID: 'PatientReportedOutcome (US3142034)', ODM File OID: 'b486ca7c-afe2-4b30-8bba-a01401fd389d' User entered 'None (0)'	System	28 Aug 2020 01:40:20
	System	28 Aug 2020 01:40:20

US3142034

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 11 Aug 2021 21:58:56

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:25:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8F5B9B48-1138-4DBF-A9AC-B36F0A557EB4)', Time: '2020-08-27T19:39:58', User OID: 'PatientReportedOutcome (US3142034)', ODM File OID: 'b486ca7c-afe2-4b30-8bba-a01401fd389d' User entered 'None (0)'	System	28 Aug 2020 01:40:20
	System	28 Aug 2020 01:40:20

US3142034

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 11 Aug 2021 21:58:56

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:25:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8F5B9B48-1138-4DBF-A9AC-B36F0A557EB4)', Time: '2020-08-27T19:40:02', User OID: 'PatientReportedOutcome (US3142034)', ODM File OID: 'b486ca7c-afe2-4b30-8bba-a01401fd389d' User entered 'None (0)'	System	28 Aug 2020 01:40:20
	System	28 Aug 2020 01:40:20

US3142034

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 11 Aug 2021 21:58:56

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:25:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8F5B9B48-1138-4DBF-A9AC-B36F0A557EB4)', Time: '2020-08-27T19:40:04', User OID: 'PatientReportedOutcome (US3142034)', ODM File OID: 'b486ca7c-afe2-4b30-8bba-a01401fd389d' User entered 'None (0)'	System	28 Aug 2020 01:40:20
	System	28 Aug 2020 01:40:20

US3142034

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 11 Aug 2021 21:58:56

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:25:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8F5B9B48-1138-4DBF-A9AC-B36F0A557EB4)', Time: '2020-08-27T19:40:06', User OID: 'PatientReportedOutcome (US3142034)', ODM File OID: 'b486ca7c-afe2-4b30-8bba-a01401fd389d' User entered 'None (0)'	System	28 Aug 2020 01:40:20
	System	28 Aug 2020 01:40:20

US3142034

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 11 Aug 2021 21:58:56

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:25:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8F5B9B48-1138-4DBF-A9AC-B36F0A557EB4)', Time: '2020-08-27T19:40:08', User OID: 'PatientReportedOutcome (US3142034)', ODM File OID: 'b486ca7c-afe2-4b30-8bba-a01401fd389d' User entered 'None (0)'	System	28 Aug 2020 01:40:20
	System	28 Aug 2020 01:40:20

US3142034

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 11 Aug 2021 21:58:56

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)	05 Mar 2021 01:25:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8F5B9B48-1138-4DBF-A9AC-B36F0A557EB4)', Time: '2020-08-27T19:40:11', User OID: 'PatientReportedOutcome (US3142034)', ODM File OID: 'b486ca7c-afe2-4b30-8bba-a01401fd389d' User entered 'No (N)'	System	28 Aug 2020 01:40:20
	System	28 Aug 2020 01:40:20

US3142034

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 11 Aug 2021 21:58:56

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:25:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8F5B9B48-1138-4DBF-A9AC-B36F0A557EB4)', Time: '2020-08-27T19:40:17', User OID: 'PatientReportedOutcome (US3142034)', ODM File OID: 'b486ca7c-afe2-4b30-8bba-a01401fd389d' User entered '27 Aug 2020 19:40'	System	28 Aug 2020 01:40:20
	System	28 Aug 2020 01:40:20

US3142034

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 11 Aug 2021 21:58:56

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:25:25
User entered '27 Aug 2020 18:40'	System	27 Aug 2020 21:06:21

US3142034

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 11 Aug 2021 21:58:56

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:25:25
User entered '28 Aug 2020 11:59'	System	27 Aug 2020 21:06:21

US3142034

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 11 Aug 2021 21:58:56

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:25:25
Data entry locked.	System	27 Aug 2020 21:06:21
User entered 'Day 2'	System	27 Aug 2020 21:06:21

US3142034

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 11 Aug 2021 21:58:56

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:25:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8F5B9B48-1138-4DBF-A9AC-B36F0A557EB4)', Time: '2020-08-28T16:30:34', User OID: 'PatientReportedOutcome (US3142034)', ODM File OID: '46352145-e5c6-40bc-8413-ca32dbe6f849'	System	28 Aug 2020 22:31:09
User entered 'None (0)'	System	28 Aug 2020 22:31:09

US3142034

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 11 Aug 2021 21:58:56

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:25:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8F5B9B48-1138-4DBF-A9AC-B36F0A557EB4)', Time: '2020-08-28T16:30:39', User OID: 'PatientReportedOutcome (US3142034)', ODM File OID: '46352145-e5c6-40bc-8413-ca32dbe6f849' User entered 'None (0)'	System	28 Aug 2020 22:31:09
	System	28 Aug 2020 22:31:09

US3142034

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 11 Aug 2021 21:58:56

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:25:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8F5B9B48-1138-4DBF-A9AC-B36F0A557EB4)', Time: '2020-08-28T16:30:42', User OID: 'PatientReportedOutcome (US3142034)', ODM File OID: '46352145-e5c6-40bc-8413-ca32dbe6f849' User entered 'None (0)'	System	28 Aug 2020 22:31:09
	System	28 Aug 2020 22:31:09

US3142034

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 11 Aug 2021 21:58:56

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:25:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8F5B9B48-1138-4DBF-A9AC-B36F0A557EB4)', Time: '2020-08-28T16:30:44', User OID: 'PatientReportedOutcome (US3142034)', ODM File OID: '46352145-e5c6-40bc-8413-ca32dbe6f849' User entered 'None (0)'	System	28 Aug 2020 22:31:09
	System	28 Aug 2020 22:31:09

US3142034

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 11 Aug 2021 21:58:56

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:25:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8F5B9B48-1138-4DBF-A9AC-B36F0A557EB4)', Time: '2020-08-28T16:30:49', User OID: 'PatientReportedOutcome (US3142034)', ODM File OID: '46352145-e5c6-40bc-8413-ca32dbe6f849' User entered 'None (0)'	System	28 Aug 2020 22:31:09
	System	28 Aug 2020 22:31:09

US3142034

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 11 Aug 2021 21:58:56

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:25:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8F5B9B48-1138-4DBF-A9AC-B36F0A557EB4)', Time: '2020-08-28T16:30:52', User OID: 'PatientReportedOutcome (US3142034)', ODM File OID: '46352145-e5c6-40bc-8413-ca32dbe6f849' User entered 'None (0)'	System	28 Aug 2020 22:31:09
	System	28 Aug 2020 22:31:09

US3142034

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 11 Aug 2021 21:58:56

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)	05 Mar 2021 01:25:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8F5B9B48-1138-4DBF-A9AC-B36F0A557EB4)', Time: '2020-08-28T16:30:55', User OID: 'PatientReportedOutcome (US3142034)', ODM File OID: '46352145-e5c6-40bc-8413-ca32dbe6f849' User entered 'No (N)'	System	28 Aug 2020 22:31:09
	System	28 Aug 2020 22:31:09

US3142034

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 11 Aug 2021 21:58:56

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:25:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8F5B9B48-1138-4DBF-A9AC-B36F0A557EB4)', Time: '2020-08-28T16:31:04', User OID: 'PatientReportedOutcome (US3142034)', ODM File OID: '46352145-e5c6-40bc-8413-ca32dbe6f849' User entered '28 Aug 2020 16:31'	System	28 Aug 2020 22:31:09
	System	28 Aug 2020 22:31:09

US3142034

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 11 Aug 2021 21:58:56

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:25:25
User entered '28 Aug 2020 12:00'	System	27 Aug 2020 21:06:21

US3142034

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 11 Aug 2021 21:58:56

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:25:25
User entered '29 Aug 2020 11:59'	System	27 Aug 2020 21:06:21

US3142034

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 11 Aug 2021 21:58:56

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:25:25
Data entry locked.	System	27 Aug 2020 21:06:21
User entered 'Day 3'	System	27 Aug 2020 21:06:21

US3142034

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 11 Aug 2021 21:58:56

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:25:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8F5B9B48-1138-4DBF-A9AC-B36F0A557EB4)', Time: '2020-08-29T18:17:43', User OID: 'PatientReportedOutcome (US3142034)', ODM File OID: '2b0f1c4a-cbb2-4d05-aa1d-8bb9c2d67e67' User entered 'None (0)'	System	30 Aug 2020 00:18:47
	System	30 Aug 2020 00:18:47

US3142034

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 11 Aug 2021 21:58:56

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:25:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8F5B9B48-1138-4DBF-A9AC-B36F0A557EB4)', Time: '2020-08-29T18:17:47', User OID: 'PatientReportedOutcome (US3142034)', ODM File OID: '2b0f1c4a-cbb2-4d05-aa1d-8bb9c2d67e67' User entered 'None (0)'	System	30 Aug 2020 00:18:47
	System	30 Aug 2020 00:18:47

US3142034

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 11 Aug 2021 21:58:56

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:25:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8F5B9B48-1138-4DBF-A9AC-B36F0A557EB4)', Time: '2020-08-29T18:17:51', User OID: 'PatientReportedOutcome (US3142034)', ODM File OID: '2b0f1c4a-cbb2-4d05-aa1d-8bb9c2d67e67' User entered 'None (0)'	System	30 Aug 2020 00:18:47
	System	30 Aug 2020 00:18:47

US3142034

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 11 Aug 2021 21:58:56

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:25:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8F5B9B48-1138-4DBF-A9AC-B36F0A557EB4)', Time: '2020-08-29T18:17:56', User OID: 'PatientReportedOutcome (US3142034)', ODM File OID: '2b0f1c4a-cbb2-4d05-aa1d-8bb9c2d67e67' User entered 'None (0)'	System	30 Aug 2020 00:18:47
	System	30 Aug 2020 00:18:47

US3142034

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 11 Aug 2021 21:58:56

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:25:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8F5B9B48-1138-4DBF-A9AC-B36F0A557EB4)', Time: '2020-08-29T18:18:27', User OID: 'PatientReportedOutcome (US3142034)', ODM File OID: '2b0f1c4a-cbb2-4d05-aa1d-8bb9c2d67e67' User entered 'None (0)'	System	30 Aug 2020 00:18:47
	System	30 Aug 2020 00:18:47

US3142034

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 11 Aug 2021 21:58:56

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:25:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8F5B9B48-1138-4DBF-A9AC-B36F0A557EB4)', Time: '2020-08-29T18:18:33', User OID: 'PatientReportedOutcome (US3142034)', ODM File OID: '2b0f1c4a-cbb2-4d05-aa1d-8bb9c2d67e67' User entered 'None (0)'	System	30 Aug 2020 00:18:47
	System	30 Aug 2020 00:18:47

US3142034

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 11 Aug 2021 21:58:56

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)	05 Mar 2021 01:25:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8F5B9B48-1138-4DBF-A9AC-B36F0A557EB4)', Time: '2020-08-29T18:18:38', User OID: 'PatientReportedOutcome (US3142034)', ODM File OID: '2b0f1c4a-cbb2-4d05-aa1d-8bb9c2d67e67' User entered 'No (N)'	System	30 Aug 2020 00:18:47
	System	30 Aug 2020 00:18:47

US3142034

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 11 Aug 2021 21:58:56

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:25:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8F5B9B48-1138-4DBF-A9AC-B36F0A557EB4)', Time: '2020-08-29T18:18:42', User OID: 'PatientReportedOutcome (US3142034)', ODM File OID: '2b0f1c4a-cbb2-4d05-aa1d-8bb9c2d67e67' User entered '29 Aug 2020 18:18'	System	30 Aug 2020 00:18:47
	System	30 Aug 2020 00:18:47

US3142034

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 11 Aug 2021 21:58:56

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:25:25
User entered '29 Aug 2020 12:00'	System	27 Aug 2020 21:06:21

US3142034

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 11 Aug 2021 21:58:56

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:25:25
User entered '30 Aug 2020 11:59'	System	27 Aug 2020 21:06:21

US3142034

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 11 Aug 2021 21:58:56

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:25:25
Data entry locked.	System	27 Aug 2020 21:06:21
User entered 'Day 4'	System	27 Aug 2020 21:06:21

US3142034

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 11 Aug 2021 21:58:56

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:25:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8F5B9B48-1138-4DBF-A9AC-B36F0A557EB4)', Time: '2020-08-30T16:51:05', User OID: 'PatientReportedOutcome (US3142034)', ODM File OID: '5c2208c0-bf24-46dd-ad49-a1089d96c7a6' User entered 'None (0)'	System	30 Aug 2020 22:51:53
	System	30 Aug 2020 22:51:53

US3142034

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 11 Aug 2021 21:58:56

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:25:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8F5B9B48-1138-4DBF-A9AC-B36F0A557EB4)', Time: '2020-08-30T16:51:32', User OID: 'PatientReportedOutcome (US3142034)', ODM File OID: '5c2208c0-bf24-46dd-ad49-a1089d96c7a6' User entered 'None (0)'	System	30 Aug 2020 22:51:53
	System	30 Aug 2020 22:51:53

US3142034

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 11 Aug 2021 21:58:56

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:25:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8F5B9B48-1138-4DBF-A9AC-B36F0A557EB4)', Time: '2020-08-30T16:51:33', User OID: 'PatientReportedOutcome (US3142034)', ODM File OID: '5c2208c0-bf24-46dd-ad49-a1089d96c7a6' User entered 'None (0)'	System	30 Aug 2020 22:51:53
	System	30 Aug 2020 22:51:53

US3142034

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 11 Aug 2021 21:58:56

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:25:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8F5B9B48-1138-4DBF-A9AC-B36F0A557EB4)', Time: '2020-08-30T16:51:36', User OID: 'PatientReportedOutcome (US3142034)', ODM File OID: '5c2208c0-bf24-46dd-ad49-a1089d96c7a6' User entered 'None (0)'	System	30 Aug 2020 22:51:53
	System	30 Aug 2020 22:51:53

US3142034

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 11 Aug 2021 21:58:56

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:25:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8F5B9B48-1138-4DBF-A9AC-B36F0A557EB4)', Time: '2020-08-30T16:51:38', User OID: 'PatientReportedOutcome (US3142034)', ODM File OID: '5c2208c0-bf24-46dd-ad49-a1089d96c7a6' User entered 'None (0)'	System	30 Aug 2020 22:51:53
	System	30 Aug 2020 22:51:53

US3142034

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 11 Aug 2021 21:58:56

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:25:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8F5B9B48-1138-4DBF-A9AC-B36F0A557EB4)', Time: '2020-08-30T16:51:40', User OID: 'PatientReportedOutcome (US3142034)', ODM File OID: '5c2208c0-bf24-46dd-ad49-a1089d96c7a6' User entered 'None (0)'	System	30 Aug 2020 22:51:53
	System	30 Aug 2020 22:51:53

US3142034

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 11 Aug 2021 21:58:56

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)	05 Mar 2021 01:25:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8F5B9B48-1138-4DBF-A9AC-B36F0A557EB4)', Time: '2020-08-30T16:51:43', User OID: 'PatientReportedOutcome (US3142034)', ODM File OID: '5c2208c0-bf24-46dd-ad49-a1089d96c7a6' User entered 'No (N)'	System	30 Aug 2020 22:51:53
	System	30 Aug 2020 22:51:53

US3142034

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 11 Aug 2021 21:58:56

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:25:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8F5B9B48-1138-4DBF-A9AC-B36F0A557EB4)', Time: '2020-08-30T16:51:49', User OID: 'PatientReportedOutcome (US3142034)', ODM File OID: '5c2208c0-bf24-46dd-ad49-a1089d96c7a6' User entered '30 Aug 2020 16:51'	System	30 Aug 2020 22:51:53
	System	30 Aug 2020 22:51:53

US3142034

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 11 Aug 2021 21:58:56

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:25:25
User entered '30 Aug 2020 12:00'	System	27 Aug 2020 21:06:21

US3142034

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 11 Aug 2021 21:58:56

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:25:25
User entered '31 Aug 2020 11:59'	System	27 Aug 2020 21:06:21

US3142034

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 11 Aug 2021 21:58:56

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:25:25
Data entry locked.	System	27 Aug 2020 21:06:21
User entered 'Day 5'	System	27 Aug 2020 21:06:21

US3142034

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 11 Aug 2021 21:58:56

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:25:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8F5B9B48-1138-4DBF-A9AC-B36F0A557EB4)', Time: '2020-08-31T17:36:09', User OID: 'PatientReportedOutcome (US3142034)', ODM File OID: 'c88fb91b-1a9e-474a-bc9f-176c6dd54ff9' User entered 'None (0)'	System	31 Aug 2020 23:36:42
	System	31 Aug 2020 23:36:42

US3142034

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 11 Aug 2021 21:58:56

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:25:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8F5B9B48-1138-4DBF-A9AC-B36F0A557EB4)', Time: '2020-08-31T17:36:15', User OID: 'PatientReportedOutcome (US3142034)', ODM File OID: 'c88fb91b-1a9e-474a-bc9f-176c6dd54ff9' User entered 'None (0)'	System	31 Aug 2020 23:36:42
	System	31 Aug 2020 23:36:42

US3142034

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 11 Aug 2021 21:58:56

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:25:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8F5B9B48-1138-4DBF-A9AC-B36F0A557EB4)', Time: '2020-08-31T17:36:22', User OID: 'PatientReportedOutcome (US3142034)', ODM File OID: 'c88fb91b-1a9e-474a-bc9f-176c6dd54ff9' User entered 'None (0)'	System	31 Aug 2020 23:36:42
	System	31 Aug 2020 23:36:42

US3142034

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 11 Aug 2021 21:58:56

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:25:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8F5B9B48-1138-4DBF-A9AC-B36F0A557EB4)', Time: '2020-08-31T17:36:24', User OID: 'PatientReportedOutcome (US3142034)', ODM File OID: 'c88fb91b-1a9e-474a-bc9f-176c6dd54ff9' User entered 'None (0)'	System	31 Aug 2020 23:36:42
	System	31 Aug 2020 23:36:42

US3142034

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 11 Aug 2021 21:58:56

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:25:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8F5B9B48-1138-4DBF-A9AC-B36F0A557EB4)', Time: '2020-08-31T17:36:26', User OID: 'PatientReportedOutcome (US3142034)', ODM File OID: 'c88fb91b-1a9e-474a-bc9f-176c6dd54ff9' User entered 'None (0)'	System	31 Aug 2020 23:36:42
	System	31 Aug 2020 23:36:42

US3142034

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 11 Aug 2021 21:58:56

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:25:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8F5B9B48-1138-4DBF-A9AC-B36F0A557EB4)', Time: '2020-08-31T17:36:29', User OID: 'PatientReportedOutcome (US3142034)', ODM File OID: 'c88fb91b-1a9e-474a-bc9f-176c6dd54ff9' User entered 'None (0)'	System	31 Aug 2020 23:36:42
	System	31 Aug 2020 23:36:42

US3142034

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 11 Aug 2021 21:58:56

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)	05 Mar 2021 01:25:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8F5B9B48-1138-4DBF-A9AC-B36F0A557EB4)', Time: '2020-08-31T17:36:31', User OID: 'PatientReportedOutcome (US3142034)', ODM File OID: 'c88fb91b-1a9e-474a-bc9f-176c6dd54ff9' User entered 'No (N)'	System	31 Aug 2020 23:36:42
	System	31 Aug 2020 23:36:42

US3142034

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 11 Aug 2021 21:58:56

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:25:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8F5B9B48-1138-4DBF-A9AC-B36F0A557EB4)', Time: '2020-08-31T17:36:41', User OID: 'PatientReportedOutcome (US3142034)', ODM File OID: 'c88fb91b-1a9e-474a-bc9f-176c6dd54ff9' User entered '31 Aug 2020 17:36'	System	31 Aug 2020 23:36:42
	System	31 Aug 2020 23:36:42

US3142034

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 11 Aug 2021 21:58:56

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:25:25
User entered '31 Aug 2020 12:00'	System	27 Aug 2020 21:06:21

US3142034

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 11 Aug 2021 21:58:56

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:25:25
User entered '01 Sep 2020 11:59'	System	27 Aug 2020 21:06:21

US3142034

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 11 Aug 2021 21:58:56

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:25:25
Data entry locked.	System	27 Aug 2020 21:06:21
User entered 'Day 6'	System	27 Aug 2020 21:06:21

US3142034

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 11 Aug 2021 21:58:56

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:25:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8F5B9B48-1138-4DBF-A9AC-B36F0A557EB4)', Time: '2020-09-01T17:20:45', User OID: 'PatientReportedOutcome (US3142034)', ODM File OID: 'ba017f94-6b6c-4e5d-b496-369ab195bed6' User entered 'None (0)'	System	01 Sep 2020 23:21:08
	System	01 Sep 2020 23:21:08

US3142034

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 11 Aug 2021 21:58:56

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:25:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8F5B9B48-1138-4DBF-A9AC-B36F0A557EB4)', Time: '2020-09-01T17:20:48', User OID: 'PatientReportedOutcome (US3142034)', ODM File OID: 'ba017f94-6b6c-4e5d-b496-369ab195bed6' User entered 'None (0)'	System	01 Sep 2020 23:21:08
	System	01 Sep 2020 23:21:08

US3142034

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 11 Aug 2021 21:58:56

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:25:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8F5B9B48-1138-4DBF-A9AC-B36F0A557EB4)', Time: '2020-09-01T17:20:49', User OID: 'PatientReportedOutcome (US3142034)', ODM File OID: 'ba017f94-6b6c-4e5d-b496-369ab195bed6' User entered 'None (0)'	System	01 Sep 2020 23:21:08
	System	01 Sep 2020 23:21:08

US3142034

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 11 Aug 2021 21:58:56

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:25:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8F5B9B48-1138-4DBF-A9AC-B36F0A557EB4)', Time: '2020-09-01T17:20:51', User OID: 'PatientReportedOutcome (US3142034)', ODM File OID: 'ba017f94-6b6c-4e5d-b496-369ab195bed6' User entered 'None (0)'	System	01 Sep 2020 23:21:08
	System	01 Sep 2020 23:21:08

US3142034

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 11 Aug 2021 21:58:56

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:25:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8F5B9B48-1138-4DBF-A9AC-B36F0A557EB4)', Time: '2020-09-01T17:20:53', User OID: 'PatientReportedOutcome (US3142034)', ODM File OID: 'ba017f94-6b6c-4e5d-b496-369ab195bed6' User entered 'None (0)'	System	01 Sep 2020 23:21:08
	System	01 Sep 2020 23:21:08

US3142034

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 11 Aug 2021 21:58:56

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:25:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8F5B9B48-1138-4DBF-A9AC-B36F0A557EB4)', Time: '2020-09-01T17:20:55', User OID: 'PatientReportedOutcome (US3142034)', ODM File OID: 'ba017f94-6b6c-4e5d-b496-369ab195bed6' User entered 'None (0)'	System	01 Sep 2020 23:21:08
	System	01 Sep 2020 23:21:08

US3142034

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 11 Aug 2021 21:58:56

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)	05 Mar 2021 01:25:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8F5B9B48-1138-4DBF-A9AC-B36F0A557EB4)', Time: '2020-09-01T17:20:57', User OID: 'PatientReportedOutcome (US3142034)', ODM File OID: 'ba017f94-6b6c-4e5d-b496-369ab195bed6' User entered 'No (N)'	System	01 Sep 2020 23:21:08
	System	01 Sep 2020 23:21:08

US3142034

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 11 Aug 2021 21:58:56

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:25:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8F5B9B48-1138-4DBF-A9AC-B36F0A557EB4)', Time: '2020-09-01T17:21:03', User OID: 'PatientReportedOutcome (US3142034)', ODM File OID: 'ba017f94-6b6c-4e5d-b496-369ab195bed6' User entered '01 Sep 2020 17:21'	System	01 Sep 2020 23:21:08
	System	01 Sep 2020 23:21:08

US3142034

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 11 Aug 2021 21:58:56

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:25:25
User entered '01 Sep 2020 12:00'	System	27 Aug 2020 21:06:21

US3142034

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 11 Aug 2021 21:58:56

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:25:25
User entered '02 Sep 2020 11:59'	System	27 Aug 2020 21:06:21

US3142034

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 11 Aug 2021 21:58:56

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:25:25
Data entry locked.	System	27 Aug 2020 21:06:21
User entered 'Day 7'	System	27 Aug 2020 21:06:21

US3142034

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 11 Aug 2021 21:58:56

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:25:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8F5B9B48-1138-4DBF-A9AC-B36F0A557EB4)', Time: '2020-09-02T16:39:50', User OID: 'PatientReportedOutcome (US3142034)', ODM File OID: '51745200-8024-433e-9f62-21ebbd24c1a' User entered 'None (0)'	System	02 Sep 2020 22:40:17
	System	02 Sep 2020 22:40:17

US3142034

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 11 Aug 2021 21:58:56

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:25:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8F5B9B48-1138-4DBF-A9AC-B36F0A557EB4)', Time: '2020-09-02T16:39:56', User OID: 'PatientReportedOutcome (US3142034)', ODM File OID: '51745200-8024-433e-9f62-21ebbd24c1a' User entered 'None (0)'	System	02 Sep 2020 22:40:17
	System	02 Sep 2020 22:40:17

US3142034

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 11 Aug 2021 21:58:56

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:25:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8F5B9B48-1138-4DBF-A9AC-B36F0A557EB4)', Time: '2020-09-02T16:39:58', User OID: 'PatientReportedOutcome (US3142034)', ODM File OID: '51745200-8024-433e-9f62-21ebbd24c1a' User entered 'None (0)'	System	02 Sep 2020 22:40:17
	System	02 Sep 2020 22:40:17

US3142034

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 11 Aug 2021 21:58:56

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:25:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8F5B9B48-1138-4DBF-A9AC-B36F0A557EB4)', Time: '2020-09-02T16:40:01', User OID: 'PatientReportedOutcome (US3142034)', ODM File OID: '51745200-8024-433e-9f62-21ebbd24c1a' User entered 'None (0)'	System	02 Sep 2020 22:40:17
	System	02 Sep 2020 22:40:17

US3142034

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 11 Aug 2021 21:58:56

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:25:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8F5B9B48-1138-4DBF-A9AC-B36F0A557EB4)', Time: '2020-09-02T16:40:03', User OID: 'PatientReportedOutcome (US3142034)', ODM File OID: '51745200-8024-433e-9f62-21ebbd24c1a' User entered 'None (0)'	System	02 Sep 2020 22:40:17
	System	02 Sep 2020 22:40:17

US3142034

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 11 Aug 2021 21:58:56

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:25:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8F5B9B48-1138-4DBF-A9AC-B36F0A557EB4)', Time: '2020-09-02T16:40:04', User OID: 'PatientReportedOutcome (US3142034)', ODM File OID: '51745200-8024-433e-9f62-21ebbd24c1a' User entered 'None (0)'	System	02 Sep 2020 22:40:17
	System	02 Sep 2020 22:40:17

US3142034

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 11 Aug 2021 21:58:56

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)	05 Mar 2021 01:25:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8F5B9B48-1138-4DBF-A9AC-B36F0A557EB4)', Time: '2020-09-02T16:40:07', User OID: 'PatientReportedOutcome (US3142034)', ODM File OID: '51745200-8024-433e-9f62-21ebbd24c1a' User entered 'No (N)'	System	02 Sep 2020 22:40:17
	System	02 Sep 2020 22:40:17

US3142034

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 11 Aug 2021 21:58:56

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:25:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8F5B9B48-1138-4DBF-A9AC-B36F0A557EB4)', Time: '2020-09-02T16:40:13', User OID: 'PatientReportedOutcome (US3142034)', ODM File OID: '51745200-8024-433e-9f62-21ebbd24c1a' User entered '02 Sep 2020 16:40'	System	02 Sep 2020 22:40:17
	System	02 Sep 2020 22:40:17

US3142034

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 11 Aug 2021 21:58:56

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:25:25
User entered '02 Sep 2020 12:00'	System	27 Aug 2020 21:06:21

US3142034

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 11 Aug 2021 21:58:56

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:25:25
User entered '03 Sep 2020 11:59'	System	27 Aug 2020 21:06:21

US3142034

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 11 Aug 2021 21:58:56

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 06:09:24
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 19:03:50
User entered 'Yes (Y)'	Jami Wagner (b) (4) (b) (4)	10 Sep 2020 21:20:29

US3142034

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 11 Aug 2021 21:58:56

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 06:09:24
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 19:03:50
User entered '04 Sep 2020'	Jami Wagner (b) (4) (b) (4)	10 Sep 2020 21:20:29

US3142034

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 11 Aug 2021 21:58:56

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 06:09:24
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 19:03:50
User entered 'Contact Made (CONTACT MADE)'	Jami Wagner (b) (4) (b) (4)	10 Sep 2020 21:20:29

US3142034

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 11 Aug 2021 21:58:56

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 06:09:24
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 19:03:50
User entered empty.	Jami Wagner (b) (4) (b) (4)	10 Sep 2020 21:20:29

US3142034

Folder: Safety Call Day 36 (1)

Form: Continuing

Generated On: 11 Aug 2021 21:58:56

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 06:09:24
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 19:03:50
User entered 'Yes (Y)'	Jami Wagner (b) (4) (b) (4)	10 Sep 2020 14:18:32

US3142034

Folder: Safety Call Day 36 (1)

Form: Continuing

Generated On: 11 Aug 2021 21:58:56

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 06:09:24
User entered '1'	System	10 Sep 2020 14:18:32

US3142034

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 11 Aug 2021 21:58:56

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 06:09:24
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 19:03:50
User entered 'Yes (Y)'	Jami Wagner (b) (4) (b) (4)	10 Sep 2020 14:19:01

US3142034

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 11 Aug 2021 21:58:56

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 06:09:24
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:03:50
User closed query 'Safety Call Day 43 'Date of Contact or Contact Attempt' is less than 14 days or greater than 17 days after Visit 2 Treatment Date on the Exposure Form. Please review and reconcile, or clarify.' (Site from System).	(b) (4), (b) (6)	18 Sep 2020 15:31:15
Query 'Safety Call Day 43 'Date of Contact or Contact Attempt' is less than 14 days or greater than 17 days after Visit 2 Treatment Date on the Exposure Form. Please review and reconcile, or clarify.' answered with 'data is correct' (Site from System).	Jami Wagner (b) (4)	10 Sep 2020 14:19:29
User opened query 'Safety Call Day 43 'Date of Contact or Contact Attempt' is less than 14 days or greater than 17 days after Visit 2 Treatment Date on the Exposure Form. Please review and reconcile, or clarify.' (Site from System).	System	10 Sep 2020 14:19:01
User entered '09 Sep 2020'	Jami Wagner (b) (4)	10 Sep 2020 14:19:01

US3142034

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 11 Aug 2021 21:58:56

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 06:09:24
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 19:03:50
User entered 'Contact Made (CONTACT MADE)'	Jami Wagner (b) (4) (b) (4)	10 Sep 2020 14:19:01

US3142034

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 11 Aug 2021 21:58:56

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 06:09:24
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 19:03:50
User entered empty.	Jami Wagner (b) (4) (b) (4)	10 Sep 2020 14:19:01

US3142034

Folder: Safety Call Day 43 (1)

Form: Continuing

Generated On: 11 Aug 2021 21:58:56

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 06:09:24
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 19:03:50
User entered 'Yes (Y)'	Jami Wagner (b) (4) (b) (4)	10 Sep 2020 14:19:37

US3142034

Folder: Safety Call Day 43 (1)

Form: Continuing

Generated On: 11 Aug 2021 21:58:56

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 06:09:24
User entered '1'	System	10 Sep 2020 14:19:37

US3142034

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 11 Aug 2021 21:58:56

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 06:09:24
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 19:03:50
User entered 'Yes (Y)'	Dalia Jeronimo (b) (4) (b) (4)	23 Sep 2020 21:20:37

US3142034

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 11 Aug 2021 21:58:56

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 06:09:24
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 19:03:50
User entered '18 Sep 2020'	Dalia Jeronimo (b) (4) (b) (4)	23 Sep 2020 21:20:37

US3142034

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 11 Aug 2021 21:58:56

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 06:09:24
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 19:03:50
User entered 'Contact Made (CONTACT MADE)'	Dalia Jeronimo (b) (4) (b) (4)	23 Sep 2020 21:20:37

US3142034

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 11 Aug 2021 21:58:56

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 06:09:24
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 19:03:50
User entered empty.	Dalia Jeronimo (b) (4) (b) (4)	23 Sep 2020 21:20:37

US3142034

Folder: Safety Call Day 50 (1)

Form: Continuing

Generated On: 11 Aug 2021 21:58:56

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 06:09:24
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 19:03:50
User entered 'Yes (Y)'	Dalia Jeronimo (b) (4) (b) (4)	23 Sep 2020 21:20:25

US3142034

Folder: Safety Call Day 50 (1)

Form: Continuing

Generated On: 11 Aug 2021 21:58:56

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 06:09:24
User entered '1'	System	23 Sep 2020 21:20:25

US3142034

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 11 Aug 2021 21:58:56

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 06:09:24
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 19:03:50
User entered 'Yes (Y)'	Shelby Pickle (b) (4) (b) (4)	29 Sep 2020 20:44:16

US3142034

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 11 Aug 2021 21:58:56

[Visit date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 06:09:24
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 19:03:50
User entered '29 Sep 2020'	Shelby Pickle (b) (4) (b) (4)	29 Sep 2020 20:44:16

US3142034

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 11 Aug 2021 21:58:56

[Was visit performed at the participant's home or at the clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 06:09:24
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 19:03:50
User entered 'Clinic (Clinic)'	Shelby Pickle (b) (4) (b) (4)	29 Sep 2020 20:44:16

US3142034

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 11 Aug 2021 21:58:56

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 06:09:24
User entered 'VISIT3'	System	29 Sep 2020 20:44:16

US3142034

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 21:58:56

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 06:09:24
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 19:03:50
User entered 'Yes (Y)'	Shelby Pickle (b) (4) (b) (4)	29 Sep 2020 20:45:01

US3142034

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 21:58:56

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 06:09:24
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 19:03:50
User entered '29 Sep 2020'	Shelby Pickle (b) (4) (b) (4)	29 Sep 2020 20:45:01

US3142034

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 21:58:56

Time of assessment (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 06:09:24
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 19:03:50
User entered '14:00'	Shelby Pickle (b) (4) (b) (4)	29 Sep 2020 20:45:01

US3142034

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 21:58:56

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 06:09:24
User entered '29 Sep 2020 14:00'	System	29 Sep 2020 20:45:01

US3142034

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 21:58:56

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 06:09:24
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 19:03:50
User entered '98.0' F	Shelby Pickle (b) (4) (b) (4)	29 Sep 2020 20:45:01

US3142034

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 21:58:56

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 06:09:24
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 19:03:50
User entered 'Other (Other)'	Shelby Pickle (b) (4) (b) (4)	29 Sep 2020 20:45:01

US3142034

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 21:58:56

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 06:09:24
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 19:03:50
User entered 'Temporal'	Shelby Pickle (b) (4) (b) (4)	29 Sep 2020 20:45:01

US3142034

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 21:58:56

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 06:09:24
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 19:03:50
User entered '67'	Shelby Pickle (b) (4) (b) (4)	29 Sep 2020 20:45:01

US3142034

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 21:58:56

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 06:09:24
User entered 'bpm'	System	29 Sep 2020 20:45:01

US3142034

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 21:58:56

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 06:09:24
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 19:03:50
User entered '10'	Shelby Pickle (b) (4) (b) (4)	29 Sep 2020 20:45:01

US3142034

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 21:58:56

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 06:09:24
User entered 'breaths/min'	System	29 Sep 2020 20:45:01

US3142034

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 21:58:56

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 06:09:24
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 19:03:50
User entered '103'	Shelby Pickle (b) (4) (b) (4)	29 Sep 2020 20:45:01

US3142034

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 21:58:56

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 06:09:24
User entered 'mmHg'	System	29 Sep 2020 20:45:01

US3142034

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 21:58:56

[Diastolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 06:09:24
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 19:03:50
User entered '69'	Shelby Pickle (b) (4) (b) (4)	29 Sep 2020 20:45:01

US3142034

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 21:58:56

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 06:09:24
User entered 'mmHg'	System	29 Sep 2020 20:45:01

US3142034

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 21:58:56

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 06:09:24

US3142034

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 21:58:56

[Weight \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 06:09:24

US3142034

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Generated On: 11 Aug 2021 21:58:56

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 06:09:24
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 19:03:50
User entered 'Yes (Y)'	Shelby Pickle (b) (4) (b) (4)	29 Sep 2020 20:45:09

US3142034

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Generated On: 11 Aug 2021 21:58:56

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 06:09:24
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:03:50
User entered '29 Sep 2020'	(b) (4) Shelby Pickle (b) (4)	29 Sep 2020 20:45:09

US3142034

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 21:58:56

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 06:09:24
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 19:03:50
User entered 'Yes (Y)'	Shelby Pickle (b) (4) (b) (4)	29 Sep 2020 20:45:19

US3142034

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 21:58:56

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 06:09:24
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 19:03:50
User entered '29 Sep 2020'	Shelby Pickle (b) (4) (b) (4)	29 Sep 2020 20:45:19

US3142034

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 21:58:56

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 06:09:24
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 19:03:50
User entered '14:15'	Shelby Pickle (b) (4) (b) (4)	29 Sep 2020 20:45:19

US3142034

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 21:58:56

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 06:09:24
User entered '29 Sep 2020 14:15'	System	29 Sep 2020 20:45:19

US3142034

Folder: Visit 3 Day 57 (1)

Form: Continuing

Generated On: 11 Aug 2021 21:58:56

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 06:09:24
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 19:03:50
User entered 'Yes (Y)'	Shelby Pickle (b) (4) (b) (4)	29 Sep 2020 20:45:25

US3142034

Folder: Visit 3 Day 57 (1)

Form: Continuing

Generated On: 11 Aug 2021 21:58:56

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 06:09:24
User entered '1'	System	29 Sep 2020 20:45:25

US3142034

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:58:56

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 11:58:45
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 11:00:46
Data entry locked.	System	31 Jul 2020 20:02:05
User entered 'Day 64'	System	31 Jul 2020 20:02:05

US3142034

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:58:56

[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)	24 Apr 2021 11:58:45
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 11:00:46

US3142034

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:58:56

Have you been exposed to someone with 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)	24 Apr 2021 11:58:45
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 11:00:46

US3142034

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:58:56

Please 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)	24 Apr 2021 11:58:45
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 11:00:46

US3142034

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:58:56

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)	24 Apr 2021 11:58:45
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 11:00:46

US3142034

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:58:56

Fever (Temperature \geq 100.4°F/38°C)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 11:58:45
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 11:00:46

US3142034

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:58:56

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 11:58:45
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 11:00:46

US3142034

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:58:56

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 11:58:45
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 11:00:46

US3142034

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:58:56

[Shortness of breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 11:58:45
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 11:00:46

US3142034

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:58:56

[Difficulty breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 11:58:45
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 11:00:46

US3142034

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:58:56

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 11:58:45
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 11:00:46

US3142034

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:58:56

[Muscle aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 11:58:45
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 11:00:46

US3142034

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:58:56

[Body aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 11:58:45
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 11:00:46

US3142034

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:58:56

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 11:58:45
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 11:00:46

US3142034

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:58:56

[New loss of taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 11:58:45
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 11:00:46

US3142034

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:58:56

[New loss of smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 11:58:45
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 11:00:46

US3142034

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:58:56

[Sore throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 11:58:45
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 11:00:46

US3142034

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:58:56

[Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 11:58:45
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 11:00:46

US3142034

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:58:56

[Runny nose](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 11:58:45
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 11:00:46

US3142034

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:58:56

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 11:58:45
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 11:00:46

US3142034

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:58:56

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 11:58:45
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 11:00:46

US3142034

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:58:56

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 11:58:45
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 11:00:46

US3142034

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:58:56

Please 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)	24 Apr 2021 11:58:45
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 11:00:46

US3142034

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:58:56

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)	24 Apr 2021 11:58:45
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 11:00:46

US3142034

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:58:56

Please 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)	24 Apr 2021 11:58:45
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 11:00:46

US3142034

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:58:56

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 11:58:45
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 11:00:46

US3142034

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:58:56

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 11:58:45
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 11:00:46
Data entry locked.	System	31 Jul 2020 20:02:05
User entered '30 Sep 2020 00:01'	System	31 Jul 2020 20:02:05

US3142034

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:58:56

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 11:58:45
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 11:00:46
Data entry locked.	System	31 Jul 2020 20:02:05
User entered '04 Oct 2020 23:59'	System	31 Jul 2020 20:02:05

US3142034

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:58:56

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 11:58:45
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 11:00:46
Data entry locked.	System	31 Jul 2020 20:02:05
User entered 'Day 71'	System	31 Jul 2020 20:02:05

US3142034

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:58:56

[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)	24 Apr 2021 11:58:45
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 11:00:46

US3142034

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:58:56

Have you been exposed to someone with 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)	24 Apr 2021 11:58:45
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 11:00:46

US3142034

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:58:56

Please 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)	24 Apr 2021 11:58:45
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 11:00:46

US3142034

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:58:56

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)	24 Apr 2021 11:58:45
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 11:00:46

US3142034

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:58:56

Fever (Temperature \geq 100.4°F/38°C)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 11:58:45
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 11:00:46

US3142034

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:58:56

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 11:58:45
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 11:00:46

US3142034

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:58:56

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 11:58:45
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 11:00:46

US3142034

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:58:56

[Shortness of breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 11:58:45
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 11:00:46

US3142034

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:58:56

[Difficulty breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 11:58:45
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 11:00:46

US3142034

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:58:56

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 11:58:45
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 11:00:46

US3142034

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:58:56

[Muscle aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 11:58:45
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 11:00:46

US3142034

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:58:56

[Body aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 11:58:45
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 11:00:46

US3142034

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:58:56

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 11:58:45
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 11:00:46

US3142034

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:58:56

[New loss of taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 11:58:45
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 11:00:46

US3142034

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:58:56

[New loss of smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 11:58:45
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 11:00:46

US3142034

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:58:56

[Sore throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 11:58:45
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 11:00:46

US3142034

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:58:56

[Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 11:58:45
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 11:00:46

US3142034

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:58:56

[Runny nose](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 11:58:45
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 11:00:46

US3142034

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:58:56

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 11:58:45
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 11:00:46

US3142034

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:58:56

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 11:58:45
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 11:00:46

US3142034

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:58:56

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 11:58:45
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 11:00:46

US3142034

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:58:56

Please 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)	24 Apr 2021 11:58:45
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 11:00:46

US3142034

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:58:56

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)	24 Apr 2021 11:58:45
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 11:00:46

US3142034

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:58:56

Please 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)	24 Apr 2021 11:58:45
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 11:00:46

US3142034

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:58:56

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 11:58:45
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 11:00:46

US3142034

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:58:56

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 11:58:45
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 11:00:46
Data entry locked.	System	31 Jul 2020 20:02:05
User entered '07 Oct 2020 00:01'	System	31 Jul 2020 20:02:05

US3142034

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:58:56

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 11:58:45
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 11:00:46
Data entry locked.	System	31 Jul 2020 20:02:05
User entered '11 Oct 2020 23:59'	System	31 Jul 2020 20:02:05

US3142034

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:58:56

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:25:25
Data entry locked.	System	31 Jul 2020 20:02:05
User entered 'Day 78'	System	31 Jul 2020 20:02:05

US3142034

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:58:56

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)	05 Mar 2021 01:25:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8F5B9B48-1138-4DBF-A9AC-B36F0A557EB4)', Time: '2020-10-17T18:00:29', User OID: 'PatientReportedOutcome (US3142034)', ODM File OID: '06cb8281-5804-4e94-8adb-2a37fb816a8d' User entered 'No (N)'	System	18 Oct 2020 00:00:51
	System	18 Oct 2020 00:00:51

US3142034

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:58:56

Have you been exposed to someone with 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)	05 Mar 2021 01:25:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8F5B9B48-1138-4DBF-A9AC-B36F0A557EB4)', Time: '2020-10-17T18:00:36', User OID: 'PatientReportedOutcome (US3142034)', ODM File OID: '06cb8281-5804-4e94-8adb-2a37fb816a8d'	System	18 Oct 2020 00:00:51
User entered 'No (N)'	System	18 Oct 2020 00:00:51

US3142034

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:58:56

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:25:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8F5B9B48-1138-4DBF-A9AC-B36F0A557EB4)', Time: '2020-10-17T18:00:48', User OID: 'PatientReportedOutcome (US3142034)', ODM File OID: '06cb8281-5804-4e94-8adb-2a37fb816a8d' User entered '17 Oct 2020 18:00:48'	System	18 Oct 2020 00:00:51
	System	18 Oct 2020 00:00:51

US3142034

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:58:56

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:25:25
Data entry locked.	System	31 Jul 2020 20:02:05
User entered '14 Oct 2020 00:01'	System	31 Jul 2020 20:02:05

US3142034

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:58:56

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:25:25
Data entry locked.	System	31 Jul 2020 20:02:05
User entered '18 Oct 2020 23:59'	System	31 Jul 2020 20:02:05

US3142034

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:58:56

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 11:58:45
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 11:00:46
Data entry locked.	System	31 Jul 2020 20:02:05
User entered 'Day 92'	System	31 Jul 2020 20:02:05

US3142034

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:58:56

[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)	24 Apr 2021 11:58:45
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 11:00:46

US3142034

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:58:56

Have you been exposed to someone with 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)	24 Apr 2021 11:58:45
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 11:00:46

US3142034

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:58:56

Please 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)	24 Apr 2021 11:58:45
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 11:00:46

US3142034

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:58:56

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)	24 Apr 2021 11:58:45
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 11:00:46

US3142034

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:58:56

Fever (Temperature \geq 100.4°F/38°C)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 11:58:45
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 11:00:46

US3142034

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:58:56

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 11:58:45
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 11:00:46

US3142034

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:58:56

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 11:58:45
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 11:00:46

US3142034

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:58:56

[Shortness of breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 11:58:45
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 11:00:46

US3142034

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:58:56

[Difficulty breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 11:58:45
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 11:00:46

US3142034

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:58:56

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 11:58:45
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 11:00:46

US3142034

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:58:56

[Muscle aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 11:58:45
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 11:00:46

US3142034

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:58:56

[Body aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 11:58:45
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 11:00:46

US3142034

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:58:56

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 11:58:45
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 11:00:46

US3142034

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:58:56

[New loss of taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 11:58:45
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 11:00:46

US3142034

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:58:56

[New loss of smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 11:58:45
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 11:00:46

US3142034

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:58:56

[Sore throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 11:58:45
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 11:00:46

US3142034

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:58:56

[Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 11:58:45
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 11:00:46

US3142034

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:58:56

[Runny nose](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 11:58:45
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 11:00:46

US3142034

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:58:56

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 11:58:45
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 11:00:46

US3142034

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:58:56

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 11:58:45
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 11:00:46

US3142034

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:58:56

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 11:58:45
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 11:00:46

US3142034

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:58:56

Please 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)	24 Apr 2021 11:58:45
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 11:00:46

US3142034

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

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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)	24 Apr 2021 11:58:45
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 11:00:46

US3142034

Folder: 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.](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 11:58:45
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 11:00:46

US3142034

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[Date and time of submission](#)

Audit	User	Time (GMT)
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US3142034

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[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 11:58:45
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 11:00:46
Data entry locked.	System	31 Jul 2020 20:02:05
User entered '28 Oct 2020 00:01'	System	31 Jul 2020 20:02:05

US3142034

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:58:56

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 11:58:45
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 11:00:46
Data entry locked.	System	31 Jul 2020 20:02:05
User entered '01 Nov 2020 23:59'	System	31 Jul 2020 20:02:05

US3142034

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:58:56

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:25:25
Data entry locked.	System	31 Jul 2020 20:02:05
User entered 'Day 99'	System	31 Jul 2020 20:02:05

US3142034

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:58:56

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)	05 Mar 2021 01:25:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8F5B9B48-1138-4DBF-A9AC-B36F0A557EB4)', Time: '2020-11-08T18:58:19', User OID: 'PatientReportedOutcome (US3142034)', ODM File OID: '4dd52708-b4a3-4284-906c-7c9dc0b37884'	System	09 Nov 2020 01:58:37
User entered 'No (N)'	System	09 Nov 2020 01:58:37

US3142034

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:58:56

Have you been exposed to someone with 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)	05 Mar 2021 01:25:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8F5B9B48-1138-4DBF-A9AC-B36F0A557EB4)', Time: '2020-11-08T18:58:29', User OID: 'PatientReportedOutcome (US3142034)', ODM File OID: '4dd52708-b4a3-4284-906c-7c9dc0b37884'	System	09 Nov 2020 01:58:37
User entered 'No (N)'	System	09 Nov 2020 01:58:37

US3142034

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:58:56

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:25:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8F5B9B48-1138-4DBF-A9AC-B36F0A557EB4)', Time: '2020-11-08T18:58:35', User OID: 'PatientReportedOutcome (US3142034)', ODM File OID: '4dd52708-b4a3-4284-906c-7c9dc0b37884'	System	09 Nov 2020 01:58:37
User entered '08 Nov 2020 18:58:35'	System	09 Nov 2020 01:58:37

US3142034

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

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[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:25:25
Data entry locked.	System	31 Jul 2020 20:02:05
User entered '04 Nov 2020 00:01'	System	31 Jul 2020 20:02:05

US3142034

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:58:56

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:25:25
Data entry locked.	System	31 Jul 2020 20:02:05
User entered '08 Nov 2020 23:59'	System	31 Jul 2020 20:02:05

US3142034

Folder: Safety Follow Up Diary (1)

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TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 11:58:45
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 11:00:46
Data entry locked.	System	31 Jul 2020 20:02:05
User entered 'Day 106'	System	31 Jul 2020 20:02:05

US3142034

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:58:56

[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)	24 Apr 2021 11:58:45
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 11:00:46

US3142034

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:58:56

Have you been exposed to someone with 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)	24 Apr 2021 11:58:45
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 11:00:46

US3142034

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:58:56

Please 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)	24 Apr 2021 11:58:45
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 11:00:46

US3142034

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:58:56

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)	24 Apr 2021 11:58:45
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 11:00:46

US3142034

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:58:56

Fever (Temperature \geq 100.4°F/38°C)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 11:58:45
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 11:00:46

US3142034

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:58:56

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 11:58:45
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 11:00:46

US3142034

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:58:56

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 11:58:45
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 11:00:46

US3142034

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:58:56

[Shortness of breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 11:58:45
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 11:00:46

US3142034

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:58:56

[Difficulty breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 11:58:45
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 11:00:46

US3142034

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:58:56

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 11:58:45
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 11:00:46

US3142034

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:58:56

[Muscle aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 11:58:45
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 11:00:46

US3142034

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:58:56

[Body aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 11:58:45
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 11:00:46

US3142034

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:58:56

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 11:58:45
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 11:00:46

US3142034

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:58:56

[New loss of taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 11:58:45
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 11:00:46

US3142034

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:58:56

[New loss of smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 11:58:45
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 11:00:46

US3142034

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:58:56

[Sore throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 11:58:45
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 11:00:46

US3142034

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:58:56

[Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 11:58:45
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 11:00:46

US3142034

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:58:56

[Runny nose](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 11:58:45
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 11:00:46

US3142034

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:58:56

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 11:58:45
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 11:00:46

US3142034

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:58:56

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 11:58:45
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 11:00:46

US3142034

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:58:56

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 11:58:45
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 11:00:46

US3142034

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:58:56

Please 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)	24 Apr 2021 11:58:45
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 11:00:46

US3142034

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:58:56

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)	24 Apr 2021 11:58:45
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 11:00:46

US3142034

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:58:56

Please 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)	24 Apr 2021 11:58:45
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 11:00:46

US3142034

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:58:56

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 11:58:45
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 11:00:46

US3142034

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:58:56

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 11:58:45
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 11:00:46
Data entry locked.	System	31 Jul 2020 20:02:05
User entered '11 Nov 2020 00:01'	System	31 Jul 2020 20:02:05

US3142034

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:58:56

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 11:58:45
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 11:00:46
Data entry locked.	System	31 Jul 2020 20:02:05
User entered '15 Nov 2020 23:59'	System	31 Jul 2020 20:02:05

US3142034

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:58:56

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:25:25
Data entry locked.	System	31 Jul 2020 20:02:05
User entered 'Day 113'	System	31 Jul 2020 20:02:05

US3142034

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:58:56

[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)	05 Mar 2021 01:25:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8F5B9B48-1138-4DBF-A9AC-B36F0A557EB4)', Time: '2020-11-18T08:48:14', User OID: 'PatientReportedOutcome (US3142034)', ODM File OID: 'd8653dfb-ddd7-408a-8d5f-a113b86507e8' User entered 'No (N)'	System	18 Nov 2020 15:48:38
	System	18 Nov 2020 15:48:38

US3142034

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:58:56

Have you been exposed to someone with 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)	05 Mar 2021 01:25:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8F5B9B48-1138-4DBF-A9AC-B36F0A557EB4)', Time: '2020-11-18T08:48:19', User OID: 'PatientReportedOutcome (US3142034)', ODM File OID: 'd8653dfb-ddd7-408a-8d5f-a113b86507e8'	System	18 Nov 2020 15:48:38
User entered 'No (N)'	System	18 Nov 2020 15:48:38

US3142034

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:58:56

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:25:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8F5B9B48-1138-4DBF-A9AC-B36F0A557EB4)', Time: '2020-11-18T08:48:35', User OID: 'PatientReportedOutcome (US3142034)', ODM File OID: 'd8653dfb-ddd7-408a-8d5f-a113b86507e8' User entered '18 Nov 2020 08:48:35'	System	18 Nov 2020 15:48:38
	System	18 Nov 2020 15:48:38

US3142034

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:58:56

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:25:25
Data entry locked.	System	31 Jul 2020 20:02:05
User entered '18 Nov 2020 00:01'	System	31 Jul 2020 20:02:05

US3142034

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:58:56

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:25:25
Data entry locked.	System	31 Jul 2020 20:02:05
User entered '22 Nov 2020 23:59'	System	31 Jul 2020 20:02:05

US3142034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:58:56

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:00:46
Amendment Manager: User entered 'Day 110'	System	19 Nov 2020 11:00:46

US3142034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:58:56

[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 (8F5B9B48-1138-4DBF-A9AC-B36F0A557EB4)', Time: '2020-11-19T16:30:21', User OID: 'PatientReportedOutcome (US3142034)', ODM File OID: '36c50978-59f0-4218-86ec-ba52300542af'	System	19 Nov 2020 23:30:36
User entered 'No (N)'	System	19 Nov 2020 23:30:36

US3142034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:58:56

[Have you been exposed to someone with 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 (8F5B9B48-1138-4DBF-A9AC-B36F0A557EB4)', Time: '2020-11-19T16:30:26', User OID: 'PatientReportedOutcome (US3142034)', ODM File OID: '36c50978-59f0-4218-86ec-ba52300542af'	System	19 Nov 2020 23:30:36
User entered 'No (N)'	System	19 Nov 2020 23:30:36

US3142034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:58:56

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8F5B9B48-1138-4DBF-A9AC-B36F0A557EB4)', Time: '2020-11-19T16:30:30', User OID: 'PatientReportedOutcome (US3142034)', ODM File OID: '36c50978-59f0-4218-86ec-ba52300542af' User entered '19 Nov 2020 16:30:30'	System	19 Nov 2020 23:30:36
	System	19 Nov 2020 23:30:36

US3142034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:58:56

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:00:46
Amendment Manager: User entered '15 Nov 2020 00:01'	System	19 Nov 2020 11:00:46

US3142034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:58:56

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:00:46
Amendment Manager: User entered '19 Nov 2020 23:59'	System	19 Nov 2020 11:00:46

US3142034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:58:56

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:00:46
Amendment Manager: User entered 'Day 117'	System	19 Nov 2020 11:00:46

US3142034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:58:56

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:00:46
Amendment Manager: User entered '22 Nov 2020 00:01'	System	19 Nov 2020 11:00:46

US3142034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:58:56

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:00:46
Amendment Manager: User entered '26 Nov 2020 23:59'	System	19 Nov 2020 11:00:46

US3142034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:58:56

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:00:46
Amendment Manager: User entered 'Day 124'	System	19 Nov 2020 11:00:46

US3142034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:58:56

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:00:46
Amendment Manager: User entered '29 Nov 2020 00:01'	System	19 Nov 2020 11:00:46

US3142034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:58:56

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:00:46
Amendment Manager: User entered '03 Dec 2020 23:59'	System	19 Nov 2020 11:00:46

US3142034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:58:56

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:00:46
Amendment Manager: User entered 'Day 131'	System	19 Nov 2020 11:00:46

US3142034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:58:56

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:00:46
Amendment Manager: User entered '06 Dec 2020 00:01'	System	19 Nov 2020 11:00:46

US3142034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:58:56

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:00:46
Amendment Manager: User entered '10 Dec 2020 23:59'	System	19 Nov 2020 11:00:46

US3142034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:58:56

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:00:46
Amendment Manager: User entered 'Day 138'	System	19 Nov 2020 11:00:46

US3142034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:58:56

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:00:46
Amendment Manager: User entered '13 Dec 2020 00:01'	System	19 Nov 2020 11:00:46

US3142034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:58:56

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:00:46
Amendment Manager: User entered '17 Dec 2020 23:59'	System	19 Nov 2020 11:00:46

US3142034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:58:56

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:00:46
Amendment Manager: User entered 'Day 145'	System	19 Nov 2020 11:00:46

US3142034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:58:56

[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 (8F5B9B48-1138-4DBF-A9AC-B36F0A557EB4)', Time: '2020-12-21T09:23:54', User OID: 'PatientReportedOutcome (US3142034)', ODM File OID: 'e27c676f-4aca-4821-b618-d9496ba380e7'	System	21 Dec 2020 16:25:28
User entered 'Yes (Y)'	System	21 Dec 2020 16:25:28

US3142034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:58:56

Have you been exposed to someone with 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 (8F5B9B48-1138-4DBF-A9AC-B36F0A557EB4)', Time: '2020-12-21T09:24:40', User OID: 'PatientReportedOutcome (US3142034)', ODM File OID: 'e27c676f-4aca-4821-b618-d9496ba380e7'	System	21 Dec 2020 16:25:28
User entered 'Yes (Y)'	System	21 Dec 2020 16:25:28

US3142034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:58:56

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8F5B9B48-1138-4DBF-A9AC-B36F0A557EB4)', Time: '2020-12-21T09:24:44', User OID: 'PatientReportedOutcome (US3142034)', ODM File OID: 'e27c676f-4aca-4821-b618-d9496ba380e7'	System	21 Dec 2020 16:25:28
User entered 'I confirm I have read this message and will call the study clinic immediately (9)'	System	21 Dec 2020 16:25:28

US3142034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:58:56

[Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8F5B9B48-1138-4DBF-A9AC-B36F0A557EB4)', Time: '2020-12-21T09:24:50', User OID: 'PatientReportedOutcome (US3142034)', ODM File OID: 'e27c676f-4aca-4821-b618-d9496ba380e7'	System	21 Dec 2020 16:25:28
User entered 'No (N)'	System	21 Dec 2020 16:25:28

US3142034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:58:56

Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8F5B9B48-1138-4DBF-A9AC-B36F0A557EB4)', Time: '2020-12-21T09:25:00', User OID: 'PatientReportedOutcome (US3142034)', ODM File OID: 'e27c676f-4aca-4821-b618-d9496ba380e7'	System	21 Dec 2020 16:25:28
User entered 'No (N)'	System	21 Dec 2020 16:25:28

US3142034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:58:56

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8F5B9B48-1138-4DBF-A9AC-B36F0A557EB4)', Time: '2020-12-21T09:25:17', User OID: 'PatientReportedOutcome (US3142034)', ODM File OID: 'e27c676f-4aca-4821-b618-d9496ba380e7' User entered '21 Dec 2020 09:25:17'	System	21 Dec 2020 16:25:28
	System	21 Dec 2020 16:25:28

US3142034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:58:56

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:00:46
Amendment Manager: User entered '20 Dec 2020 00:01'	System	19 Nov 2020 11:00:46

US3142034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:58:56

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:00:46
Amendment Manager: User entered '24 Dec 2020 23:59'	System	19 Nov 2020 11:00:46

US3142034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:58:56

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:00:46
Amendment Manager: User entered 'Day 152'	System	19 Nov 2020 11:00:46

US3142034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:58:56

[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 (8F5B9B48-1138-4DBF-A9AC-B36F0A557EB4)', Time: '2020-12-27T13:03:39', User OID: 'PatientReportedOutcome (US3142034)', ODM File OID: '3b5fb004-f4a7-4d95-924e-e829830e037e'	System	27 Dec 2020 20:04:07
User entered 'No (N)'	System	27 Dec 2020 20:04:07

US3142034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:58:56

Have you been exposed to someone with 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 (8F5B9B48-1138-4DBF-A9AC-B36F0A557EB4)', Time: '2020-12-27T13:03:43', User OID: 'PatientReportedOutcome (US3142034)', ODM File OID: '3b5fb004-f4a7-4d95-924e-e829830e037e'	System	27 Dec 2020 20:04:07
User entered 'Yes (Y)'	System	27 Dec 2020 20:04:07

US3142034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:58:56

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8F5B9B48-1138-4DBF-A9AC-B36F0A557EB4)', Time: '2020-12-27T13:03:47', User OID: 'PatientReportedOutcome (US3142034)', ODM File OID: '3b5fb004-f4a7-4d95-924e-e829830e037e'	System	27 Dec 2020 20:04:07
User entered 'I confirm I have read this message and will call the study clinic immediately (9)'	System	27 Dec 2020 20:04:07

US3142034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:58:56

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8F5B9B48-1138-4DBF-A9AC-B36F0A557EB4)', Time: '2020-12-27T13:03:57', User OID: 'PatientReportedOutcome (US3142034)', ODM File OID: '3b5fb004-f4a7-4d95-924e-e829830e037e' User entered '27 Dec 2020 13:03:57'	System	27 Dec 2020 20:04:07
	System	27 Dec 2020 20:04:07

US3142034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:58:56

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:00:46
Amendment Manager: User entered '27 Dec 2020 00:01'	System	19 Nov 2020 11:00:46

US3142034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:58:56

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:00:46
Amendment Manager: User entered '31 Dec 2020 23:59'	System	19 Nov 2020 11:00:46

US3142034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:58:56

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:00:46
Amendment Manager: User entered 'Day 159'	System	19 Nov 2020 11:00:46

US3142034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:58:56

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:00:46
Amendment Manager: User entered '03 Jan 2021 00:01'	System	19 Nov 2020 11:00:46

US3142034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:58:56

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:00:46
Amendment Manager: User entered '07 Jan 2021 23:59'	System	19 Nov 2020 11:00:46

US3142034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:58:56

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:00:46
Amendment Manager: User entered 'Day 166'	System	19 Nov 2020 11:00:46

US3142034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:58:56

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:00:46
Amendment Manager: User entered '10 Jan 2021 00:01'	System	19 Nov 2020 11:00:46

US3142034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:58:56

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:00:46
Amendment Manager: User entered '14 Jan 2021 23:59'	System	19 Nov 2020 11:00:46

US3142034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:58:56

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:00:46
Amendment Manager: User entered 'Day 173'	System	19 Nov 2020 11:00:46

US3142034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:58:56

[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 (8F5B9B48-1138-4DBF-A9AC-B36F0A557EB4)', Time: '2021-01-17T15:26:31', User OID: 'PatientReportedOutcome (US3142034)', ODM File OID: '178b0ffb-c7c4-4656-a3ab-c1e400cd9827'	System	17 Jan 2021 22:26:43
User entered 'No (N)'	System	17 Jan 2021 22:26:43

US3142034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:58:56

Have you been exposed to someone with 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 (8F5B9B48-1138-4DBF-A9AC-B36F0A557EB4)', Time: '2021-01-17T15:26:34', User OID: 'PatientReportedOutcome (US3142034)', ODM File OID: '178b0ffb-c7c4-4656-a3ab-c1e400cd9827'	System	17 Jan 2021 22:26:43
User entered 'No (N)'	System	17 Jan 2021 22:26:43

US3142034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:58:56

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8F5B9B48-1138-4DBF-A9AC-B36F0A557EB4)', Time: '2021-01-17T15:26:39', User OID: 'PatientReportedOutcome (US3142034)', ODM File OID: '178b0ffb-c7c4-4656-a3ab-c1e400cd9827'	System	17 Jan 2021 22:26:43
User entered '17 Jan 2021 15:26:39'	System	17 Jan 2021 22:26:43

US3142034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:58:56

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:00:46
Amendment Manager: User entered '17 Jan 2021 00:01'	System	19 Nov 2020 11:00:46

US3142034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:58:56

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:00:46
Amendment Manager: User entered '21 Jan 2021 23:59'	System	19 Nov 2020 11:00:46

US3142034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:58:56

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:00:46
Amendment Manager: User entered 'Day 180'	System	19 Nov 2020 11:00:46

US3142034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:58:56

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:00:46
Amendment Manager: User entered '24 Jan 2021 00:01'	System	19 Nov 2020 11:00:46

US3142034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:58:56

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:00:46
Amendment Manager: User entered '28 Jan 2021 23:59'	System	19 Nov 2020 11:00:46

US3142034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:58:56

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:00:46
Amendment Manager: User entered 'Day 187'	System	19 Nov 2020 11:00:46

US3142034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:58:56

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:00:46
Amendment Manager: User entered '31 Jan 2021 00:01'	System	19 Nov 2020 11:00:46

US3142034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:58:56

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:00:46
Amendment Manager: User entered '04 Feb 2021 23:59'	System	19 Nov 2020 11:00:46

US3142034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:58:56

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:00:46
Amendment Manager: User entered 'Day 194'	System	19 Nov 2020 11:00:46

US3142034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:58:56

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:00:46
Amendment Manager: User entered '07 Feb 2021 00:01'	System	19 Nov 2020 11:00:46

US3142034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:58:56

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:00:46
Amendment Manager: User entered '11 Feb 2021 23:59'	System	19 Nov 2020 11:00:46

US3142034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:58:56

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:00:46
Amendment Manager: User entered 'Day 201'	System	19 Nov 2020 11:00:46

US3142034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:58:56

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:00:46
Amendment Manager: User entered '14 Feb 2021 00:01'	System	19 Nov 2020 11:00:46

US3142034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:58:56

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:00:46
Amendment Manager: User entered '18 Feb 2021 23:59'	System	19 Nov 2020 11:00:46

US3142034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:58:56

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:00:46
Amendment Manager: User entered 'Day 208'	System	19 Nov 2020 11:00:46

US3142034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:58:56

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:00:46
Amendment Manager: User entered '21 Feb 2021 00:01'	System	19 Nov 2020 11:00:46

US3142034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:58:56

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:00:46
Amendment Manager: User entered '25 Feb 2021 23:59'	System	19 Nov 2020 11:00:46

US3142034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:58:56

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:00:46
Amendment Manager: User entered 'Day 215'	System	19 Nov 2020 11:00:46

US3142034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:58:56

[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 (8F5B9B48-1138-4DBF-A9AC-B36F0A557EB4)', Time: '2021-03-01T06:59:51', User OID: 'PatientReportedOutcome (US3142034)', ODM File OID: '1b6cc593-2b91-4a4b-bad5-e2e3978a3c22'	System	01 Mar 2021 14:00:09
User entered 'No (N)'	System	01 Mar 2021 14:00:09

US3142034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:58:56

Have you been exposed to someone with 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 (8F5B9B48-1138-4DBF-A9AC-B36F0A557EB4)', Time: '2021-03-01T06:59:56', User OID: 'PatientReportedOutcome (US3142034)', ODM File OID: '1b6cc593-2b91-4a4b-bad5-e2e3978a3c22'	System	01 Mar 2021 14:00:09
User entered 'No (N)'	System	01 Mar 2021 14:00:09

US3142034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:58:56

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8F5B9B48-1138-4DBF-A9AC-B36F0A557EB4)', Time: '2021-03-01T07:00:05', User OID: 'PatientReportedOutcome (US3142034)', ODM File OID: '1b6cc593-2b91-4a4b-bad5-e2e3978a3c22'	System	01 Mar 2021 14:00:09
User entered '01 Mar 2021 07:00:05'	System	01 Mar 2021 14:00:09

US3142034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:58:56

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:00:46
Amendment Manager: User entered '28 Feb 2021 00:01'	System	19 Nov 2020 11:00:46

US3142034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:58:56

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:00:46
Amendment Manager: User entered '04 Mar 2021 23:59'	System	19 Nov 2020 11:00:46

US3142034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:58:56

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:00:46
Amendment Manager: User entered 'Day 222'	System	19 Nov 2020 11:00:46

US3142034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:58:56

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:00:46
Amendment Manager: User entered '07 Mar 2021 00:01'	System	19 Nov 2020 11:00:46

US3142034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:58:56

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:00:46
Amendment Manager: User entered '11 Mar 2021 23:59'	System	19 Nov 2020 11:00:46

US3142034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:58:56

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:00:46
Amendment Manager: User entered 'Day 229'	System	19 Nov 2020 11:00:46

US3142034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:58:56

[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 (8F5B9B48-1138-4DBF-A9AC-B36F0A557EB4)', Time: '2021-03-14T10:08:49', User OID: 'PatientReportedOutcome (US3142034)', ODM File OID: '9ff14bc3-ded6-4e3f-b801-a3d5ff083cd1'	System	14 Mar 2021 16:10:01
User entered 'No (N)'	System	14 Mar 2021 16:10:01

US3142034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:58:56

Have you been exposed to someone with 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 (8F5B9B48-1138-4DBF-A9AC-B36F0A557EB4)', Time: '2021-03-14T10:08:53', User OID: 'PatientReportedOutcome (US3142034)', ODM File OID: '9ff14bc3-ded6-4e3f-b801-a3d5ff083cd1'	System	14 Mar 2021 16:10:01
User entered 'No (N)'	System	14 Mar 2021 16:10:01

US3142034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:58:56

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8F5B9B48-1138-4DBF-A9AC-B36F0A557EB4)', Time: '2021-03-14T10:09:01', User OID: 'PatientReportedOutcome (US3142034)', ODM File OID: '9ff14bc3-ded6-4e3f-b801-a3d5ff083cd1' User entered '14 Mar 2021 10:09:01'	System	14 Mar 2021 16:10:01
	System	14 Mar 2021 16:10:01

US3142034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:58:56

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:00:46
Amendment Manager: User entered '14 Mar 2021 00:01'	System	19 Nov 2020 11:00:46

US3142034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:58:56

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:00:46
Amendment Manager: User entered '18 Mar 2021 23:59'	System	19 Nov 2020 11:00:46

US3142034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:58:56

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:00:46
Amendment Manager: User entered 'Day 236'	System	19 Nov 2020 11:00:46

US3142034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:58:56

[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 (8F5B9B48-1138-4DBF-A9AC-B36F0A557EB4)', Time: '2021-03-23T07:16:19', User OID: 'PatientReportedOutcome (US3142034)', ODM File OID: '60a26268-bd0a-4e07-9800-a3171ff87431' User entered 'No (N)'	System	23 Mar 2021 13:16:34
	System	23 Mar 2021 13:16:34

US3142034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:58:56

Have you been exposed to someone with 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 (8F5B9B48-1138-4DBF-A9AC-B36F0A557EB4)', Time: '2021-03-23T07:16:22', User OID: 'PatientReportedOutcome (US3142034)', ODM File OID: '60a26268-bd0a-4e07-9800-a3171ff87431'	System	23 Mar 2021 13:16:34
User entered 'No (N)'	System	23 Mar 2021 13:16:34

US3142034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:58:56

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8F5B9B48-1138-4DBF-A9AC-B36F0A557EB4)', Time: '2021-03-23T07:16:29', User OID: 'PatientReportedOutcome (US3142034)', ODM File OID: '60a26268-bd0a-4e07-9800-a3171ff87431' User entered '23 Mar 2021 07:16:29'	System	23 Mar 2021 13:16:34
	System	23 Mar 2021 13:16:34

US3142034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:58:56

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:00:46
Amendment Manager: User entered '21 Mar 2021 00:01'	System	19 Nov 2020 11:00:46

US3142034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:58:56

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:00:46
Amendment Manager: User entered '25 Mar 2021 23:59'	System	19 Nov 2020 11:00:46

US3142034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:58:56

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:00:46
Amendment Manager: User entered 'Day 243'	System	19 Nov 2020 11:00:46

US3142034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:58:56

[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 (8F5B9B48-1138-4DBF-A9AC-B36F0A557EB4)', Time: '2021-03-28T17:52:57', User OID: 'PatientReportedOutcome (US3142034)', ODM File OID: 'ac8219c2-57fb-4d76-a829-f4352c9f6ac0'	System	28 Mar 2021 23:53:08
User entered 'No (N)'	System	28 Mar 2021 23:53:08

US3142034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:58:56

Have you been exposed to someone with 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 (8F5B9B48-1138-4DBF-A9AC-B36F0A557EB4)', Time: '2021-03-28T17:53:01', User OID: 'PatientReportedOutcome (US3142034)', ODM File OID: 'ac8219c2-57fb-4d76-a829-f4352c9f6ac0'	System	28 Mar 2021 23:53:08
User entered 'No (N)'	System	28 Mar 2021 23:53:08

US3142034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:58:56

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8F5B9B48-1138-4DBF-A9AC-B36F0A557EB4)', Time: '2021-03-28T17:53:06', User OID: 'PatientReportedOutcome (US3142034)', ODM File OID: 'ac8219c2-57fb-4d76-a829-f4352c9f6ac0' User entered '28 Mar 2021 17:53:06'	System	28 Mar 2021 23:53:08
	System	28 Mar 2021 23:53:08

US3142034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:58:56

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:00:46
Amendment Manager: User entered '28 Mar 2021 00:01'	System	19 Nov 2020 11:00:46

US3142034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:58:56

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:00:46
Amendment Manager: User entered '01 Apr 2021 23:59'	System	19 Nov 2020 11:00:46

US3142034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:58:56

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:00:46
Amendment Manager: User entered 'Day 250'	System	19 Nov 2020 11:00:46

US3142034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:58:56

[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 (8F5B9B48-1138-4DBF-A9AC-B36F0A557EB4)', Time: '2021-04-08T07:23:53', User OID: 'PatientReportedOutcome (US3142034)', ODM File OID: '5e4e4203-726f-4ee2-9184-98af87862e72'	System	08 Apr 2021 13:24:04
User entered 'No (N)'	System	08 Apr 2021 13:24:04

US3142034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:58:56

Have you been exposed to someone with 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 (8F5B9B48-1138-4DBF-A9AC-B36F0A557EB4)', Time: '2021-04-08T07:23:57', User OID: 'PatientReportedOutcome (US3142034)', ODM File OID: '5e4e4203-726f-4ee2-9184-98af87862e72'	System	08 Apr 2021 13:24:04
User entered 'No (N)'	System	08 Apr 2021 13:24:04

US3142034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:58:56

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8F5B9B48-1138-4DBF-A9AC-B36F0A557EB4)', Time: '2021-04-08T07:24:00', User OID: 'PatientReportedOutcome (US3142034)', ODM File OID: '5e4e4203-726f-4ee2-9184-98af87862e72'	System	08 Apr 2021 13:24:04
User entered '08 Apr 2021 07:24:00'	System	08 Apr 2021 13:24:04

US3142034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:58:56

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:00:46
Amendment Manager: User entered '04 Apr 2021 00:01'	System	19 Nov 2020 11:00:46

US3142034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:58:56

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:00:46
Amendment Manager: User entered '08 Apr 2021 23:59'	System	19 Nov 2020 11:00:46

US3142034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:58:56

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:00:46
Amendment Manager: User entered 'Day 257'	System	19 Nov 2020 11:00:46

US3142034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:58:56

[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 (8F5B9B48-1138-4DBF-A9AC-B36F0A557EB4)', Time: '2021-04-12T12:13:44', User OID: 'PatientReportedOutcome (US3142034)', ODM File OID: '205ffb0e-fd6d-478e-92be-f9b9be8c7fdf'	System	12 Apr 2021 18:13:56
User entered 'No (N)'	System	12 Apr 2021 18:13:56

US3142034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:58:56

Have you been exposed to someone with 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 (8F5B9B48-1138-4DBF-A9AC-B36F0A557EB4)', Time: '2021-04-12T12:13:49', User OID: 'PatientReportedOutcome (US3142034)', ODM File OID: '205ffb0e-fd6d-478e-92be-f9b9be8c7fd'	System	12 Apr 2021 18:13:56
User entered 'No (N)'	System	12 Apr 2021 18:13:56

US3142034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:58:56

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8F5B9B48-1138-4DBF-A9AC-B36F0A557EB4)', Time: '2021-04-12T12:13:52', User OID: 'PatientReportedOutcome (US3142034)', ODM File OID: '205ffb0e-fd6d-478e-92be-f9b9be8c7fdf' User entered '12 Apr 2021 12:13:52'	System	12 Apr 2021 18:13:56
	System	12 Apr 2021 18:13:56

US3142034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:58:56

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:00:46
Amendment Manager: User entered '11 Apr 2021 00:01'	System	19 Nov 2020 11:00:46

US3142034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:58:56

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:00:46
Amendment Manager: User entered '15 Apr 2021 23:59'	System	19 Nov 2020 11:00:46

US3142034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:58:56

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:00:46
Amendment Manager: User entered 'Day 264'	System	19 Nov 2020 11:00:46

US3142034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:58:56

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:00:46
Amendment Manager: User entered '18 Apr 2021 00:01'	System	19 Nov 2020 11:00:46

US3142034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:58:56

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:00:46
Amendment Manager: User entered '22 Apr 2021 23:59'	System	19 Nov 2020 11:00:46

US3142034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:58:56

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:00:46
Amendment Manager: User entered 'Day 271'	System	19 Nov 2020 11:00:46

US3142034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:58:56

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:00:46
Amendment Manager: User entered '25 Apr 2021 00:01'	System	19 Nov 2020 11:00:46

US3142034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:58:56

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:00:46
Amendment Manager: User entered '29 Apr 2021 23:59'	System	19 Nov 2020 11:00:46

US3142034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:58:56

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:00:46
Amendment Manager: User entered 'Day 278'	System	19 Nov 2020 11:00:46

US3142034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:58:56

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:00:46
Amendment Manager: User entered '02 May 2021 00:01'	System	19 Nov 2020 11:00:46

US3142034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:58:56

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:00:46
Amendment Manager: User entered '06 May 2021 23:59'	System	19 Nov 2020 11:00:46

US3142034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:58:56

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:00:46
Amendment Manager: User entered 'Day 285'	System	19 Nov 2020 11:00:46

US3142034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:58:56

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:00:46
Amendment Manager: User entered '09 May 2021 00:01'	System	19 Nov 2020 11:00:46

US3142034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:58:56

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:00:46
Amendment Manager: User entered '13 May 2021 23:59'	System	19 Nov 2020 11:00:46

US3142034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:58:56

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:00:46
Amendment Manager: User entered 'Day 292'	System	19 Nov 2020 11:00:46

US3142034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:58:56

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:00:46
Amendment Manager: User entered '16 May 2021 00:01'	System	19 Nov 2020 11:00:46

US3142034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:58:56

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:00:46
Amendment Manager: User entered '20 May 2021 23:59'	System	19 Nov 2020 11:00:46

US3142034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:58:56

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:00:46
Amendment Manager: User entered 'Day 299'	System	19 Nov 2020 11:00:46

US3142034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:58:56

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:00:46
Amendment Manager: User entered '23 May 2021 00:01'	System	19 Nov 2020 11:00:46

US3142034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:58:56

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:00:46
Amendment Manager: User entered '27 May 2021 23:59'	System	19 Nov 2020 11:00:46

US3142034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:58:56

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:00:46
Amendment Manager: User entered 'Day 306'	System	19 Nov 2020 11:00:46

US3142034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:58:56

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:00:46
Amendment Manager: User entered '30 May 2021 00:01'	System	19 Nov 2020 11:00:46

US3142034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:58:56

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:00:46
Amendment Manager: User entered '03 Jun 2021 23:59'	System	19 Nov 2020 11:00:46

US3142034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:58:56

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:00:46
Amendment Manager: User entered 'Day 313'	System	19 Nov 2020 11:00:46

US3142034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:58:56

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:00:46
Amendment Manager: User entered '06 Jun 2021 00:01'	System	19 Nov 2020 11:00:46

US3142034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:58:56

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:00:46
Amendment Manager: User entered '10 Jun 2021 23:59'	System	19 Nov 2020 11:00:46

US3142034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:58:56

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:00:46
Amendment Manager: User entered 'Day 320'	System	19 Nov 2020 11:00:46

US3142034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:58:56

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:00:46
Amendment Manager: User entered '13 Jun 2021 00:01'	System	19 Nov 2020 11:00:46

US3142034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:58:56

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:00:46
Amendment Manager: User entered '17 Jun 2021 23:59'	System	19 Nov 2020 11:00:46

US3142034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:58:56

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:00:46
Amendment Manager: User entered 'Day 327'	System	19 Nov 2020 11:00:46

US3142034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:58:56

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:00:46
Amendment Manager: User entered '20 Jun 2021 00:01'	System	19 Nov 2020 11:00:46

US3142034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:58:56

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:00:46
Amendment Manager: User entered '24 Jun 2021 23:59'	System	19 Nov 2020 11:00:46

US3142034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:58:56

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:00:46
Amendment Manager: User entered 'Day 334'	System	19 Nov 2020 11:00:46

US3142034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:58:56

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:00:46
Amendment Manager: User entered '27 Jun 2021 00:01'	System	19 Nov 2020 11:00:46

US3142034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:58:56

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:00:46
Amendment Manager: User entered '01 Jul 2021 23:59'	System	19 Nov 2020 11:00:46

US3142034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:58:56

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:00:46
Amendment Manager: User entered 'Day 341'	System	19 Nov 2020 11:00:46

US3142034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:58:56

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:00:46
Amendment Manager: User entered '04 Jul 2021 00:01'	System	19 Nov 2020 11:00:46

US3142034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:58:56

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:00:46
Amendment Manager: User entered '08 Jul 2021 23:59'	System	19 Nov 2020 11:00:46

US3142034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:58:56

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:00:46
Amendment Manager: User entered 'Day 348'	System	19 Nov 2020 11:00:46

US3142034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:58:56

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:00:46
Amendment Manager: User entered '11 Jul 2021 00:01'	System	19 Nov 2020 11:00:46

US3142034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:58:56

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:00:46
Amendment Manager: User entered '15 Jul 2021 23:59'	System	19 Nov 2020 11:00:46

US3142034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:58:56

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:00:46
Amendment Manager: User entered 'Day 355'	System	19 Nov 2020 11:00:46

US3142034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:58:56

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:00:46
Amendment Manager: User entered '18 Jul 2021 00:01'	System	19 Nov 2020 11:00:46

US3142034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:58:56

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:00:46
Amendment Manager: User entered '22 Jul 2021 23:59'	System	19 Nov 2020 11:00:46

US3142034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:58:56

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:00:46
Amendment Manager: User entered 'Day 362'	System	19 Nov 2020 11:00:46

US3142034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:58:56

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:00:46
Amendment Manager: User entered '25 Jul 2021 00:01'	System	19 Nov 2020 11:00:46

US3142034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:58:56

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:00:46
Amendment Manager: User entered '29 Jul 2021 23:59'	System	19 Nov 2020 11:00:46

US3142034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:58:56

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:00:46
Amendment Manager: User entered 'Day 369'	System	19 Nov 2020 11:00:46

US3142034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:58:56

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:00:46
Amendment Manager: User entered '01 Aug 2021 00:01'	System	19 Nov 2020 11:00:46

US3142034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:58:56

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:00:46
Amendment Manager: User entered '05 Aug 2021 23:59'	System	19 Nov 2020 11:00:46

US3142034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:58:56

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:00:46
Amendment Manager: User entered 'Day 376'	System	19 Nov 2020 11:00:46

US3142034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:58:56

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:00:46
Amendment Manager: User entered '08 Aug 2021 00:01'	System	19 Nov 2020 11:00:46

US3142034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:58:56

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:00:46
Amendment Manager: User entered '12 Aug 2021 23:59'	System	19 Nov 2020 11:00:46

US3142034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:58:56

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:00:46
Amendment Manager: User entered 'Day 383'	System	19 Nov 2020 11:00:46

US3142034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:58:56

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:00:46
Amendment Manager: User entered '15 Aug 2021 00:01'	System	19 Nov 2020 11:00:46

US3142034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:58:56

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:00:46
Amendment Manager: User entered '19 Aug 2021 23:59'	System	19 Nov 2020 11:00:46

US3142034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:58:56

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:00:46
Amendment Manager: User entered 'Day 390'	System	19 Nov 2020 11:00:46

US3142034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:58:56

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:00:46
Amendment Manager: User entered '22 Aug 2021 00:01'	System	19 Nov 2020 11:00:46

US3142034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:58:56

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:00:46
Amendment Manager: User entered '26 Aug 2021 23:59'	System	19 Nov 2020 11:00:46

US3142034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:58:56

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:00:46
Amendment Manager: User entered 'Day 397'	System	19 Nov 2020 11:00:46

US3142034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:58:56

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:00:46
Amendment Manager: User entered '29 Aug 2021 00:01'	System	19 Nov 2020 11:00:46

US3142034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:58:56

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:00:46
Amendment Manager: User entered '02 Sep 2021 23:59'	System	19 Nov 2020 11:00:46

US3142034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:58:56

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:00:46
Amendment Manager: User entered 'Day 404'	System	19 Nov 2020 11:00:46

US3142034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:58:56

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:00:46
Amendment Manager: User entered '05 Sep 2021 00:01'	System	19 Nov 2020 11:00:46

US3142034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:58:56

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:00:46
Amendment Manager: User entered '09 Sep 2021 23:59'	System	19 Nov 2020 11:00:46

US3142034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:58:56

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:00:46
Amendment Manager: User entered 'Day 411'	System	19 Nov 2020 11:00:46

US3142034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:58:56

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:00:46
Amendment Manager: User entered '12 Sep 2021 00:01'	System	19 Nov 2020 11:00:46

US3142034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:58:56

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:00:46
Amendment Manager: User entered '16 Sep 2021 23:59'	System	19 Nov 2020 11:00:46

US3142034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:58:56

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:00:46
Amendment Manager: User entered 'Day 418'	System	19 Nov 2020 11:00:46

US3142034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:58:56

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:00:46
Amendment Manager: User entered '19 Sep 2021 00:01'	System	19 Nov 2020 11:00:46

US3142034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:58:56

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:00:46
Amendment Manager: User entered '23 Sep 2021 23:59'	System	19 Nov 2020 11:00:46

US3142034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:58:56

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:00:46
Amendment Manager: User entered 'Day 425'	System	19 Nov 2020 11:00:46

US3142034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:58:56

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:00:46
Amendment Manager: User entered '26 Sep 2021 00:01'	System	19 Nov 2020 11:00:46

US3142034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:58:56

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:00:46
Amendment Manager: User entered '30 Sep 2021 23:59'	System	19 Nov 2020 11:00:46

US3142034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:58:56

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:00:46
Amendment Manager: User entered 'Day 432'	System	19 Nov 2020 11:00:46

US3142034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:58:56

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:00:46
Amendment Manager: User entered '03 Oct 2021 00:01'	System	19 Nov 2020 11:00:46

US3142034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:58:56

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:00:46
Amendment Manager: User entered '07 Oct 2021 23:59'	System	19 Nov 2020 11:00:46

US3142034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:58:56

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:00:46
Amendment Manager: User entered 'Day 439'	System	19 Nov 2020 11:00:46

US3142034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:58:56

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:00:46
Amendment Manager: User entered '10 Oct 2021 00:01'	System	19 Nov 2020 11:00:46

US3142034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:58:56

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:00:46
Amendment Manager: User entered '14 Oct 2021 23:59'	System	19 Nov 2020 11:00:46

US3142034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:58:56

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:00:46
Amendment Manager: User entered 'Day 446'	System	19 Nov 2020 11:00:46

US3142034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:58:56

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:00:46
Amendment Manager: User entered '17 Oct 2021 00:01'	System	19 Nov 2020 11:00:46

US3142034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:58:56

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:00:46
Amendment Manager: User entered '21 Oct 2021 23:59'	System	19 Nov 2020 11:00:46

US3142034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:58:56

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:00:46
Amendment Manager: User entered 'Day 453'	System	19 Nov 2020 11:00:46

US3142034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:58:56

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:00:46
Amendment Manager: User entered '24 Oct 2021 00:01'	System	19 Nov 2020 11:00:46

US3142034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:58:56

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:00:46
Amendment Manager: User entered '28 Oct 2021 23:59'	System	19 Nov 2020 11:00:46

US3142034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:58:56

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:00:46
Amendment Manager: User entered 'Day 460'	System	19 Nov 2020 11:00:46

US3142034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:58:56

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:00:46
Amendment Manager: User entered '31 Oct 2021 00:01'	System	19 Nov 2020 11:00:46

US3142034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:58:56

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:00:46
Amendment Manager: User entered '04 Nov 2021 23:59'	System	19 Nov 2020 11:00:46

US3142034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:58:56

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:00:46
Amendment Manager: User entered 'Day 467'	System	19 Nov 2020 11:00:46

US3142034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:58:56

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:00:46
Amendment Manager: User entered '07 Nov 2021 00:01'	System	19 Nov 2020 11:00:46

US3142034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:58:56

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:00:46
Amendment Manager: User entered '11 Nov 2021 23:59'	System	19 Nov 2020 11:00:46

US3142034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:58:56

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:00:46
Amendment Manager: User entered 'Day 474'	System	19 Nov 2020 11:00:46

US3142034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:58:56

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:00:46
Amendment Manager: User entered '14 Nov 2021 00:01'	System	19 Nov 2020 11:00:46

US3142034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:58:56

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:00:46
Amendment Manager: User entered '18 Nov 2021 23:59'	System	19 Nov 2020 11:00:46

US3142034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:58:56

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:00:46
Amendment Manager: User entered 'Day 481'	System	19 Nov 2020 11:00:46

US3142034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:58:56

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:00:46
Amendment Manager: User entered '21 Nov 2021 00:01'	System	19 Nov 2020 11:00:46

US3142034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:58:56

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:00:46
Amendment Manager: User entered '25 Nov 2021 23:59'	System	19 Nov 2020 11:00:46

US3142034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:58:56

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:00:46
Amendment Manager: User entered 'Day 488'	System	19 Nov 2020 11:00:46

US3142034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:58:56

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:00:46
Amendment Manager: User entered '28 Nov 2021 00:01'	System	19 Nov 2020 11:00:46

US3142034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:58:56

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:00:46
Amendment Manager: User entered '02 Dec 2021 23:59'	System	19 Nov 2020 11:00:46

US3142034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:58:56

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:00:46
Amendment Manager: User entered 'Day 495'	System	19 Nov 2020 11:00:46

US3142034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:58:56

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:00:46
Amendment Manager: User entered '05 Dec 2021 00:01'	System	19 Nov 2020 11:00:46

US3142034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:58:56

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:00:46
Amendment Manager: User entered '09 Dec 2021 23:59'	System	19 Nov 2020 11:00:46

US3142034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:58:56

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:00:46
Amendment Manager: User entered 'Day 502'	System	19 Nov 2020 11:00:46

US3142034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:58:56

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:00:46
Amendment Manager: User entered '12 Dec 2021 00:01'	System	19 Nov 2020 11:00:46

US3142034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:58:56

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:00:46
Amendment Manager: User entered '16 Dec 2021 23:59'	System	19 Nov 2020 11:00:46

US3142034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:58:56

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:00:46
Amendment Manager: User entered 'Day 509'	System	19 Nov 2020 11:00:46

US3142034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:58:56

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:00:46
Amendment Manager: User entered '19 Dec 2021 00:01'	System	19 Nov 2020 11:00:46

US3142034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:58:56

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:00:46
Amendment Manager: User entered '23 Dec 2021 23:59'	System	19 Nov 2020 11:00:46

US3142034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:58:56

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:00:46
Amendment Manager: User entered 'Day 516'	System	19 Nov 2020 11:00:46

US3142034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:58:56

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:00:46
Amendment Manager: User entered '26 Dec 2021 00:01'	System	19 Nov 2020 11:00:46

US3142034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:58:56

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:00:46
Amendment Manager: User entered '30 Dec 2021 23:59'	System	19 Nov 2020 11:00:46

US3142034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:58:56

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:00:46
Amendment Manager: User entered 'Day 523'	System	19 Nov 2020 11:00:46

US3142034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:58:56

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:00:46
Amendment Manager: User entered '02 Jan 2022 00:01'	System	19 Nov 2020 11:00:46

US3142034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:58:56

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:00:46
Amendment Manager: User entered '06 Jan 2022 23:59'	System	19 Nov 2020 11:00:46

US3142034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:58:56

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:00:46
Amendment Manager: User entered 'Day 530'	System	19 Nov 2020 11:00:46

US3142034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:58:56

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:00:46
Amendment Manager: User entered '09 Jan 2022 00:01'	System	19 Nov 2020 11:00:46

US3142034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:58:56

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:00:46
Amendment Manager: User entered '13 Jan 2022 23:59'	System	19 Nov 2020 11:00:46

US3142034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:58:56

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:00:46
Amendment Manager: User entered 'Day 537'	System	19 Nov 2020 11:00:46

US3142034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:58:56

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:00:46
Amendment Manager: User entered '16 Jan 2022 00:01'	System	19 Nov 2020 11:00:46

US3142034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:58:56

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:00:46
Amendment Manager: User entered '20 Jan 2022 23:59'	System	19 Nov 2020 11:00:46

US3142034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:58:56

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:00:46
Amendment Manager: User entered 'Day 544'	System	19 Nov 2020 11:00:46

US3142034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:58:56

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:00:46
Amendment Manager: User entered '23 Jan 2022 00:01'	System	19 Nov 2020 11:00:46

US3142034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:58:56

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:00:46
Amendment Manager: User entered '27 Jan 2022 23:59'	System	19 Nov 2020 11:00:46

US3142034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:58:56

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:00:46
Amendment Manager: User entered 'Day 551'	System	19 Nov 2020 11:00:46

US3142034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:58:56

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:00:46
Amendment Manager: User entered '30 Jan 2022 00:01'	System	19 Nov 2020 11:00:46

US3142034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:58:56

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:00:46
Amendment Manager: User entered '03 Feb 2022 23:59'	System	19 Nov 2020 11:00:46

US3142034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:58:56

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:00:46
Amendment Manager: User entered 'Day 558'	System	19 Nov 2020 11:00:46

US3142034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:58:56

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:00:46
Amendment Manager: User entered '06 Feb 2022 00:01'	System	19 Nov 2020 11:00:46

US3142034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:58:56

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:00:46
Amendment Manager: User entered '10 Feb 2022 23:59'	System	19 Nov 2020 11:00:46

US3142034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:58:56

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:00:46
Amendment Manager: User entered 'Day 565'	System	19 Nov 2020 11:00:46

US3142034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:58:56

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:00:46
Amendment Manager: User entered '13 Feb 2022 00:01'	System	19 Nov 2020 11:00:46

US3142034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:58:56

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:00:46
Amendment Manager: User entered '17 Feb 2022 23:59'	System	19 Nov 2020 11:00:46

US3142034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:58:56

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:00:46
Amendment Manager: User entered 'Day 572'	System	19 Nov 2020 11:00:46

US3142034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:58:56

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:00:46
Amendment Manager: User entered '20 Feb 2022 00:01'	System	19 Nov 2020 11:00:46

US3142034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:58:56

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:00:46
Amendment Manager: User entered '24 Feb 2022 23:59'	System	19 Nov 2020 11:00:46

US3142034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:58:56

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:00:46
Amendment Manager: User entered 'Day 579'	System	19 Nov 2020 11:00:46

US3142034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:58:56

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:00:46
Amendment Manager: User entered '27 Feb 2022 00:01'	System	19 Nov 2020 11:00:46

US3142034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:58:56

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:00:46
Amendment Manager: User entered '03 Mar 2022 23:59'	System	19 Nov 2020 11:00:46

US3142034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:58:56

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:00:46
Amendment Manager: User entered 'Day 586'	System	19 Nov 2020 11:00:46

US3142034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:58:56

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:00:46
Amendment Manager: User entered '06 Mar 2022 00:01'	System	19 Nov 2020 11:00:46

US3142034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:58:56

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:00:46
Amendment Manager: User entered '10 Mar 2022 23:59'	System	19 Nov 2020 11:00:46

US3142034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:58:56

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:00:46
Amendment Manager: User entered 'Day 593'	System	19 Nov 2020 11:00:46

US3142034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:58:56

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:00:46
Amendment Manager: User entered '13 Mar 2022 00:01'	System	19 Nov 2020 11:00:46

US3142034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:58:56

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:00:46
Amendment Manager: User entered '17 Mar 2022 23:59'	System	19 Nov 2020 11:00:46

US3142034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:58:56

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:00:46
Amendment Manager: User entered 'Day 600'	System	19 Nov 2020 11:00:46

US3142034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:58:56

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:00:46
Amendment Manager: User entered '20 Mar 2022 00:01'	System	19 Nov 2020 11:00:46

US3142034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:58:56

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:00:46
Amendment Manager: User entered '24 Mar 2022 23:59'	System	19 Nov 2020 11:00:46

US3142034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:58:56

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:00:46
Amendment Manager: User entered 'Day 607'	System	19 Nov 2020 11:00:46

US3142034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:58:56

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:00:46
Amendment Manager: User entered '27 Mar 2022 00:01'	System	19 Nov 2020 11:00:46

US3142034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:58:56

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:00:46
Amendment Manager: User entered '31 Mar 2022 23:59'	System	19 Nov 2020 11:00:46

US3142034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:58:56

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:00:46
Amendment Manager: User entered 'Day 614'	System	19 Nov 2020 11:00:46

US3142034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:58:56

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:00:46
Amendment Manager: User entered '03 Apr 2022 00:01'	System	19 Nov 2020 11:00:46

US3142034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:58:56

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:00:46
Amendment Manager: User entered '07 Apr 2022 23:59'	System	19 Nov 2020 11:00:46

US3142034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:58:56

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:00:46
Amendment Manager: User entered 'Day 621'	System	19 Nov 2020 11:00:46

US3142034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:58:56

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:00:46
Amendment Manager: User entered '10 Apr 2022 00:01'	System	19 Nov 2020 11:00:46

US3142034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:58:56

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:00:46
Amendment Manager: User entered '14 Apr 2022 23:59'	System	19 Nov 2020 11:00:46

US3142034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:58:56

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:00:46
Amendment Manager: User entered 'Day 628'	System	19 Nov 2020 11:00:46

US3142034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:58:56

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:00:46
Amendment Manager: User entered '17 Apr 2022 00:01'	System	19 Nov 2020 11:00:46

US3142034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:58:56

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:00:46
Amendment Manager: User entered '21 Apr 2022 23:59'	System	19 Nov 2020 11:00:46

US3142034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:58:56

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:00:46
Amendment Manager: User entered 'Day 635'	System	19 Nov 2020 11:00:46

US3142034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:58:56

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:00:46
Amendment Manager: User entered '24 Apr 2022 00:01'	System	19 Nov 2020 11:00:46

US3142034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:58:56

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:00:46
Amendment Manager: User entered '28 Apr 2022 23:59'	System	19 Nov 2020 11:00:46

US3142034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:58:56

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:00:46
Amendment Manager: User entered 'Day 642'	System	19 Nov 2020 11:00:46

US3142034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:58:56

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:00:46
Amendment Manager: User entered '01 May 2022 00:01'	System	19 Nov 2020 11:00:46

US3142034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:58:56

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:00:46
Amendment Manager: User entered '05 May 2022 23:59'	System	19 Nov 2020 11:00:46

US3142034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:58:56

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:00:46
Amendment Manager: User entered 'Day 649'	System	19 Nov 2020 11:00:46

US3142034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:58:56

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:00:46
Amendment Manager: User entered '08 May 2022 00:01'	System	19 Nov 2020 11:00:46

US3142034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:58:56

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:00:46
Amendment Manager: User entered '12 May 2022 23:59'	System	19 Nov 2020 11:00:46

US3142034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:58:56

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:00:46
Amendment Manager: User entered 'Day 656'	System	19 Nov 2020 11:00:46

US3142034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:58:56

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:00:46
Amendment Manager: User entered '15 May 2022 00:01'	System	19 Nov 2020 11:00:46

US3142034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:58:56

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:00:46
Amendment Manager: User entered '19 May 2022 23:59'	System	19 Nov 2020 11:00:46

US3142034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:58:56

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:00:46
Amendment Manager: User entered 'Day 663'	System	19 Nov 2020 11:00:46

US3142034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:58:56

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:00:46
Amendment Manager: User entered '22 May 2022 00:01'	System	19 Nov 2020 11:00:46

US3142034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:58:56

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:00:46
Amendment Manager: User entered '26 May 2022 23:59'	System	19 Nov 2020 11:00:46

US3142034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:58:56

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:00:46
Amendment Manager: User entered 'Day 670'	System	19 Nov 2020 11:00:46

US3142034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:58:56

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:00:46
Amendment Manager: User entered '29 May 2022 00:01'	System	19 Nov 2020 11:00:46

US3142034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:58:56

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:00:46
Amendment Manager: User entered '02 Jun 2022 23:59'	System	19 Nov 2020 11:00:46

US3142034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:58:56

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:00:46
Amendment Manager: User entered 'Day 677'	System	19 Nov 2020 11:00:46

US3142034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:58:56

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:00:46
Amendment Manager: User entered '05 Jun 2022 00:01'	System	19 Nov 2020 11:00:46

US3142034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:58:56

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:00:46
Amendment Manager: User entered '09 Jun 2022 23:59'	System	19 Nov 2020 11:00:46

US3142034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:58:56

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:00:46
Amendment Manager: User entered 'Day 684'	System	19 Nov 2020 11:00:46

US3142034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:58:56

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:00:46
Amendment Manager: User entered '12 Jun 2022 00:01'	System	19 Nov 2020 11:00:46

US3142034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:58:56

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:00:46
Amendment Manager: User entered '16 Jun 2022 23:59'	System	19 Nov 2020 11:00:46

US3142034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:58:56

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:00:46
Amendment Manager: User entered 'Day 691'	System	19 Nov 2020 11:00:46

US3142034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:58:56

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:00:46
Amendment Manager: User entered '19 Jun 2022 00:01'	System	19 Nov 2020 11:00:46

US3142034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:58:56

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:00:46
Amendment Manager: User entered '23 Jun 2022 23:59'	System	19 Nov 2020 11:00:46

US3142034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:58:56

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:00:46
Amendment Manager: User entered 'Day 698'	System	19 Nov 2020 11:00:46

US3142034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:58:56

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:00:46
Amendment Manager: User entered '26 Jun 2022 00:01'	System	19 Nov 2020 11:00:46

US3142034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:58:56

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:00:46
Amendment Manager: User entered '30 Jun 2022 23:59'	System	19 Nov 2020 11:00:46

US3142034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:58:56

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:00:46
Amendment Manager: User entered 'Day 705'	System	19 Nov 2020 11:00:46

US3142034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:58:56

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:00:46
Amendment Manager: User entered '03 Jul 2022 00:01'	System	19 Nov 2020 11:00:46

US3142034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:58:56

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:00:46
Amendment Manager: User entered '07 Jul 2022 23:59'	System	19 Nov 2020 11:00:46

US3142034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:58:56

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:00:46
Amendment Manager: User entered 'Day 712'	System	19 Nov 2020 11:00:46

US3142034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:58:56

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:00:46
Amendment Manager: User entered '10 Jul 2022 00:01'	System	19 Nov 2020 11:00:46

US3142034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:58:56

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:00:46
Amendment Manager: User entered '14 Jul 2022 23:59'	System	19 Nov 2020 11:00:46

US3142034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:58:56

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:00:46
Amendment Manager: User entered 'Day 719'	System	19 Nov 2020 11:00:46

US3142034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:58:56

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:00:46
Amendment Manager: User entered '17 Jul 2022 00:01'	System	19 Nov 2020 11:00:46

US3142034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:58:56

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:00:46
Amendment Manager: User entered '21 Jul 2022 23:59'	System	19 Nov 2020 11:00:46

US3142034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:58:56

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:00:46
Amendment Manager: User entered 'Day 726'	System	19 Nov 2020 11:00:46

US3142034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:58:56

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:00:46
Amendment Manager: User entered '24 Jul 2022 00:01'	System	19 Nov 2020 11:00:46

US3142034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:58:56

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:00:46
Amendment Manager: User entered '28 Jul 2022 23:59'	System	19 Nov 2020 11:00:46

US3142034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:58:56

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:00:46
Amendment Manager: User entered 'Day 733'	System	19 Nov 2020 11:00:46

US3142034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:58:56

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:00:46
Amendment Manager: User entered '31 Jul 2022 00:01'	System	19 Nov 2020 11:00:46

US3142034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:58:56

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:00:46
Amendment Manager: User entered '04 Aug 2022 23:59'	System	19 Nov 2020 11:00:46

US3142034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:58:56

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:00:46
Amendment Manager: User entered 'Day 740'	System	19 Nov 2020 11:00:46

US3142034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:58:56

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:00:46
Amendment Manager: User entered '07 Aug 2022 00:01'	System	19 Nov 2020 11:00:46

US3142034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:58:56

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:00:46
Amendment Manager: User entered '11 Aug 2022 23:59'	System	19 Nov 2020 11:00:46

US3142034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:58:56

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:00:46
Amendment Manager: User entered 'Day 747'	System	19 Nov 2020 11:00:46

US3142034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:58:56

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:00:46
Amendment Manager: User entered '14 Aug 2022 00:01'	System	19 Nov 2020 11:00:46

US3142034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:58:56

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:00:46
Amendment Manager: User entered '18 Aug 2022 23:59'	System	19 Nov 2020 11:00:46

US3142034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:58:56

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:00:46
Amendment Manager: User entered 'Day 754'	System	19 Nov 2020 11:00:46

US3142034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:58:56

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:00:46
Amendment Manager: User entered '21 Aug 2022 00:01'	System	19 Nov 2020 11:00:46

US3142034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:58:56

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:00:46
Amendment Manager: User entered '25 Aug 2022 23:59'	System	19 Nov 2020 11:00:46

US3142034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:58:56

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:00:46
Amendment Manager: User entered 'Day 761'	System	19 Nov 2020 11:00:46

US3142034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:58:56

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:00:46
Amendment Manager: User entered '28 Aug 2022 00:01'	System	19 Nov 2020 11:00:46

US3142034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:58:56

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:00:46
Amendment Manager: User entered '01 Sep 2022 23:59'	System	19 Nov 2020 11:00:46

US3142034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:58:56

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:00:46
Amendment Manager: User entered 'Day 768'	System	19 Nov 2020 11:00:46

US3142034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:58:56

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:00:46
Amendment Manager: User entered '04 Sep 2022 00:01'	System	19 Nov 2020 11:00:46

US3142034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:58:56

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:00:46
Amendment Manager: User entered '08 Sep 2022 23:59'	System	19 Nov 2020 11:00:46

US3142034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:58:56

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:00:46
Amendment Manager: User entered 'Day 775'	System	19 Nov 2020 11:00:46

US3142034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:58:56

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:00:46
Amendment Manager: User entered '11 Sep 2022 00:01'	System	19 Nov 2020 11:00:46

US3142034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:58:56

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:00:46
Amendment Manager: User entered '15 Sep 2022 23:59'	System	19 Nov 2020 11:00:46

US3142034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:58:56

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:00:46
Amendment Manager: User entered 'Day 782'	System	19 Nov 2020 11:00:46

US3142034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:58:56

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:00:46
Amendment Manager: User entered '18 Sep 2022 00:01'	System	19 Nov 2020 11:00:46

US3142034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:58:56

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:00:46
Amendment Manager: User entered '22 Sep 2022 23:59'	System	19 Nov 2020 11:00:46

US3142034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:58:56

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:00:46
Amendment Manager: User entered 'Day 789'	System	19 Nov 2020 11:00:46

US3142034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:58:56

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:00:46
Amendment Manager: User entered '25 Sep 2022 00:01'	System	19 Nov 2020 11:00:46

US3142034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:58:56

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:00:46
Amendment Manager: User entered '29 Sep 2022 23:59'	System	19 Nov 2020 11:00:46

US3142034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:58:56

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:00:46
Amendment Manager: User entered 'Day 796'	System	19 Nov 2020 11:00:46

US3142034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:58:56

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:00:46
Amendment Manager: User entered '02 Oct 2022 00:01'	System	19 Nov 2020 11:00:46

US3142034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:58:56

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:00:46
Amendment Manager: User entered '06 Oct 2022 23:59'	System	19 Nov 2020 11:00:46

US3142034

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection_ Dermal Filler eDiary (1)

Generated On: 11 Aug 2021 21:58:56

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 11:58:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8F5B9B48-1138-4DBF-A9AC-B36F0A557EB4)', Time: '2021-03-01T07:00:17', User OID: 'PatientReportedOutcome (US3142034)', ODM File OID: '26ac1293-a0bd-4901-966b-72d35055189e'	System	01 Mar 2021 14:01:01
User entered 'No (N)'	System	01 Mar 2021 14:01:01

US3142034

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection_ Dermal Filler eDiary (1)

Generated On: 11 Aug 2021 21:58:56

[Date & Time of Submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 11:58:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8F5B9B48-1138-4DBF-A9AC-B36F0A557EB4)', Time: '2021-03-01T07:00:26', User OID: 'PatientReportedOutcome (US3142034)', ODM File OID: '26ac1293-a0bd-4901-966b-72d35055189e' User entered '01 Mar 2021 07:00:26'	System	01 Mar 2021 14:01:01
	System	01 Mar 2021 14:01:01

US3142034

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 11 Aug 2021 21:58:56

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 06:09:24
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 19:03:50
User entered 'Yes (Y)'	Dalia Jeronimo (b) (4) (b) (4)	20 Oct 2020 19:38:28

US3142034

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 11 Aug 2021 21:58:56

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 06:09:24
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:03:50
User entered '19 Oct 2020'	Dalia Jeronimo (b) (4)	20 Oct 2020 19:38:28

US3142034

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 11 Aug 2021 21:58:56

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 06:09:24
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 19:03:50
User entered 'Contact Made (CONTACT MADE)'	Dalia Jeronimo (b) (4) (b) (4)	20 Oct 2020 19:38:28

US3142034

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 11 Aug 2021 21:58:56

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 06:09:24
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 19:03:50
User entered empty.	Dalia Jeronimo (b) (4) (b) (4)	20 Oct 2020 19:38:28

US3142034

Folder: Safety Call Day 85 (1)

Form: Continuing

Generated On: 11 Aug 2021 21:58:56

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 06:09:24
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 19:03:50
User entered 'Yes (Y)'	Dalia Jeronimo (b) (4) (b) (4)	20 Oct 2020 19:38:35

US3142034

Folder: Safety Call Day 85 (1)

Form: Continuing

Generated On: 11 Aug 2021 21:58:56

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 06:09:24
User entered '1'	System	20 Oct 2020 19:38:35

US3142034

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 11 Aug 2021 21:58:56

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:39:30
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:03:50
User entered 'Yes (Y)'	Jami Wagner (b) (4)	01 Dec 2020 22:34:07

US3142034

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 11 Aug 2021 21:58:56

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:39:30
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:03:50
User entered '30 Nov 2020'	Jami Wagner (b) (4)	01 Dec 2020 22:34:07

US3142034

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 11 Aug 2021 21:58:56

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:39:30
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:03:50
User entered 'Contact Made (CONTACT MADE)'	Jami Wagner (b) (4)	01 Dec 2020 22:34:07

US3142034

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 11 Aug 2021 21:58:56

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:39:30
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:03:50
User entered empty.	Jami Wagner (b) (4)	01 Dec 2020 22:34:07

US3142034

Folder: Safety Call Day 119 (1)

Form: Continuing

Generated On: 11 Aug 2021 21:58:56

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:39:30
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:03:50
User entered 'Yes (Y)'	Jami Wagner (b) (4)	01 Dec 2020 22:34:15

US3142034

Folder: Safety Call Day 119 (1)

Form: Continuing

Generated On: 11 Aug 2021 21:58:56

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:39:30
User entered 'I'	System	01 Dec 2020 22:34:15

US3142034

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 11 Aug 2021 21:58:56

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:39:30
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 19:03:50
User entered 'Yes (Y)'	Jami Wagner (b) (4) (b) (4)	22 Dec 2020 20:25:43

US3142034

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 11 Aug 2021 21:58:56

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:39:30
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:03:50
User entered '22 Dec 2020'	Jami Wagner (b) (4)	22 Dec 2020 20:25:43

US3142034

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 11 Aug 2021 21:58:56

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:39:30
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:03:50
User entered 'Contact Made (CONTACT MADE)'	Jami Wagner (b) (4)	22 Dec 2020 20:25:43

US3142034

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 11 Aug 2021 21:58:56

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:39:30
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:03:50
User entered empty.	Jami Wagner (b) (4)	22 Dec 2020 20:25:43

US3142034

Folder: Safety Call Day 149 (1)

Form: Continuing

Generated On: 11 Aug 2021 21:58:56

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:39:30
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:03:50
User entered 'Yes (Y)'	Jami Wagner (b) (4)	22 Dec 2020 20:25:48

US3142034

Folder: Safety Call Day 149 (1)

Form: Continuing

Generated On: 11 Aug 2021 21:58:56

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:39:30
User entered 'I'	System	22 Dec 2020 20:25:48

US3142034

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 11 Aug 2021 21:58:56

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:39:30
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 19:03:50
User entered 'Yes (Y)'	Jami Wagner (b) (4) (b) (4)	01 Feb 2021 22:22:48

US3142034

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 11 Aug 2021 21:58:56

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:39:30
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:03:50
User entered '26 Jan 2021'	Jami Wagner (b) (4)	01 Feb 2021 22:22:48

US3142034

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 11 Aug 2021 21:58:56

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:39:30
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:03:50
User entered 'Contact Made (CONTACT MADE)'	Jami Wagner (b) (4)	01 Feb 2021 22:22:48

US3142034

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 11 Aug 2021 21:58:56

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:39:30
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:03:50
User entered empty.	Jami Wagner (b) (4)	01 Feb 2021 22:22:48

US3142034

Folder: Safety Call Day 179 (1)

Form: Continuing

Generated On: 11 Aug 2021 21:58:56

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:39:30
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 19:03:50
User entered 'Yes (Y)'	Jami Wagner (b) (4) (b) (4)	01 Feb 2021 22:22:53

US3142034

Folder: Safety Call Day 179 (1)

Form: Continuing

Generated On: 11 Aug 2021 21:58:56

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:39:30
User entered '1'	System	01 Feb 2021 22:22:53

US3142034

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 11 Aug 2021 21:58:56

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:52:49
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 19:03:50
User entered 'Yes (Y)'	Jami Wagner (b) (4) (b) (4)	01 Mar 2021 18:21:23

US3142034

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 11 Aug 2021 21:58:56

Visit date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:52:49
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 19:03:50
User entered '02 Mar 2021' reason for change: Data Entry Error	Shelby Pickle (b) (4) (b) (4)	02 Mar 2021 20:41:10
User entered '1 Mar 2021'	Jami Wagner (b) (4) (b) (4)	01 Mar 2021 18:21:23

US3142034

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 11 Aug 2021 21:58:56

[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 17:52:49
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:03:50
User entered 'Clinic (Clinic)'	Jami Wagner (b) (4)	01 Mar 2021 18:21:23

US3142034

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 11 Aug 2021 21:58:56

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:52:49
User entered 'VISIT4'	System	01 Mar 2021 18:21:23

US3142034

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 21:58:56

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:52:49
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 19:03:50
User entered 'Yes (Y)'	Jami Wagner (b) (4) (b) (4)	05 Apr 2021 22:41:13

US3142034

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 21:58:56

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:52:49
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:03:50
User entered '2 Mar 2021'	Jami Wagner (b) (4)	05 Apr 2021 22:41:13

US3142034

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 21:58:56

Time of assessment (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:52:49
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 19:03:50
User entered '10:16'	Jami Wagner (b) (4) (b) (4)	05 Apr 2021 22:41:13

US3142034

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 21:58:56

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:52:49
User entered '2 Mar 2021 10:16'	System	05 Apr 2021 22:41:13

US3142034

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 21:58:56

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:52:49
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 19:03:50
User entered '97.8' F	Jami Wagner (b) (4) (b) (4)	05 Apr 2021 22:41:13

US3142034

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 21:58:56

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:52:49
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 19:03:50
User entered 'Other (Other)'	Jami Wagner (b) (4) (b) (4)	05 Apr 2021 22:41:13

US3142034

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 21:58:56

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:52:49
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:03:50
User entered 'temporal'	Jami Wagner (b) (4)	05 Apr 2021 22:41:13

US3142034

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 21:58:56

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:52:49
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:03:50
User entered '64'	Jami Wagner (b) (4)	05 Apr 2021 22:41:13

US3142034

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 21:58:56

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:52:49
User entered 'bpm'	System	05 Apr 2021 22:41:13

US3142034

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 21:58:56

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:52:49
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 19:03:50
User entered '10'	Jami Wagner (b) (4) (b) (4)	05 Apr 2021 22:41:13

US3142034

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 21:58:56

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:52:49
User entered 'breaths/min'	System	05 Apr 2021 22:41:13

US3142034

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 21:58:56

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:52:49
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:03:50
User entered '113'	Jami Wagner (b) (4)	05 Apr 2021 22:41:13

US3142034

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 21:58:56

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:52:49
User entered 'mmHg'	System	05 Apr 2021 22:41:13

US3142034

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 21:58:56

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:52:49
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:03:50
User entered '70'	Jami Wagner (b) (4)	05 Apr 2021 22:41:13

US3142034

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 21:58:56

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:52:49
User entered 'mmHg'	System	05 Apr 2021 22:41:13

US3142034

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 21:58:56

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:52:49

US3142034

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 21:58:56

[Weight \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:52:49

US3142034

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Generated On: 11 Aug 2021 21:58:56

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:52:49
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:03:50
User closed query 'Per CDM: Visit 4 Day 209 and Participant Decision Visit / OL-D1 are both dated 02MAR2021 however, the data on the Physical Examination forms in these two visits do not match. If confirmed the visits occurred on the same day, the data must match. Please review and reconcile.' (Site from DM).	(b) (4) (b) (4), (b) (6)	01 Apr 2021 10:38:31
Query 'Per CDM: Visit 4 Day 209 and Participant Decision Visit / OL-D1 are both dated 02MAR2021 however, the data on the Physical Examination forms in these two visits do not match. If confirmed the visits occurred on the same day, the data must match. Please review and reconcile.' answered with 'Visits occurred same day. Information provided here documented by physical exam form under OL-D1.' (Site from DM).	Shelby Pickle (b) (4) (b) (4)	31 Mar 2021 19:57:09
User entered 'Yes (Y)' reason for change: Data Entry Error	Shelby Pickle (b) (4) (b) (4)	31 Mar 2021 19:56:40
User opened query 'Per CDM: Visit 4 Day 209 and Participant Decision Visit / OL-D1 are both dated 02MAR2021 however, the data on the Physical Examination forms in these two visits do not match. If confirmed the visits occurred on the same day, the data must match. Please review and reconcile.' (Site from DM).	(b) (4), (b) (6)	30 Mar 2021 22:02:22
User entered 'No (N)'	Jami Wagner (b) (4) (b) (4)	01 Mar 2021 18:21:32

US3142034

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Generated On: 11 Aug 2021 21:58:56

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:52:49
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 19:03:50
User entered '02 Mar 2021' reason for change: Data Entry Error	Shelby Pickle (b) (4) (b) (4)	31 Mar 2021 19:56:40
User entered empty.	Jami Wagner (b) (4) (b) (4)	01 Mar 2021 18:21:32

US3142034

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 21:58:56

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:52:49
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:03:50
User entered 'Yes (Y)'	Jami Wagner (b) (4)	01 Mar 2021 18:21:49

US3142034

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 21:58:56

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:52:49
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 19:03:50
User closed query 'The Collection Date is not equal to Visit Date. Please review and reconcile.' (Site from System).	System	02 Mar 2021 20:41:31
Query 'The Collection Date is not equal to Visit Date. System Please review and reconcile.' answered by data change (Site from System).		02 Mar 2021 20:41:31
User entered '02 Mar 2021' reason for change: Data Entry Error	Shelby Pickle (b) (4) (b) (4)	02 Mar 2021 20:41:31
User opened query 'The Collection Date is not equal to Visit Date. Please review and reconcile.' (Site from System).	System	02 Mar 2021 20:41:10
User entered '1 Mar 2021'	Jami Wagner (b) (4) (b) (4)	01 Mar 2021 18:21:49

US3142034

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 21:58:56

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:52:49
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 19:03:50
User entered '10:56' reason for change: Data Entry Error	Shelby Pickle (b) (4) (b) (4)	02 Mar 2021 20:41:31
User entered '10:44'	Jami Wagner (b) (4) (b) (4)	01 Mar 2021 18:21:49

US3142034

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 21:58:56

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:52:49
User entered '02 Mar 2021 10:56'	System	02 Mar 2021 20:41:31
User entered '1 Mar 2021 10:44'	System	01 Mar 2021 18:21:49

US3142034

Folder: Visit 4 Day 209 (1)

Form: Continuing

Generated On: 11 Aug 2021 21:58:56

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:52:49
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:03:50
User entered 'Yes (Y)'	Jami Wagner (b) (4)	01 Mar 2021 18:21:55

US3142034

Folder: Visit 4 Day 209 (1)

Form: Continuing

Generated On: 11 Aug 2021 21:58:56

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:52:49
User entered '1'	System	01 Mar 2021 18:21:55

US3142034

Folder: Safety Call Day 239 (1)

Form: Safety Call

Generated On: 11 Aug 2021 21:58:56

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:04:22
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 19:03:50
User entered 'Yes (Y)'	Lisa Jackson (b) (4) (b) (4)	29 Mar 2021 19:03:43

US3142034

Folder: Safety Call Day 239 (1)

Form: Safety Call

Generated On: 11 Aug 2021 21:58:56

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:04:22
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:03:50
User entered '23 Mar 2021'	(b) (4) Lisa Jackson (b) (4)	29 Mar 2021 19:03:43

US3142034

Folder: Safety Call Day 239 (1)

Form: Safety Call

Generated On: 11 Aug 2021 21:58:56

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:04:22
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 19:03:50
User entered 'Contact Made (CONTACT MADE)'	Lisa Jackson (b) (4) (b) (4)	29 Mar 2021 19:03:43

US3142034

Folder: Safety Call Day 239 (1)

Form: Safety Call

Generated On: 11 Aug 2021 21:58:56

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:04:22
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 19:03:50
User entered empty.	Lisa Jackson (b) (4) (b) (4)	29 Mar 2021 19:03:43

US3142034

Folder: Safety Call Day 239 (1)

Form: Continuing

Generated On: 11 Aug 2021 21:58:56

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:04:22
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:03:50
User entered 'Yes (Y)'	Lisa Jackson (b) (4)	29 Mar 2021 19:03:54

US3142034

Folder: Safety Call Day 239 (1)

Form: Continuing

Generated On: 11 Aug 2021 21:58:56

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:04:22
User entered 'I'	System	29 Mar 2021 19:03:54

US3142034

Folder: Safety Call Day 269 (1)

Form: Safety Call

Generated On: 11 Aug 2021 21:58:56

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4)	26 Apr 2021 02:38:24
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	23 Apr 2021 15:24:30

US3142034

Folder: Safety Call Day 269 (1)

Form: Safety Call

Generated On: 11 Aug 2021 21:58:56

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4)	26 Apr 2021 02:38:24
User entered '21 Apr 2021'	(b) (4) (b) (4), (b) (6)	23 Apr 2021 15:24:30

US3142034

Folder: Safety Call Day 269 (1)

Form: Safety Call

Generated On: 11 Aug 2021 21:58:56

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4)	26 Apr 2021 02:38:24
User entered 'Contact Made (CONTACT MADE)'	(b) (4) (b) (4), (b) (6)	23 Apr 2021 15:24:30

US3142034

Folder: Safety Call Day 269 (1)

Form: Safety Call

Generated On: 11 Aug 2021 21:58:56

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4)	26 Apr 2021 02:38:24
User entered empty.	(b) (4) (b) (4), (b) (6)	23 Apr 2021 15:24:30

US3142034

Folder: Safety Call Day 269 (1)

Form: Continuing

Generated On: 11 Aug 2021 21:58:56

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4)	26 Apr 2021 02:38:24
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	23 Apr 2021 15:24:39

US3142034

Folder: Safety Call Day 269 (1)

Form: Continuing

Generated On: 11 Aug 2021 21:58:56

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered '1'	System	23 Apr 2021 15:24:39

US3142034

Folder: Covid-19 Assessment 14 Dec 2020

Form: COVID-19 Contact

Generated On: 11 Aug 2021 21:58:56

[Date of Contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:54:58
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:03:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 18:03:46
User entered '14 Dec 2020'	Shelby Pickle (b) (4) (b) (4)	16 Dec 2020 19:48:27

US3142034

Folder: Covid-19 Assessment 14 Dec 2020

Form: COVID-19 Contact

Generated On: 11 Aug 2021 21:58:56

[Time of Contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:54:58
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:03:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 18:03:52
User entered '09:30'	Shelby Pickle (b) (4) (b) (4)	16 Dec 2020 19:48:27

US3142034

Folder: Covid-19 Assessment 14 Dec 2020

Form: COVID-19 Contact

Generated On: 11 Aug 2021 21:58:56

[Date and Time of Contact \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:54:58
User entered '14 Dec 2020 09:30'	System	16 Dec 2020 19:48:27

US3142034

Folder: Covid-19 Assessment 14 Dec 2020

Form: COVID-19 Contact

Generated On: 11 Aug 2021 21:58:56

[Type of Contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:54:58
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:03:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 18:03:55
User entered 'Clinical Visit - Unscheduled (Clinical Visit - Unscheduled)'	Shelby Pickle (b) (4) (b) (4)	16 Dec 2020 19:48:27

US3142034

Folder: Covid-19 Assessment 14 Dec 2020

Form: COVID-19 Contact

Generated On: 11 Aug 2021 21:58:56

[Has the subject reported symptoms of SARS-COV-2?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:54:58
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:03:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 18:03:57
User entered 'Yes (Y)'	Shelby Pickle (b) (4) (b) (4)	16 Dec 2020 19:48:27

US3142034

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (1)

Generated On: 11 Aug 2021 21:58:56

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:55:45
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 19:03:31
User entered 'Day 1 (Day 1)'	Shelby Pickle (b) (4) (b) (4)	16 Dec 2020 19:50:00

US3142034

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (1)

Generated On: 11 Aug 2021 21:58:56

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:55:45
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:03:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 18:04:25
User entered '10 Dec 2020'	Shelby Pickle (b) (4) (b) (4)	16 Dec 2020 19:50:00

US3142034

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (1)

Generated On: 11 Aug 2021 21:58:56

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:55:45
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:03:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 18:04:25
User entered '0'	Shelby Pickle (b) (4) (b) (4)	16 Dec 2020 19:50:00

US3142034

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (1)

Generated On: 11 Aug 2021 21:58:56

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:55:45
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:03:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 18:04:25
User entered missing code ND - Not Done.	Shelby Pickle (b) (4) (b) (4)	16 Dec 2020 19:50:00

US3142034

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (1)

Generated On: 11 Aug 2021 21:58:56

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:55:45
User entered '%'	System	16 Dec 2020 19:50:00

US3142034

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (1)

Generated On: 11 Aug 2021 21:58:56

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:55:45
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:03:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 18:04:25
User entered missing code ND - Not Done.	Shelby Pickle (b) (4) (b) (4)	16 Dec 2020 19:50:00

US3142034

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (1)

Generated On: 11 Aug 2021 21:58:56

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:55:45
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:03:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 18:04:25
User entered 'None (None)'	Shelby Pickle (b) (4) (b) (4)	16 Dec 2020 19:50:00

US3142034

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (1)

Generated On: 11 Aug 2021 21:58:56

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:55:45
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:03:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 18:04:25
User entered 'Mild (Mild)'	Shelby Pickle (b) (4) (b) (4)	16 Dec 2020 19:50:00

US3142034

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (1)

Generated On: 11 Aug 2021 21:58:56

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:55:45
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:03:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 18:04:25
User entered 'None (None)'	Shelby Pickle (b) (4) (b) (4)	16 Dec 2020 19:50:00

US3142034

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (1)

Generated On: 11 Aug 2021 21:58:56

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:55:45
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:03:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 18:04:25
User entered 'None (None)'	Shelby Pickle (b) (4) (b) (4)	16 Dec 2020 19:50:00

US3142034

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (1)

Generated On: 11 Aug 2021 21:58:56

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:55:45
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:03:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 18:04:25
User entered 'Mild (Mild)'	Shelby Pickle (b) (4) (b) (4)	16 Dec 2020 19:50:00

US3142034

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (1)

Generated On: 11 Aug 2021 21:58:56

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:55:45
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:03:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 18:04:25
User entered 'None (None)'	Shelby Pickle (b) (4) (b) (4)	16 Dec 2020 19:50:00

US3142034

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (1)

Generated On: 11 Aug 2021 21:58:56

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:55:45
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:03:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 18:04:25
User entered 'None (None)'	Shelby Pickle (b) (4) (b) (4)	16 Dec 2020 19:50:00

US3142034

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (1)

Generated On: 11 Aug 2021 21:58:56

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:55:45
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:03:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 18:04:25
User entered 'None (None)'	Shelby Pickle (b) (4) (b) (4)	16 Dec 2020 19:50:00

US3142034

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (1)

Generated On: 11 Aug 2021 21:58:56

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:55:45
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:03:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 18:04:25
User entered 'None (None)'	Shelby Pickle (b) (4) (b) (4)	16 Dec 2020 19:50:00

US3142034

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (1)

Generated On: 11 Aug 2021 21:58:56

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:55:45
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:03:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 18:04:25
User entered 'None (None)'	Shelby Pickle (b) (4) (b) (4)	16 Dec 2020 19:50:00

US3142034

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (1)

Generated On: 11 Aug 2021 21:58:56

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:55:45
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:03:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 18:04:25
User entered 'Mild (Mild)'	Shelby Pickle (b) (4) (b) (4)	16 Dec 2020 19:50:00

US3142034

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (1)

Generated On: 11 Aug 2021 21:58:56

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:55:45
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:03:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 18:04:25
User entered 'Mild (Mild)'	Shelby Pickle (b) (4) (b) (4)	16 Dec 2020 19:50:00

US3142034

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (1)

Generated On: 11 Aug 2021 21:58:56

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:55:45
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:03:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 18:04:25
User entered 'None (None)'	Shelby Pickle (b) (4) (b) (4)	16 Dec 2020 19:50:00

US3142034

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (1)

Generated On: 11 Aug 2021 21:58:56

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:55:45
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:03:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 18:04:25
User entered 'None (None)'	Shelby Pickle (b) (4) (b) (4)	16 Dec 2020 19:50:00

US3142034

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (1)

Generated On: 11 Aug 2021 21:58:56

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:55:45
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:03:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 18:04:25
User entered 'None (None)'	Shelby Pickle (b) (4) (b) (4)	16 Dec 2020 19:50:00

US3142034

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (1)

Generated On: 11 Aug 2021 21:58:56

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:55:45
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:03:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 18:04:25
User entered 'None (None)'	Shelby Pickle (b) (4) (b) (4)	16 Dec 2020 19:50:00

US3142034

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (2)

Generated On: 11 Aug 2021 21:58:56

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:55:45
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 19:03:31
User entered 'Day 2 (Day 2)'	Shelby Pickle (b) (4) (b) (4)	16 Dec 2020 19:50:43

US3142034

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (2)

Generated On: 11 Aug 2021 21:58:56

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:55:45
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:03:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 18:04:25
User entered '11 Dec 2020'	Shelby Pickle (b) (4) (b) (4)	16 Dec 2020 19:50:43

US3142034

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (2)

Generated On: 11 Aug 2021 21:58:56

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:55:45
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:03:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 18:04:25
User entered '0'	Shelby Pickle (b) (4) (b) (4)	16 Dec 2020 19:50:43

US3142034

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (2)

Generated On: 11 Aug 2021 21:58:56

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:55:45
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:03:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 18:04:25
User entered missing code ND - Not Done.	Shelby Pickle (b) (4) (b) (4)	16 Dec 2020 19:50:43

US3142034

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (2)

Generated On: 11 Aug 2021 21:58:56

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:55:45
User entered '%'	System	16 Dec 2020 19:50:43

US3142034

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (2)

Generated On: 11 Aug 2021 21:58:56

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:55:45
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:03:31
DataPoint Verified.	(b) (4), (b) (6)	02 Feb 2021 18:04:25
User entered missing code ND - Not Done.	Shelby Pickle (b) (4)	16 Dec 2020 19:50:43

US3142034

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (2)

Generated On: 11 Aug 2021 21:58:56

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:55:45
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:03:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 18:04:25
User entered 'None (None)'	Shelby Pickle (b) (4) (b) (4)	16 Dec 2020 19:50:43

US3142034

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (2)

Generated On: 11 Aug 2021 21:58:56

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:55:45
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:03:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 18:04:25
User entered 'Mild (Mild)'	Shelby Pickle (b) (4) (b) (4)	16 Dec 2020 19:50:43

US3142034

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (2)

Generated On: 11 Aug 2021 21:58:56

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:55:45
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:03:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 18:04:25
User entered 'None (None)'	Shelby Pickle (b) (4) (b) (4)	16 Dec 2020 19:50:43

US3142034

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (2)

Generated On: 11 Aug 2021 21:58:56

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:55:45
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:03:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 18:04:25
User entered 'None (None)'	Shelby Pickle (b) (4) (b) (4)	16 Dec 2020 19:50:43

US3142034

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (2)

Generated On: 11 Aug 2021 21:58:56

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:55:45
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:03:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 18:04:25
User entered 'Mild (Mild)'	Shelby Pickle (b) (4) (b) (4)	16 Dec 2020 19:50:43

US3142034

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (2)

Generated On: 11 Aug 2021 21:58:56

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:55:45
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:03:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 18:04:25
User entered 'None (None)'	Shelby Pickle (b) (4) (b) (4)	16 Dec 2020 19:50:43

US3142034

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (2)

Generated On: 11 Aug 2021 21:58:56

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:55:45
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:03:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 18:04:25
User entered 'None (None)'	Shelby Pickle (b) (4) (b) (4)	16 Dec 2020 19:50:43

US3142034

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (2)

Generated On: 11 Aug 2021 21:58:56

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:55:45
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:03:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 18:04:25
User entered 'None (None)'	Shelby Pickle (b) (4) (b) (4)	16 Dec 2020 19:50:43

US3142034

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (2)

Generated On: 11 Aug 2021 21:58:56

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:55:45
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:03:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 18:04:25
User entered 'None (None)'	Shelby Pickle (b) (4) (b) (4)	16 Dec 2020 19:50:43

US3142034

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (2)

Generated On: 11 Aug 2021 21:58:56

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:55:45
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:03:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 18:04:25
User entered 'None (None)'	Shelby Pickle (b) (4) (b) (4)	16 Dec 2020 19:50:43

US3142034

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (2)

Generated On: 11 Aug 2021 21:58:56

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:55:45
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:03:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 18:04:25
User entered 'Mild (Mild)'	Shelby Pickle (b) (4) (b) (4)	16 Dec 2020 19:50:43

US3142034

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (2)

Generated On: 11 Aug 2021 21:58:56

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:55:45
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:03:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 18:04:25
User entered 'Mild (Mild)'	Shelby Pickle (b) (4) (b) (4)	16 Dec 2020 19:50:43

US3142034

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (2)

Generated On: 11 Aug 2021 21:58:56

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:55:45
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:03:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 18:04:25
User entered 'None (None)'	Shelby Pickle (b) (4) (b) (4)	16 Dec 2020 19:50:43

US3142034

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (2)

Generated On: 11 Aug 2021 21:58:56

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:55:45
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:03:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 18:04:25
User entered 'None (None)'	Shelby Pickle (b) (4) (b) (4)	16 Dec 2020 19:50:43

US3142034

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (2)

Generated On: 11 Aug 2021 21:58:56

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:55:45
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:03:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 18:04:25
User entered 'None (None)'	Shelby Pickle (b) (4) (b) (4)	16 Dec 2020 19:50:43

US3142034

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (2)

Generated On: 11 Aug 2021 21:58:56

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:55:45
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:03:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 18:04:25
User entered 'None (None)'	Shelby Pickle (b) (4) (b) (4)	16 Dec 2020 19:50:43

US3142034

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (3)

Generated On: 11 Aug 2021 21:58:56

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:55:45
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 19:03:31
User entered 'Day 3 (Day 3)'	Shelby Pickle (b) (4) (b) (4)	16 Dec 2020 19:51:24

US3142034

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (3)

Generated On: 11 Aug 2021 21:58:56

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:55:45
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:03:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 18:04:25
User entered '12 Dec 2020'	Shelby Pickle (b) (4) (b) (4)	16 Dec 2020 19:51:24

US3142034

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (3)

Generated On: 11 Aug 2021 21:58:56

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:55:45
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:03:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 18:04:25
User entered '0'	Shelby Pickle (b) (4) (b) (4)	16 Dec 2020 19:51:24

US3142034

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (3)

Generated On: 11 Aug 2021 21:58:56

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:55:45
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:03:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 18:04:25
User entered missing code ND - Not Done.	Shelby Pickle (b) (4) (b) (4)	16 Dec 2020 19:51:24

US3142034

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (3)

Generated On: 11 Aug 2021 21:58:56

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:55:45
User entered '%'	System	16 Dec 2020 19:51:24

US3142034

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (3)

Generated On: 11 Aug 2021 21:58:56

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:55:45
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:03:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 18:04:25
User entered missing code ND - Not Done.	Shelby Pickle (b) (4) (b) (4)	16 Dec 2020 19:51:24

US3142034

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (3)

Generated On: 11 Aug 2021 21:58:56

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:55:45
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:03:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 18:04:25
User entered 'None (None)'	Shelby Pickle (b) (4) (b) (4)	16 Dec 2020 19:51:24

US3142034

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (3)

Generated On: 11 Aug 2021 21:58:56

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:55:45
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:03:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 18:04:25
User entered 'Mild (Mild)'	Shelby Pickle (b) (4) (b) (4)	16 Dec 2020 19:51:24

US3142034

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (3)

Generated On: 11 Aug 2021 21:58:56

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:55:45
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:03:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 18:04:25
User entered 'None (None)'	Shelby Pickle (b) (4) (b) (4)	16 Dec 2020 19:51:24

US3142034

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (3)

Generated On: 11 Aug 2021 21:58:56

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:55:45
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:03:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 18:04:25
User entered 'None (None)'	Shelby Pickle (b) (4) (b) (4)	16 Dec 2020 19:51:24

US3142034

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (3)

Generated On: 11 Aug 2021 21:58:56

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:55:45
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:03:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 18:04:25
User entered 'Mild (Mild)'	Shelby Pickle (b) (4) (b) (4)	16 Dec 2020 19:51:24

US3142034

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (3)

Generated On: 11 Aug 2021 21:58:56

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:55:45
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:03:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 18:04:25
User entered 'None (None)'	Shelby Pickle (b) (4) (b) (4)	16 Dec 2020 19:51:24

US3142034

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (3)

Generated On: 11 Aug 2021 21:58:56

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:55:45
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:03:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 18:04:25
User entered 'None (None)'	Shelby Pickle (b) (4) (b) (4)	16 Dec 2020 19:51:24

US3142034

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (3)

Generated On: 11 Aug 2021 21:58:56

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:55:45
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:03:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 18:04:25
User entered 'None (None)'	Shelby Pickle (b) (4) (b) (4)	16 Dec 2020 19:51:24

US3142034

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (3)

Generated On: 11 Aug 2021 21:58:56

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:55:45
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:03:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 18:04:25
User entered 'None (None)'	Shelby Pickle (b) (4) (b) (4)	16 Dec 2020 19:51:24

US3142034

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (3)

Generated On: 11 Aug 2021 21:58:56

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:55:45
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:03:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 18:04:25
User entered 'None (None)'	Shelby Pickle (b) (4) (b) (4)	16 Dec 2020 19:51:24

US3142034

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (3)

Generated On: 11 Aug 2021 21:58:56

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:55:45
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:03:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 18:04:25
User entered 'Mild (Mild)'	Shelby Pickle (b) (4) (b) (4)	16 Dec 2020 19:51:24

US3142034

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (3)

Generated On: 11 Aug 2021 21:58:56

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:55:45
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:03:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 18:04:25
User entered 'Mild (Mild)'	Shelby Pickle (b) (4) (b) (4)	16 Dec 2020 19:51:24

US3142034

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (3)

Generated On: 11 Aug 2021 21:58:56

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:55:45
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:03:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 18:04:25
User entered 'None (None)'	Shelby Pickle (b) (4) (b) (4)	16 Dec 2020 19:51:24

US3142034

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (3)

Generated On: 11 Aug 2021 21:58:56

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:55:45
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:03:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 18:04:25
User entered 'None (None)'	Shelby Pickle (b) (4) (b) (4)	16 Dec 2020 19:51:24

US3142034

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (3)

Generated On: 11 Aug 2021 21:58:56

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:55:45
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:03:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 18:04:25
User entered 'None (None)'	Shelby Pickle (b) (4) (b) (4)	16 Dec 2020 19:51:24

US3142034

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (3)

Generated On: 11 Aug 2021 21:58:56

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:55:45
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:03:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 18:04:25
User entered 'None (None)'	Shelby Pickle (b) (4) (b) (4)	16 Dec 2020 19:51:24

US3142034

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (4)

Generated On: 11 Aug 2021 21:58:56

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:55:45
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 19:03:31
User entered 'Day 4 (Day 4)'	Shelby Pickle (b) (4) (b) (4)	16 Dec 2020 19:52:14

US3142034

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (4)

Generated On: 11 Aug 2021 21:58:56

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:55:45
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:03:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 18:04:25
User entered '13 Dec 2020'	Shelby Pickle (b) (4) (b) (4)	16 Dec 2020 19:52:14

US3142034

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (4)

Generated On: 11 Aug 2021 21:58:56

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:55:45
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:03:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 18:04:25
User entered '0'	Shelby Pickle (b) (4) (b) (4)	16 Dec 2020 19:52:14

US3142034

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (4)

Generated On: 11 Aug 2021 21:58:56

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:55:45
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:03:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 18:04:25
User entered missing code ND - Not Done.	Shelby Pickle (b) (4) (b) (4)	16 Dec 2020 19:52:14

US3142034

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (4)

Generated On: 11 Aug 2021 21:58:56

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:55:45
User entered '%'	System	16 Dec 2020 19:52:14

US3142034

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (4)

Generated On: 11 Aug 2021 21:58:56

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:55:45
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:03:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 18:04:25
User entered missing code ND - Not Done.	Shelby Pickle (b) (4) (b) (4)	16 Dec 2020 19:52:14

US3142034

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (4)

Generated On: 11 Aug 2021 21:58:56

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:55:45
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:03:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 18:04:25
User entered 'None (None)'	Shelby Pickle (b) (4) (b) (4)	16 Dec 2020 19:52:14

US3142034

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (4)

Generated On: 11 Aug 2021 21:58:56

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:55:45
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:03:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 18:04:25
User entered 'Mild (Mild)'	Shelby Pickle (b) (4) (b) (4)	16 Dec 2020 19:52:14

US3142034

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (4)

Generated On: 11 Aug 2021 21:58:56

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:55:45
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:03:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 18:04:25
User entered 'None (None)'	Shelby Pickle (b) (4) (b) (4)	16 Dec 2020 19:52:14

US3142034

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (4)

Generated On: 11 Aug 2021 21:58:56

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:55:45
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:03:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 18:04:25
User entered 'None (None)'	Shelby Pickle (b) (4) (b) (4)	16 Dec 2020 19:52:14

US3142034

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (4)

Generated On: 11 Aug 2021 21:58:56

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:55:45
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:03:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 18:04:25
User entered 'Mild (Mild)'	Shelby Pickle (b) (4) (b) (4)	16 Dec 2020 19:52:14

US3142034

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (4)

Generated On: 11 Aug 2021 21:58:56

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:55:45
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:03:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 18:04:25
User entered 'None (None)'	Shelby Pickle (b) (4) (b) (4)	16 Dec 2020 19:52:14

US3142034

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (4)

Generated On: 11 Aug 2021 21:58:56

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:55:45
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:03:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 18:04:25
User entered 'None (None)'	Shelby Pickle (b) (4) (b) (4)	16 Dec 2020 19:52:14

US3142034

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (4)

Generated On: 11 Aug 2021 21:58:56

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:55:45
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:03:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 18:04:25
User entered 'None (None)'	Shelby Pickle (b) (4) (b) (4)	16 Dec 2020 19:52:14

US3142034

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (4)

Generated On: 11 Aug 2021 21:58:56

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:55:45
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:03:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 18:04:25
User entered 'None (None)'	Shelby Pickle (b) (4) (b) (4)	16 Dec 2020 19:52:14

US3142034

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (4)

Generated On: 11 Aug 2021 21:58:56

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:55:45
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:03:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 18:04:25
User entered 'None (None)'	Shelby Pickle (b) (4) (b) (4)	16 Dec 2020 19:52:14

US3142034

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (4)

Generated On: 11 Aug 2021 21:58:56

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:55:45
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:03:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 18:04:25
User entered 'Mild (Mild)'	Shelby Pickle (b) (4) (b) (4)	16 Dec 2020 19:52:14

US3142034

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (4)

Generated On: 11 Aug 2021 21:58:56

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:55:45
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:03:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 18:04:25
User entered 'Mild (Mild)'	Shelby Pickle (b) (4) (b) (4)	16 Dec 2020 19:52:14

US3142034

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (4)

Generated On: 11 Aug 2021 21:58:56

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:55:45
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:03:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 18:04:25
User entered 'None (None)'	Shelby Pickle (b) (4) (b) (4)	16 Dec 2020 19:52:14

US3142034

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (4)

Generated On: 11 Aug 2021 21:58:56

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:55:45
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:03:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 18:04:25
User entered 'None (None)'	Shelby Pickle (b) (4) (b) (4)	16 Dec 2020 19:52:14

US3142034

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (4)

Generated On: 11 Aug 2021 21:58:56

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:55:45
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:03:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 18:04:25
User entered 'None (None)'	Shelby Pickle (b) (4) (b) (4)	16 Dec 2020 19:52:14

US3142034

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (4)

Generated On: 11 Aug 2021 21:58:56

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:55:45
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:03:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 18:04:25
User entered 'None (None)'	Shelby Pickle (b) (4) (b) (4)	16 Dec 2020 19:52:14

US3142034

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (5)

Generated On: 11 Aug 2021 21:58:56

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:55:45
User closed query 'Please enter Dec 15 contact into EDC' (Site from CRA).	(b) (4)	21 Apr 2021 18:39:29
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:03:31
Query 'Please enter Dec 15 contact into EDC' answered with 'Entered, log line 19' (Site from CRA).	(b) (4)	31 Mar 2021 20:25:08
User opened query 'Please enter Dec 15 contact into EDC' (Site from CRA).	(b) (4), (b) (6)	16 Feb 2021 21:04:14
User closed query 'Please enter Dec 15 contact into EDC' (Site from CRA).	(b) (4), (b) (6)	16 Feb 2021 21:04:14
Query 'Please enter Dec 15 contact into EDC' answered with 'Ok' (Site from CRA).	Shelby Pickle (b) (4)	04 Feb 2021 22:02:43
User opened query 'Please enter Dec 15 contact into EDC' (Site from CRA).	(b) (4), (b) (6)	02 Feb 2021 18:15:03
User entered 'Day 5 (Day 5)'	Shelby Pickle (b) (4)	16 Dec 2020 19:53:29
	(b) (4)	

US3142034

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (5)

Generated On: 11 Aug 2021 21:58:56

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:55:45
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:03:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 18:04:25
User entered '14 Dec 2020'	Shelby Pickle (b) (4) (b) (4)	16 Dec 2020 19:53:29

US3142034

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (5)

Generated On: 11 Aug 2021 21:58:56

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:55:45
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:03:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 18:04:25
User entered '0'	Shelby Pickle (b) (4) (b) (4)	16 Dec 2020 19:53:29

US3142034

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (5)

Generated On: 11 Aug 2021 21:58:56

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:55:45
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:03:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 18:04:25
User entered '93'	Shelby Pickle (b) (4) (b) (4)	16 Dec 2020 19:53:29

US3142034

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (5)

Generated On: 11 Aug 2021 21:58:56

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:55:45
User entered '%'	System	16 Dec 2020 19:53:29

US3142034

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (5)

Generated On: 11 Aug 2021 21:58:56

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:55:45
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:03:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 18:04:25
User entered '97.8' F	Shelby Pickle (b) (4) (b) (4)	16 Dec 2020 19:53:29

US3142034

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (5)

Generated On: 11 Aug 2021 21:58:56

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:55:45
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:03:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 18:12:54
Query 'Please provide source documents for "Chills"' canceled (Site from CRA).		02 Feb 2021 18:12:51
User opened query 'Please provide source documents for "Chills"' (Site from CRA).		02 Feb 2021 18:09:54
DataPoint Un-verified.		02 Feb 2021 18:06:05
DataPoint Verified.		02 Feb 2021 18:04:25
User entered 'None (None)'	Shelby Pickle (b) (4) (b) (4)	16 Dec 2020 19:53:29

US3142034

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (5)

Generated On: 11 Aug 2021 21:58:56

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:55:45
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:03:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 18:12:34
Query 'Please provide SD for severity of symptom.' canceled (Site from CRA).		02 Feb 2021 18:12:22
User opened query 'Please provide SD for severity of symptom.' (Site from CRA).		02 Feb 2021 18:11:46
DataPoint Un-verified.		02 Feb 2021 18:10:24
DataPoint Verified.		02 Feb 2021 18:10:21
DataPoint Un-verified.		02 Feb 2021 18:09:59
DataPoint Verified.		02 Feb 2021 18:04:25
User entered 'Mild (Mild)'	Shelby Pickle (b) (4) (b) (4)	16 Dec 2020 19:53:29

US3142034

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (5)

Generated On: 11 Aug 2021 21:58:56

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:55:45
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:03:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 18:04:25
User entered 'None (None)'	Shelby Pickle (b) (4) (b) (4)	16 Dec 2020 19:53:29

US3142034

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (5)

Generated On: 11 Aug 2021 21:58:56

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:55:45
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:03:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 18:04:25
User entered 'None (None)'	Shelby Pickle (b) (4) (b) (4)	16 Dec 2020 19:53:29

US3142034

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (5)

Generated On: 11 Aug 2021 21:58:56

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:55:45
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:03:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 18:04:25
User entered 'None (None)'	Shelby Pickle (b) (4) (b) (4)	16 Dec 2020 19:53:29

US3142034

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (5)

Generated On: 11 Aug 2021 21:58:56

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:55:45
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:03:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 18:04:25
User entered 'None (None)'	Shelby Pickle (b) (4) (b) (4)	16 Dec 2020 19:53:29

US3142034

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (5)

Generated On: 11 Aug 2021 21:58:56

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:55:45
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:03:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 18:04:25
User entered 'None (None)'	Shelby Pickle (b) (4) (b) (4)	16 Dec 2020 19:53:29

US3142034

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (5)

Generated On: 11 Aug 2021 21:58:56

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:55:45
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:03:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 18:04:25
User entered 'None (None)'	Shelby Pickle (b) (4) (b) (4)	16 Dec 2020 19:53:29

US3142034

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (5)

Generated On: 11 Aug 2021 21:58:56

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:55:45
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:03:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 18:04:25
User entered 'None (None)'	Shelby Pickle (b) (4) (b) (4)	16 Dec 2020 19:53:29

US3142034

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (5)

Generated On: 11 Aug 2021 21:58:56

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:55:45
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:03:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 18:04:25
User entered 'None (None)'	Shelby Pickle (b) (4) (b) (4)	16 Dec 2020 19:53:29

US3142034

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (5)

Generated On: 11 Aug 2021 21:58:56

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:55:45
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:03:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 18:04:25
User entered 'Mild (Mild)'	Shelby Pickle (b) (4) (b) (4)	16 Dec 2020 19:53:29

US3142034

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (5)

Generated On: 11 Aug 2021 21:58:56

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:55:45
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:03:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 18:04:25
User entered 'Mild (Mild)'	Shelby Pickle (b) (4) (b) (4)	16 Dec 2020 19:53:29

US3142034

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (5)

Generated On: 11 Aug 2021 21:58:56

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:55:45
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:03:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 18:04:25
User entered 'None (None)'	Shelby Pickle (b) (4) (b) (4)	16 Dec 2020 19:53:29

US3142034

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (5)

Generated On: 11 Aug 2021 21:58:56

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:55:45
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:03:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 18:04:25
User entered 'None (None)'	Shelby Pickle (b) (4) (b) (4)	16 Dec 2020 19:53:29

US3142034

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (5)

Generated On: 11 Aug 2021 21:58:56

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:55:45
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:03:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 18:04:25
User entered 'None (None)'	Shelby Pickle (b) (4) (b) (4)	16 Dec 2020 19:53:29

US3142034

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (5)

Generated On: 11 Aug 2021 21:58:56

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:55:45
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:03:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 18:04:25
User entered 'None (None)'	Shelby Pickle (b) (4) (b) (4)	16 Dec 2020 19:53:29

US3142034

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (6)

Generated On: 11 Aug 2021 21:58:56

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:55:45
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 19:03:31
User entered 'Day 7 (Day 7)' reason for change: Data Entry Error	Shelby Pickle (b) (4) (b) (4)	23 Dec 2020 00:20:52
User entered 'Day 6 (Day 6)'	Jami Wagner (b) (4) (b) (4)	21 Dec 2020 18:27:30

US3142034

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (6)

Generated On: 11 Aug 2021 21:58:56

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:55:45
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:03:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 18:04:25
User entered '16 Dec 2020'	Jami Wagner (b) (4) (b) (4)	21 Dec 2020 18:27:30

US3142034

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (6)

Generated On: 11 Aug 2021 21:58:56

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:55:45
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:03:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 18:04:25
User entered '0'	Jami Wagner (b) (4) (b) (4)	21 Dec 2020 18:27:30

US3142034

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (6)

Generated On: 11 Aug 2021 21:58:56

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:55:45
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:03:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 18:04:25
User entered '93'	Jami Wagner (b) (4) (b) (4)	21 Dec 2020 18:27:30

US3142034

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (6)

Generated On: 11 Aug 2021 21:58:56

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:55:45
User entered '%'	System	21 Dec 2020 18:27:30

US3142034

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (6)

Generated On: 11 Aug 2021 21:58:56

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:55:45
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:03:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 18:04:25
User entered '97.6' F	Jami Wagner (b) (4) (b) (4)	21 Dec 2020 18:27:30

US3142034

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (6)

Generated On: 11 Aug 2021 21:58:56

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:55:45
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:03:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 18:04:25
User entered 'None (None)'	Jami Wagner (b) (4) (b) (4)	21 Dec 2020 18:27:30

US3142034

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (6)

Generated On: 11 Aug 2021 21:58:56

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:55:45
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:03:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 18:04:25
User entered 'None (None)'	Jami Wagner (b) (4) (b) (4)	21 Dec 2020 18:27:30

US3142034

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (6)

Generated On: 11 Aug 2021 21:58:56

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:55:45
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:03:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 18:04:25
User entered 'None (None)'	Jami Wagner (b) (4) (b) (4)	21 Dec 2020 18:27:30

US3142034

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (6)

Generated On: 11 Aug 2021 21:58:56

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:55:45
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:03:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 18:04:25
User entered 'None (None)'	Jami Wagner (b) (4) (b) (4)	21 Dec 2020 18:27:30

US3142034

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (6)

Generated On: 11 Aug 2021 21:58:56

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:55:45
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:03:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 18:04:25
User entered 'None (None)'	Jami Wagner (b) (4) (b) (4)	21 Dec 2020 18:27:30

US3142034

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (6)

Generated On: 11 Aug 2021 21:58:56

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:55:45
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:03:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 18:04:25
User entered 'None (None)'	Jami Wagner (b) (4) (b) (4)	21 Dec 2020 18:27:30

US3142034

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (6)

Generated On: 11 Aug 2021 21:58:56

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:55:45
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:03:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 18:04:25
User entered 'None (None)'	Jami Wagner (b) (4) (b) (4)	21 Dec 2020 18:27:30

US3142034

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (6)

Generated On: 11 Aug 2021 21:58:56

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:55:45
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:03:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 18:04:25
User entered 'None (None)'	Jami Wagner (b) (4) (b) (4)	21 Dec 2020 18:27:30

US3142034

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (6)

Generated On: 11 Aug 2021 21:58:56

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:55:45
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:03:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 18:04:25
User entered 'None (None)'	Jami Wagner (b) (4) (b) (4)	21 Dec 2020 18:27:30

US3142034

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (6)

Generated On: 11 Aug 2021 21:58:56

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:55:45
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:03:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 18:04:25
User entered 'None (None)'	Jami Wagner (b) (4) (b) (4)	21 Dec 2020 18:27:30

US3142034

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (6)

Generated On: 11 Aug 2021 21:58:56

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:55:45
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:03:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 18:04:25
User entered 'Mild (Mild)'	Jami Wagner (b) (4) (b) (4)	21 Dec 2020 18:27:30

US3142034

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (6)

Generated On: 11 Aug 2021 21:58:56

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:55:45
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:03:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 18:04:25
User entered 'Mild (Mild)'	Jami Wagner (b) (4) (b) (4)	21 Dec 2020 18:27:30

US3142034

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (6)

Generated On: 11 Aug 2021 21:58:56

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:55:45
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:03:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 18:04:25
User entered 'None (None)'	Jami Wagner (b) (4) (b) (4)	21 Dec 2020 18:27:30

US3142034

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (6)

Generated On: 11 Aug 2021 21:58:56

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:55:45
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:03:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 18:04:25
User entered 'None (None)'	Jami Wagner (b) (4) (b) (4)	21 Dec 2020 18:27:30

US3142034

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (6)

Generated On: 11 Aug 2021 21:58:56

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:55:45
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:03:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 18:04:25
User entered 'None (None)'	Jami Wagner (b) (4) (b) (4)	21 Dec 2020 18:27:30

US3142034

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (6)

Generated On: 11 Aug 2021 21:58:56

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:55:45
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:03:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 18:04:25
User entered 'None (None)'	Jami Wagner (b) (4) (b) (4)	21 Dec 2020 18:27:30

US3142034

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (7)

Generated On: 11 Aug 2021 21:58:56

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:55:45
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 19:03:31
User entered 'Day 8 (Day 8)'	Shelby Pickle (b) (4) (b) (4)	23 Dec 2020 00:20:52

US3142034

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (7)

Generated On: 11 Aug 2021 21:58:56

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:55:45
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:03:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 18:04:25
User entered '17 Dec 2020'	Shelby Pickle (b) (4) (b) (4)	23 Dec 2020 00:20:52

US3142034

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (7)

Generated On: 11 Aug 2021 21:58:56

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:55:45
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:03:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 18:04:25
User entered '1'	Shelby Pickle (b) (4) (b) (4)	23 Dec 2020 00:20:52

US3142034

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (7)

Generated On: 11 Aug 2021 21:58:56

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:55:45
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:03:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 18:04:25
User entered empty.	Shelby Pickle (b) (4) (b) (4)	23 Dec 2020 00:20:52

US3142034

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (7)

Generated On: 11 Aug 2021 21:58:56

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:55:45
User entered empty.	System	23 Dec 2020 00:20:52

US3142034

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (7)

Generated On: 11 Aug 2021 21:58:56

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:55:45
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:03:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 18:04:25
User entered empty.	Shelby Pickle (b) (4) (b) (4)	23 Dec 2020 00:20:52

US3142034

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (7)

Generated On: 11 Aug 2021 21:58:56

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:55:45
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:03:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 18:04:25
User entered empty.	Shelby Pickle (b) (4) (b) (4)	23 Dec 2020 00:20:52

US3142034

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (7)

Generated On: 11 Aug 2021 21:58:56

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:55:45
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:03:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 18:04:25
User entered empty.	Shelby Pickle (b) (4) (b) (4)	23 Dec 2020 00:20:52

US3142034

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (7)

Generated On: 11 Aug 2021 21:58:56

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:55:45
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:03:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 18:04:25
User entered empty.	Shelby Pickle (b) (4) (b) (4)	23 Dec 2020 00:20:52

US3142034

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (7)

Generated On: 11 Aug 2021 21:58:56

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:55:45
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:03:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 18:04:25
User entered empty.	Shelby Pickle (b) (4) (b) (4)	23 Dec 2020 00:20:52

US3142034

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (7)

Generated On: 11 Aug 2021 21:58:56

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:55:45
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:03:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 18:04:25
User entered empty.	Shelby Pickle (b) (4) (b) (4)	23 Dec 2020 00:20:52

US3142034

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (7)

Generated On: 11 Aug 2021 21:58:56

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:55:45
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:03:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 18:04:25
User entered empty.	Shelby Pickle (b) (4) (b) (4)	23 Dec 2020 00:20:52

US3142034

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (7)

Generated On: 11 Aug 2021 21:58:56

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:55:45
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:03:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 18:04:25
User entered empty.	Shelby Pickle (b) (4) (b) (4)	23 Dec 2020 00:20:52

US3142034

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (7)

Generated On: 11 Aug 2021 21:58:56

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:55:45
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:03:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 18:04:25
User entered empty.	Shelby Pickle (b) (4) (b) (4)	23 Dec 2020 00:20:52

US3142034

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (7)

Generated On: 11 Aug 2021 21:58:56

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:55:45
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:03:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 18:04:25
User entered empty.	Shelby Pickle (b) (4) (b) (4)	23 Dec 2020 00:20:52

US3142034

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (7)

Generated On: 11 Aug 2021 21:58:56

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:55:45
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:03:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 18:04:25
User entered empty.	Shelby Pickle (b) (4) (b) (4)	23 Dec 2020 00:20:52

US3142034

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (7)

Generated On: 11 Aug 2021 21:58:56

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:55:45
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:03:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 18:04:25
User entered empty.	Shelby Pickle (b) (4) (b) (4)	23 Dec 2020 00:20:52

US3142034

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (7)

Generated On: 11 Aug 2021 21:58:56

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:55:45
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:03:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 18:04:25
User entered empty.	Shelby Pickle (b) (4) (b) (4)	23 Dec 2020 00:20:52

US3142034

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (7)

Generated On: 11 Aug 2021 21:58:56

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:55:45
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:03:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 18:04:25
User entered empty.	Shelby Pickle (b) (4) (b) (4)	23 Dec 2020 00:20:52

US3142034

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (7)

Generated On: 11 Aug 2021 21:58:56

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:55:45
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:03:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 18:04:25
User entered empty.	Shelby Pickle (b) (4) (b) (4)	23 Dec 2020 00:20:52

US3142034

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (7)

Generated On: 11 Aug 2021 21:58:56

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:55:45
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:03:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 18:04:25
User entered empty.	Shelby Pickle (b) (4) (b) (4)	23 Dec 2020 00:20:52

US3142034

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (7)

Generated On: 11 Aug 2021 21:58:56

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:55:45
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:03:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 18:04:25
User entered empty.	Shelby Pickle (b) (4) (b) (4)	23 Dec 2020 00:20:52

US3142034

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (8)

Generated On: 11 Aug 2021 21:58:56

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:55:45
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 19:03:31
User entered 'Day 9 (Day 9)'	Shelby Pickle (b) (4) (b) (4)	23 Dec 2020 00:21:12

US3142034

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (8)

Generated On: 11 Aug 2021 21:58:56

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:55:45
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:03:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 18:04:25
User entered '18 Dec 2020'	Shelby Pickle (b) (4) (b) (4)	23 Dec 2020 00:21:12

US3142034

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (8)

Generated On: 11 Aug 2021 21:58:56

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:55:45
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:03:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 18:04:25
User entered 'l'	Shelby Pickle (b) (4) (b) (4)	23 Dec 2020 00:21:12

US3142034

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (8)

Generated On: 11 Aug 2021 21:58:56

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:55:45
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:03:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 18:04:25
User entered empty.	Shelby Pickle (b) (4) (b) (4)	23 Dec 2020 00:21:12

US3142034

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (8)

Generated On: 11 Aug 2021 21:58:56

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:55:45
User entered empty.	System	23 Dec 2020 00:21:12

US3142034

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (8)

Generated On: 11 Aug 2021 21:58:56

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:55:45
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:03:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 18:04:25
User entered empty.	Shelby Pickle (b) (4) (b) (4)	23 Dec 2020 00:21:12

US3142034

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (8)

Generated On: 11 Aug 2021 21:58:56

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:55:45
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:03:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 18:04:25
User entered empty.	Shelby Pickle (b) (4) (b) (4)	23 Dec 2020 00:21:12

US3142034

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (8)

Generated On: 11 Aug 2021 21:58:56

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:55:45
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:03:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 18:04:25
User entered empty.	Shelby Pickle (b) (4) (b) (4)	23 Dec 2020 00:21:12

US3142034

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (8)

Generated On: 11 Aug 2021 21:58:56

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:55:45
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:03:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 18:04:25
User entered empty.	Shelby Pickle (b) (4) (b) (4)	23 Dec 2020 00:21:12

US3142034

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (8)

Generated On: 11 Aug 2021 21:58:56

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:55:45
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:03:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 18:04:25
User entered empty.	Shelby Pickle (b) (4) (b) (4)	23 Dec 2020 00:21:12

US3142034

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (8)

Generated On: 11 Aug 2021 21:58:56

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:55:45
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:03:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 18:04:25
User entered empty.	Shelby Pickle (b) (4) (b) (4)	23 Dec 2020 00:21:12

US3142034

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (8)

Generated On: 11 Aug 2021 21:58:56

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:55:45
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:03:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 18:04:25
User entered empty.	Shelby Pickle (b) (4) (b) (4)	23 Dec 2020 00:21:12

US3142034

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (8)

Generated On: 11 Aug 2021 21:58:56

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:55:45
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:03:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 18:04:25
User entered empty.	Shelby Pickle (b) (4) (b) (4)	23 Dec 2020 00:21:12

US3142034

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (8)

Generated On: 11 Aug 2021 21:58:56

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:55:45
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:03:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 18:04:25
User entered empty.	Shelby Pickle (b) (4) (b) (4)	23 Dec 2020 00:21:12

US3142034

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (8)

Generated On: 11 Aug 2021 21:58:56

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:55:45
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:03:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 18:04:25
User entered empty.	Shelby Pickle (b) (4) (b) (4)	23 Dec 2020 00:21:12

US3142034

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (8)

Generated On: 11 Aug 2021 21:58:56

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:55:45
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:03:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 18:04:25
User entered empty.	Shelby Pickle (b) (4) (b) (4)	23 Dec 2020 00:21:12

US3142034

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (8)

Generated On: 11 Aug 2021 21:58:56

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:55:45
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:03:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 18:04:25
User entered empty.	Shelby Pickle (b) (4) (b) (4)	23 Dec 2020 00:21:12

US3142034

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (8)

Generated On: 11 Aug 2021 21:58:56

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:55:45
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:03:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 18:04:25
User entered empty.	Shelby Pickle (b) (4) (b) (4)	23 Dec 2020 00:21:12

US3142034

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (8)

Generated On: 11 Aug 2021 21:58:56

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:55:45
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:03:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 18:04:25
User entered empty.	Shelby Pickle (b) (4) (b) (4)	23 Dec 2020 00:21:12

US3142034

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (8)

Generated On: 11 Aug 2021 21:58:56

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:55:45
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:03:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 18:04:25
User entered empty.	Shelby Pickle (b) (4) (b) (4)	23 Dec 2020 00:21:12

US3142034

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (8)

Generated On: 11 Aug 2021 21:58:56

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:55:45
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:03:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 18:04:25
User entered empty.	Shelby Pickle (b) (4) (b) (4)	23 Dec 2020 00:21:12

US3142034

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (8)

Generated On: 11 Aug 2021 21:58:56

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:55:45
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:03:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 18:04:25
User entered empty.	Shelby Pickle (b) (4) (b) (4)	23 Dec 2020 00:21:12

US3142034

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (9)

Generated On: 11 Aug 2021 21:58:56

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:55:45
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 19:03:31
User entered 'Day 10 (Day 10)'	Shelby Pickle (b) (4) (b) (4)	23 Dec 2020 00:21:32

US3142034

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (9)

Generated On: 11 Aug 2021 21:58:56

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:55:45
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:03:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 18:04:25
User entered '19 Dec 2020'	Shelby Pickle (b) (4) (b) (4)	23 Dec 2020 00:21:32

US3142034

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (9)

Generated On: 11 Aug 2021 21:58:56

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:55:45
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:03:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 18:04:25
User entered '1'	Shelby Pickle (b) (4) (b) (4)	23 Dec 2020 00:21:32

US3142034

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (9)

Generated On: 11 Aug 2021 21:58:56

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:55:45
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:03:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 18:04:25
User entered empty.	Shelby Pickle (b) (4) (b) (4)	23 Dec 2020 00:21:32

US3142034

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (9)

Generated On: 11 Aug 2021 21:58:56

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:55:45
User entered empty.	System	23 Dec 2020 00:21:32

US3142034

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (9)

Generated On: 11 Aug 2021 21:58:56

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:55:45
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:03:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 18:04:25
User entered empty.	Shelby Pickle (b) (4) (b) (4)	23 Dec 2020 00:21:32

US3142034

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (9)

Generated On: 11 Aug 2021 21:58:56

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:55:45
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:03:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 18:04:25
User entered empty.	Shelby Pickle (b) (4) (b) (4)	23 Dec 2020 00:21:32

US3142034

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (9)

Generated On: 11 Aug 2021 21:58:56

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:55:45
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:03:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 18:04:25
User entered empty.	Shelby Pickle (b) (4) (b) (4)	23 Dec 2020 00:21:32

US3142034

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (9)

Generated On: 11 Aug 2021 21:58:56

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:55:45
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:03:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 18:04:25
User entered empty.	Shelby Pickle (b) (4) (b) (4)	23 Dec 2020 00:21:32

US3142034

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (9)

Generated On: 11 Aug 2021 21:58:56

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:55:45
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:03:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 18:04:25
User entered empty.	Shelby Pickle (b) (4) (b) (4)	23 Dec 2020 00:21:32

US3142034

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (9)

Generated On: 11 Aug 2021 21:58:56

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:55:45
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:03:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 18:04:25
User entered empty.	Shelby Pickle (b) (4) (b) (4)	23 Dec 2020 00:21:32

US3142034

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (9)

Generated On: 11 Aug 2021 21:58:56

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:55:45
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:03:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 18:04:25
User entered empty.	Shelby Pickle (b) (4) (b) (4)	23 Dec 2020 00:21:32

US3142034

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (9)

Generated On: 11 Aug 2021 21:58:56

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:55:45
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:03:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 18:04:25
User entered empty.	Shelby Pickle (b) (4) (b) (4)	23 Dec 2020 00:21:32

US3142034

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (9)

Generated On: 11 Aug 2021 21:58:56

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:55:45
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:03:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 18:04:25
User entered empty.	Shelby Pickle (b) (4) (b) (4)	23 Dec 2020 00:21:32

US3142034

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (9)

Generated On: 11 Aug 2021 21:58:56

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:55:45
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:03:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 18:04:25
User entered empty.	Shelby Pickle (b) (4) (b) (4)	23 Dec 2020 00:21:32

US3142034

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (9)

Generated On: 11 Aug 2021 21:58:56

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:55:45
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:03:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 18:04:25
User entered empty.	Shelby Pickle (b) (4) (b) (4)	23 Dec 2020 00:21:32

US3142034

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (9)

Generated On: 11 Aug 2021 21:58:56

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:55:45
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:03:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 18:04:25
User entered empty.	Shelby Pickle (b) (4) (b) (4)	23 Dec 2020 00:21:32

US3142034

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (9)

Generated On: 11 Aug 2021 21:58:56

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:55:45
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:03:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 18:04:25
User entered empty.	Shelby Pickle (b) (4) (b) (4)	23 Dec 2020 00:21:32

US3142034

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (9)

Generated On: 11 Aug 2021 21:58:56

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:55:45
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:03:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 18:04:25
User entered empty.	Shelby Pickle (b) (4) (b) (4)	23 Dec 2020 00:21:32

US3142034

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (9)

Generated On: 11 Aug 2021 21:58:56

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:55:45
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:03:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 18:04:25
User entered empty.	Shelby Pickle (b) (4) (b) (4)	23 Dec 2020 00:21:32

US3142034

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (9)

Generated On: 11 Aug 2021 21:58:56

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:55:45
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:03:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 18:04:25
User entered empty.	Shelby Pickle (b) (4) (b) (4)	23 Dec 2020 00:21:32

US3142034

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (9)

Generated On: 11 Aug 2021 21:58:56

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:55:45
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:03:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 18:04:25
User entered empty.	Shelby Pickle (b) (4) (b) (4)	23 Dec 2020 00:21:32

US3142034

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (10)

Generated On: 11 Aug 2021 21:58:56

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:55:45
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 19:03:31
User entered 'Day 11 (Day 11)'	Shelby Pickle (b) (4) (b) (4)	23 Dec 2020 00:22:37

US3142034

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (10)

Generated On: 11 Aug 2021 21:58:56

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:55:45
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:03:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 18:04:25
User entered '20 Dec 2020'	Shelby Pickle (b) (4) (b) (4)	23 Dec 2020 00:22:37

US3142034

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (10)

Generated On: 11 Aug 2021 21:58:56

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:55:45
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:03:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 18:04:25
User entered '0'	Shelby Pickle (b) (4) (b) (4)	23 Dec 2020 00:22:37

US3142034

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (10)

Generated On: 11 Aug 2021 21:58:56

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:55:45
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:03:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 18:04:25
User entered '94'	Shelby Pickle (b) (4) (b) (4)	23 Dec 2020 00:22:37

US3142034

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (10)

Generated On: 11 Aug 2021 21:58:56

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:55:45
User entered '%'	System	23 Dec 2020 00:22:37

US3142034

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (10)

Generated On: 11 Aug 2021 21:58:56

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:55:45
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:03:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 18:04:25
User entered '97.5' F	Shelby Pickle (b) (4) (b) (4)	23 Dec 2020 00:22:37

US3142034

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (10)

Generated On: 11 Aug 2021 21:58:56

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:55:45
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:03:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 18:04:25
User entered 'None (None)'	Shelby Pickle (b) (4) (b) (4)	23 Dec 2020 00:22:37

US3142034

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (10)

Generated On: 11 Aug 2021 21:58:56

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:55:45
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:03:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 18:04:25
User entered 'None (None)'	Shelby Pickle (b) (4) (b) (4)	23 Dec 2020 00:22:37

US3142034

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (10)

Generated On: 11 Aug 2021 21:58:56

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:55:45
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:03:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 18:04:25
User entered 'None (None)'	Shelby Pickle (b) (4) (b) (4)	23 Dec 2020 00:22:37

US3142034

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (10)

Generated On: 11 Aug 2021 21:58:56

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:55:45
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:03:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 18:04:25
User entered 'None (None)'	Shelby Pickle (b) (4) (b) (4)	23 Dec 2020 00:22:37

US3142034

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (10)

Generated On: 11 Aug 2021 21:58:56

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:55:45
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:03:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 18:04:25
User entered 'None (None)'	Shelby Pickle (b) (4) (b) (4)	23 Dec 2020 00:22:37

US3142034

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (10)

Generated On: 11 Aug 2021 21:58:56

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:55:45
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:03:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 18:04:25
User entered 'None (None)'	Shelby Pickle (b) (4) (b) (4)	23 Dec 2020 00:22:37

US3142034

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (10)

Generated On: 11 Aug 2021 21:58:56

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:55:45
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:03:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 18:04:25
User entered 'None (None)'	Shelby Pickle (b) (4) (b) (4)	23 Dec 2020 00:22:37

US3142034

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (10)

Generated On: 11 Aug 2021 21:58:56

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:55:45
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:03:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 18:04:25
User entered 'None (None)'	Shelby Pickle (b) (4) (b) (4)	23 Dec 2020 00:22:37

US3142034

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (10)

Generated On: 11 Aug 2021 21:58:56

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:55:45
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:03:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 18:04:25
User entered 'None (None)'	Shelby Pickle (b) (4) (b) (4)	23 Dec 2020 00:22:37

US3142034

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (10)

Generated On: 11 Aug 2021 21:58:56

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:55:45
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:03:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 18:04:25
User entered 'None (None)'	Shelby Pickle (b) (4) (b) (4)	23 Dec 2020 00:22:37

US3142034

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (10)

Generated On: 11 Aug 2021 21:58:56

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:55:45
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:03:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 18:04:25
User entered 'Mild (Mild)'	Shelby Pickle (b) (4) (b) (4)	23 Dec 2020 00:22:37

US3142034

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (10)

Generated On: 11 Aug 2021 21:58:56

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:55:45
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:03:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 18:04:25
User entered 'Mild (Mild)'	Shelby Pickle (b) (4) (b) (4)	23 Dec 2020 00:22:37

US3142034

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (10)

Generated On: 11 Aug 2021 21:58:56

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:55:45
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:03:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 18:04:25
User entered 'None (None)'	Shelby Pickle (b) (4) (b) (4)	23 Dec 2020 00:22:37

US3142034

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (10)

Generated On: 11 Aug 2021 21:58:56

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:55:45
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:03:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 18:04:25
User entered 'None (None)'	Shelby Pickle (b) (4) (b) (4)	23 Dec 2020 00:22:37

US3142034

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (10)

Generated On: 11 Aug 2021 21:58:56

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:55:45
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:03:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 18:04:25
User entered 'None (None)'	Shelby Pickle (b) (4) (b) (4)	23 Dec 2020 00:22:37

US3142034

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (10)

Generated On: 11 Aug 2021 21:58:56

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:55:45
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:03:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 18:04:25
User entered 'None (None)'	Shelby Pickle (b) (4) (b) (4)	23 Dec 2020 00:22:37

US3142034

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (11)

Generated On: 11 Aug 2021 21:58:56

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:55:45
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 19:03:31
User entered 'Day 12 (Day 12)'	Shelby Pickle (b) (4) (b) (4)	23 Dec 2020 00:23:40

US3142034

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (11)

Generated On: 11 Aug 2021 21:58:56

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:55:45
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:03:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 18:04:25
User entered '21 Dec 2020'	Shelby Pickle (b) (4) (b) (4)	23 Dec 2020 00:23:40

US3142034

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (11)

Generated On: 11 Aug 2021 21:58:56

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:55:45
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:03:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 18:04:25
User entered '0'	Shelby Pickle (b) (4) (b) (4)	23 Dec 2020 00:23:40

US3142034

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (11)

Generated On: 11 Aug 2021 21:58:56

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:55:45
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:03:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 18:04:25
User entered '93'	Shelby Pickle (b) (4) (b) (4)	23 Dec 2020 00:23:40

US3142034

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (11)

Generated On: 11 Aug 2021 21:58:56

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:55:45
User entered '%'	System	23 Dec 2020 00:23:40

US3142034

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (11)

Generated On: 11 Aug 2021 21:58:56

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:55:45
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:03:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 18:04:25
User entered '97.8' F	Shelby Pickle (b) (4) (b) (4)	23 Dec 2020 00:23:40

US3142034

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (11)

Generated On: 11 Aug 2021 21:58:56

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:55:45
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:03:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 18:04:25
User entered 'None (None)'	Shelby Pickle (b) (4) (b) (4)	23 Dec 2020 00:23:40

US3142034

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (11)

Generated On: 11 Aug 2021 21:58:56

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:55:45
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:03:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 18:04:25
User entered 'None (None)'	Shelby Pickle (b) (4) (b) (4)	23 Dec 2020 00:23:40

US3142034

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (11)

Generated On: 11 Aug 2021 21:58:56

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:55:45
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:03:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 18:04:25
User entered 'None (None)'	Shelby Pickle (b) (4) (b) (4)	23 Dec 2020 00:23:40

US3142034

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (11)

Generated On: 11 Aug 2021 21:58:56

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:55:45
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:03:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 18:04:25
User entered 'None (None)'	Shelby Pickle (b) (4) (b) (4)	23 Dec 2020 00:23:40

US3142034

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (11)

Generated On: 11 Aug 2021 21:58:56

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:55:45
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:03:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 18:04:25
User entered 'None (None)'	Shelby Pickle (b) (4) (b) (4)	23 Dec 2020 00:23:40

US3142034

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (11)

Generated On: 11 Aug 2021 21:58:56

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:55:45
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:03:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 18:04:25
User entered 'None (None)'	Shelby Pickle (b) (4) (b) (4)	23 Dec 2020 00:23:40

US3142034

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (11)

Generated On: 11 Aug 2021 21:58:56

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:55:45
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:03:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 18:04:25
User entered 'None (None)'	Shelby Pickle (b) (4) (b) (4)	23 Dec 2020 00:23:40

US3142034

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (11)

Generated On: 11 Aug 2021 21:58:56

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:55:45
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:03:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 18:04:25
User entered 'None (None)'	Shelby Pickle (b) (4) (b) (4)	23 Dec 2020 00:23:40

US3142034

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (11)

Generated On: 11 Aug 2021 21:58:56

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:55:45
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:03:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 18:04:25
User entered 'None (None)'	Shelby Pickle (b) (4) (b) (4)	23 Dec 2020 00:23:40

US3142034

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (11)

Generated On: 11 Aug 2021 21:58:56

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:55:45
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:03:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 18:04:25
User entered 'None (None)'	Shelby Pickle (b) (4) (b) (4)	23 Dec 2020 00:23:40

US3142034

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (11)

Generated On: 11 Aug 2021 21:58:56

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:55:45
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:03:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 18:04:25
User entered 'Mild (Mild)'	Shelby Pickle (b) (4) (b) (4)	23 Dec 2020 00:23:40

US3142034

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (11)

Generated On: 11 Aug 2021 21:58:56

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:55:45
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:03:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 18:04:25
User entered 'Mild (Mild)'	Shelby Pickle (b) (4) (b) (4)	23 Dec 2020 00:23:40

US3142034

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (11)

Generated On: 11 Aug 2021 21:58:56

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:55:45
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:03:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 18:04:25
User entered 'None (None)'	Shelby Pickle (b) (4) (b) (4)	23 Dec 2020 00:23:40

US3142034

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (11)

Generated On: 11 Aug 2021 21:58:56

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:55:45
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:03:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 18:04:25
User entered 'None (None)'	Shelby Pickle (b) (4) (b) (4)	23 Dec 2020 00:23:40

US3142034

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (11)

Generated On: 11 Aug 2021 21:58:56

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:55:45
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:03:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 18:04:25
User entered 'None (None)'	Shelby Pickle (b) (4) (b) (4)	23 Dec 2020 00:23:40

US3142034

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (11)

Generated On: 11 Aug 2021 21:58:56

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:55:45
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:03:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 18:04:25
User entered 'None (None)'	Shelby Pickle (b) (4) (b) (4)	23 Dec 2020 00:23:40

US3142034

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (12)

Generated On: 11 Aug 2021 21:58:56

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:55:45
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 19:03:31
User entered 'Day 13 (Day 13)'	Shelby Pickle (b) (4) (b) (4)	22 Jan 2021 00:14:12

US3142034

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (12)

Generated On: 11 Aug 2021 21:58:56

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:55:45
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:03:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 18:04:25
User entered '22 Dec 2020'	Shelby Pickle (b) (4) (b) (4)	22 Jan 2021 00:14:12

US3142034

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (12)

Generated On: 11 Aug 2021 21:58:56

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:55:45
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:03:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 18:04:25
User entered '0'	Shelby Pickle (b) (4) (b) (4)	22 Jan 2021 00:14:12

US3142034

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (12)

Generated On: 11 Aug 2021 21:58:56

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:55:45
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:03:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 18:04:25
User entered '94'	Shelby Pickle (b) (4) (b) (4)	22 Jan 2021 00:14:12

US3142034

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (12)

Generated On: 11 Aug 2021 21:58:56

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:55:45
User entered '%'	System	22 Jan 2021 00:14:12

US3142034

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (12)

Generated On: 11 Aug 2021 21:58:56

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:55:45
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:03:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 18:04:25
User entered '97.9' F	Shelby Pickle (b) (4) (b) (4)	22 Jan 2021 00:14:12

US3142034

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (12)

Generated On: 11 Aug 2021 21:58:56

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:55:45
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:03:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 18:04:25
User entered 'None (None)'	Shelby Pickle (b) (4) (b) (4)	22 Jan 2021 00:14:12

US3142034

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (12)

Generated On: 11 Aug 2021 21:58:56

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:55:45
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:03:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 18:04:25
User entered 'None (None)'	Shelby Pickle (b) (4) (b) (4)	22 Jan 2021 00:14:12

US3142034

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (12)

Generated On: 11 Aug 2021 21:58:56

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:55:45
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:03:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 18:04:25
User entered 'None (None)'	Shelby Pickle (b) (4) (b) (4)	22 Jan 2021 00:14:12

US3142034

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (12)

Generated On: 11 Aug 2021 21:58:56

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:55:45
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:03:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 18:04:25
User entered 'None (None)'	Shelby Pickle (b) (4) (b) (4)	22 Jan 2021 00:14:12

US3142034

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (12)

Generated On: 11 Aug 2021 21:58:56

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:55:45
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:03:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 18:04:25
User entered 'Mild (Mild)'	Shelby Pickle (b) (4) (b) (4)	22 Jan 2021 00:14:12

US3142034

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (12)

Generated On: 11 Aug 2021 21:58:56

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:55:45
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:03:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 18:04:25
User entered 'None (None)'	Shelby Pickle (b) (4) (b) (4)	22 Jan 2021 00:14:12

US3142034

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (12)

Generated On: 11 Aug 2021 21:58:56

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:55:45
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:03:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 18:04:25
User entered 'None (None)'	Shelby Pickle (b) (4) (b) (4)	22 Jan 2021 00:14:12

US3142034

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (12)

Generated On: 11 Aug 2021 21:58:56

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:55:45
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:03:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 18:04:25
User entered 'None (None)'	Shelby Pickle (b) (4) (b) (4)	22 Jan 2021 00:14:12

US3142034

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (12)

Generated On: 11 Aug 2021 21:58:56

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:55:45
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:03:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 18:04:25
User entered 'None (None)'	Shelby Pickle (b) (4) (b) (4)	22 Jan 2021 00:14:12

US3142034

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (12)

Generated On: 11 Aug 2021 21:58:56

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:55:45
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:03:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 18:04:25
User entered 'None (None)'	Shelby Pickle (b) (4) (b) (4)	22 Jan 2021 00:14:12

US3142034

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (12)

Generated On: 11 Aug 2021 21:58:56

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:55:45
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:03:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 18:04:25
User entered 'Mild (Mild)'	Shelby Pickle (b) (4) (b) (4)	22 Jan 2021 00:14:12

US3142034

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (12)

Generated On: 11 Aug 2021 21:58:56

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:55:45
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:03:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 18:04:25
User entered 'Mild (Mild)'	Shelby Pickle (b) (4) (b) (4)	22 Jan 2021 00:14:12

US3142034

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (12)

Generated On: 11 Aug 2021 21:58:56

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:55:45
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:03:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 18:04:25
User entered 'None (None)'	Shelby Pickle (b) (4) (b) (4)	22 Jan 2021 00:14:12

US3142034

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (12)

Generated On: 11 Aug 2021 21:58:56

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:55:45
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:03:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 18:04:25
User entered 'None (None)'	Shelby Pickle (b) (4) (b) (4)	22 Jan 2021 00:14:12

US3142034

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (12)

Generated On: 11 Aug 2021 21:58:56

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:55:45
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:03:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 18:04:25
User entered 'None (None)'	Shelby Pickle (b) (4) (b) (4)	22 Jan 2021 00:14:12

US3142034

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (12)

Generated On: 11 Aug 2021 21:58:56

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:55:45
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:03:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 18:04:25
User entered 'None (None)'	Shelby Pickle (b) (4) (b) (4)	22 Jan 2021 00:14:12

US3142034

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (13)

Generated On: 11 Aug 2021 21:58:56

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:55:45
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 19:03:31
User entered 'Day 14 (Day 14)'	Shelby Pickle (b) (4) (b) (4)	22 Jan 2021 00:14:31

US3142034

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (13)

Generated On: 11 Aug 2021 21:58:56

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:55:45
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:03:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 18:04:25
User entered '23 Dec 2020'	Shelby Pickle (b) (4) (b) (4)	22 Jan 2021 00:14:31

US3142034

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (13)

Generated On: 11 Aug 2021 21:58:56

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:55:45
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:03:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 18:04:25
User entered '1'	Shelby Pickle (b) (4) (b) (4)	22 Jan 2021 00:14:31

US3142034

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (13)

Generated On: 11 Aug 2021 21:58:56

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:55:45
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:03:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 18:04:25
User entered empty.	Shelby Pickle (b) (4) (b) (4)	22 Jan 2021 00:14:31

US3142034

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (13)

Generated On: 11 Aug 2021 21:58:56

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:55:45
User entered empty.	System	22 Jan 2021 00:14:31

US3142034

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (13)

Generated On: 11 Aug 2021 21:58:56

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:55:45
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:03:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 18:04:25
User entered empty.	Shelby Pickle (b) (4) (b) (4)	22 Jan 2021 00:14:31

US3142034

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (13)

Generated On: 11 Aug 2021 21:58:56

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:55:45
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:03:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 18:04:25
User entered empty.	Shelby Pickle (b) (4) (b) (4)	22 Jan 2021 00:14:31

US3142034

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (13)

Generated On: 11 Aug 2021 21:58:56

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:55:45
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:03:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 18:04:25
User entered empty.	Shelby Pickle (b) (4) (b) (4)	22 Jan 2021 00:14:31

US3142034

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (13)

Generated On: 11 Aug 2021 21:58:56

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:55:45
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:03:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 18:04:25
User entered empty.	Shelby Pickle (b) (4) (b) (4)	22 Jan 2021 00:14:31

US3142034

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (13)

Generated On: 11 Aug 2021 21:58:56

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:55:45
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:03:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 18:04:25
User entered empty.	Shelby Pickle (b) (4) (b) (4)	22 Jan 2021 00:14:31

US3142034

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (13)

Generated On: 11 Aug 2021 21:58:56

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:55:45
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:03:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 18:04:25
User entered empty.	Shelby Pickle (b) (4) (b) (4)	22 Jan 2021 00:14:31

US3142034

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (13)

Generated On: 11 Aug 2021 21:58:56

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:55:45
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:03:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 18:04:25
User entered empty.	Shelby Pickle (b) (4) (b) (4)	22 Jan 2021 00:14:31

US3142034

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (13)

Generated On: 11 Aug 2021 21:58:56

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:55:45
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:03:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 18:04:25
User entered empty.	Shelby Pickle (b) (4) (b) (4)	22 Jan 2021 00:14:31

US3142034

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (13)

Generated On: 11 Aug 2021 21:58:56

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:55:45
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:03:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 18:04:25
User entered empty.	Shelby Pickle (b) (4) (b) (4)	22 Jan 2021 00:14:31

US3142034

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (13)

Generated On: 11 Aug 2021 21:58:56

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:55:45
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:03:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 18:04:25
User entered empty.	Shelby Pickle (b) (4) (b) (4)	22 Jan 2021 00:14:31

US3142034

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (13)

Generated On: 11 Aug 2021 21:58:56

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:55:45
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:03:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 18:04:25
User entered empty.	Shelby Pickle (b) (4) (b) (4)	22 Jan 2021 00:14:31

US3142034

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (13)

Generated On: 11 Aug 2021 21:58:56

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:55:45
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:03:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 18:04:25
User entered empty.	Shelby Pickle (b) (4) (b) (4)	22 Jan 2021 00:14:31

US3142034

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (13)

Generated On: 11 Aug 2021 21:58:56

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:55:45
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:03:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 18:04:25
User entered empty.	Shelby Pickle (b) (4) (b) (4)	22 Jan 2021 00:14:31

US3142034

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (13)

Generated On: 11 Aug 2021 21:58:56

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:55:45
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:03:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 18:04:25
User entered empty.	Shelby Pickle (b) (4) (b) (4)	22 Jan 2021 00:14:31

US3142034

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (13)

Generated On: 11 Aug 2021 21:58:56

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:55:45
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:03:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 18:04:25
User entered empty.	Shelby Pickle (b) (4) (b) (4)	22 Jan 2021 00:14:31

US3142034

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (13)

Generated On: 11 Aug 2021 21:58:56

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:55:45
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:03:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 18:04:25
User entered empty.	Shelby Pickle (b) (4) (b) (4)	22 Jan 2021 00:14:31

US3142034

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (13)

Generated On: 11 Aug 2021 21:58:56

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:55:45
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:03:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 18:04:25
User entered empty.	Shelby Pickle (b) (4) (b) (4)	22 Jan 2021 00:14:31

US3142034

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (14)

Generated On: 11 Aug 2021 21:58:56

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:55:45
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 19:03:31
User entered 'Day 15 (Day 15)'	Shelby Pickle (b) (4) (b) (4)	22 Jan 2021 00:14:40

US3142034

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (14)

Generated On: 11 Aug 2021 21:58:56

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:55:45
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:03:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 18:04:25
User entered '24 Dec 2020'	Shelby Pickle (b) (4) (b) (4)	22 Jan 2021 00:14:40

US3142034

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (14)

Generated On: 11 Aug 2021 21:58:56

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:55:45
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:03:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 18:04:25
User entered '1'	Shelby Pickle (b) (4) (b) (4)	22 Jan 2021 00:14:40

US3142034

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (14)

Generated On: 11 Aug 2021 21:58:56

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:55:45
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:03:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 18:04:25
User entered empty.	Shelby Pickle (b) (4) (b) (4)	22 Jan 2021 00:14:40

US3142034

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (14)

Generated On: 11 Aug 2021 21:58:56

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:55:45
User entered empty.	System	22 Jan 2021 00:14:40

US3142034

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (14)

Generated On: 11 Aug 2021 21:58:56

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:55:45
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:03:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 18:04:25
User entered empty.	Shelby Pickle (b) (4) (b) (4)	22 Jan 2021 00:14:40

US3142034

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (14)

Generated On: 11 Aug 2021 21:58:56

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:55:45
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:03:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 18:04:25
User entered empty.	Shelby Pickle (b) (4) (b) (4)	22 Jan 2021 00:14:40

US3142034

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (14)

Generated On: 11 Aug 2021 21:58:56

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:55:45
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:03:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 18:04:25
User entered empty.	Shelby Pickle (b) (4) (b) (4)	22 Jan 2021 00:14:40

US3142034

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (14)

Generated On: 11 Aug 2021 21:58:56

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:55:45
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:03:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 18:04:25
User entered empty.	Shelby Pickle (b) (4) (b) (4)	22 Jan 2021 00:14:40

US3142034

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (14)

Generated On: 11 Aug 2021 21:58:56

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:55:45
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:03:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 18:04:25
User entered empty.	Shelby Pickle (b) (4) (b) (4)	22 Jan 2021 00:14:40

US3142034

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (14)

Generated On: 11 Aug 2021 21:58:56

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:55:45
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:03:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 18:04:25
User entered empty.	Shelby Pickle (b) (4) (b) (4)	22 Jan 2021 00:14:40

US3142034

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (14)

Generated On: 11 Aug 2021 21:58:56

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:55:45
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:03:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 18:04:25
User entered empty.	Shelby Pickle (b) (4) (b) (4)	22 Jan 2021 00:14:40

US3142034

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (14)

Generated On: 11 Aug 2021 21:58:56

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:55:45
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:03:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 18:04:25
User entered empty.	Shelby Pickle (b) (4) (b) (4)	22 Jan 2021 00:14:40

US3142034

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (14)

Generated On: 11 Aug 2021 21:58:56

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:55:45
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:03:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 18:04:25
User entered empty.	Shelby Pickle (b) (4) (b) (4)	22 Jan 2021 00:14:40

US3142034

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (14)

Generated On: 11 Aug 2021 21:58:56

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:55:45
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:03:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 18:04:25
User entered empty.	Shelby Pickle (b) (4) (b) (4)	22 Jan 2021 00:14:40

US3142034

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (14)

Generated On: 11 Aug 2021 21:58:56

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:55:45
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:03:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 18:04:25
User entered empty.	Shelby Pickle (b) (4) (b) (4)	22 Jan 2021 00:14:40

US3142034

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (14)

Generated On: 11 Aug 2021 21:58:56

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:55:45
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:03:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 18:04:25
User entered empty.	Shelby Pickle (b) (4) (b) (4)	22 Jan 2021 00:14:40

US3142034

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (14)

Generated On: 11 Aug 2021 21:58:56

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:55:45
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:03:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 18:04:25
User entered empty.	Shelby Pickle (b) (4) (b) (4)	22 Jan 2021 00:14:40

US3142034

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (14)

Generated On: 11 Aug 2021 21:58:56

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:55:45
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:03:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 18:04:25
User entered empty.	Shelby Pickle (b) (4) (b) (4)	22 Jan 2021 00:14:40

US3142034

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (14)

Generated On: 11 Aug 2021 21:58:56

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:55:45
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:03:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 18:04:25
User entered empty.	Shelby Pickle (b) (4) (b) (4)	22 Jan 2021 00:14:40

US3142034

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (14)

Generated On: 11 Aug 2021 21:58:56

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:55:45
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:03:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 18:04:25
User entered empty.	Shelby Pickle (b) (4) (b) (4)	22 Jan 2021 00:14:40

US3142034

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (14)

Generated On: 11 Aug 2021 21:58:56

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:55:45
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:03:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 18:04:25
User entered empty.	Shelby Pickle (b) (4) (b) (4)	22 Jan 2021 00:14:40

US3142034

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (15)

Generated On: 11 Aug 2021 21:58:56

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:55:45
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 19:03:31
User entered 'Day 16 (Day 16)'	Shelby Pickle (b) (4) (b) (4)	22 Jan 2021 00:14:54

US3142034

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (15)

Generated On: 11 Aug 2021 21:58:56

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:55:45
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:03:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 18:04:25
User entered '25 Dec 2020'	Shelby Pickle (b) (4) (b) (4)	22 Jan 2021 00:14:54

US3142034

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (15)

Generated On: 11 Aug 2021 21:58:56

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:55:45
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:03:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 18:04:25
User entered '1'	Shelby Pickle (b) (4) (b) (4)	22 Jan 2021 00:14:54

US3142034

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (15)

Generated On: 11 Aug 2021 21:58:56

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:55:45
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:03:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 18:04:25
User entered empty.	Shelby Pickle (b) (4) (b) (4)	22 Jan 2021 00:14:54

US3142034

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (15)

Generated On: 11 Aug 2021 21:58:56

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:55:45
User entered empty.	System	22 Jan 2021 00:14:54

US3142034

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (15)

Generated On: 11 Aug 2021 21:58:56

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:55:45
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:03:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 18:04:25
User entered empty.	Shelby Pickle (b) (4) (b) (4)	22 Jan 2021 00:14:54

US3142034

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (15)

Generated On: 11 Aug 2021 21:58:56

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:55:45
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:03:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 18:04:25
User entered empty.	Shelby Pickle (b) (4) (b) (4)	22 Jan 2021 00:14:54

US3142034

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (15)

Generated On: 11 Aug 2021 21:58:56

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:55:45
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:03:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 18:04:25
User entered empty.	Shelby Pickle (b) (4) (b) (4)	22 Jan 2021 00:14:54

US3142034

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (15)

Generated On: 11 Aug 2021 21:58:56

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:55:45
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:03:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 18:04:25
User entered empty.	Shelby Pickle (b) (4) (b) (4)	22 Jan 2021 00:14:54

US3142034

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (15)

Generated On: 11 Aug 2021 21:58:56

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:55:45
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:03:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 18:04:25
User entered empty.	Shelby Pickle (b) (4) (b) (4)	22 Jan 2021 00:14:54

US3142034

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (15)

Generated On: 11 Aug 2021 21:58:56

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:55:45
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:03:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 18:04:25
User entered empty.	Shelby Pickle (b) (4) (b) (4)	22 Jan 2021 00:14:54

US3142034

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (15)

Generated On: 11 Aug 2021 21:58:56

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:55:45
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:03:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 18:04:25
User entered empty.	Shelby Pickle (b) (4) (b) (4)	22 Jan 2021 00:14:54

US3142034

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (15)

Generated On: 11 Aug 2021 21:58:56

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:55:45
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:03:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 18:04:25
User entered empty.	Shelby Pickle (b) (4) (b) (4)	22 Jan 2021 00:14:54

US3142034

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (15)

Generated On: 11 Aug 2021 21:58:56

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:55:45
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:03:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 18:04:25
User entered empty.	Shelby Pickle (b) (4) (b) (4)	22 Jan 2021 00:14:54

US3142034

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (15)

Generated On: 11 Aug 2021 21:58:56

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:55:45
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:03:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 18:04:25
User entered empty.	Shelby Pickle (b) (4) (b) (4)	22 Jan 2021 00:14:54

US3142034

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (15)

Generated On: 11 Aug 2021 21:58:56

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:55:45
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:03:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 18:04:25
User entered empty.	Shelby Pickle (b) (4) (b) (4)	22 Jan 2021 00:14:54

US3142034

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (15)

Generated On: 11 Aug 2021 21:58:56

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:55:45
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:03:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 18:04:25
User entered empty.	Shelby Pickle (b) (4) (b) (4)	22 Jan 2021 00:14:54

US3142034

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (15)

Generated On: 11 Aug 2021 21:58:56

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:55:45
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:03:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 18:04:25
User entered empty.	Shelby Pickle (b) (4) (b) (4)	22 Jan 2021 00:14:54

US3142034

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (15)

Generated On: 11 Aug 2021 21:58:56

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:55:45
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:03:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 18:04:25
User entered empty.	Shelby Pickle (b) (4) (b) (4)	22 Jan 2021 00:14:54

US3142034

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (15)

Generated On: 11 Aug 2021 21:58:56

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:55:45
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:03:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 18:04:25
User entered empty.	Shelby Pickle (b) (4) (b) (4)	22 Jan 2021 00:14:54

US3142034

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (15)

Generated On: 11 Aug 2021 21:58:56

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:55:45
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:03:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 18:04:25
User entered empty.	Shelby Pickle (b) (4) (b) (4)	22 Jan 2021 00:14:54

US3142034

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (15)

Generated On: 11 Aug 2021 21:58:56

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:55:45
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:03:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 18:04:25
User entered empty.	Shelby Pickle (b) (4) (b) (4)	22 Jan 2021 00:14:54

US3142034

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (16)

Generated On: 11 Aug 2021 21:58:56

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:55:45
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 19:03:31
User entered 'Day 17 (Day 17)'	Shelby Pickle (b) (4) (b) (4)	22 Jan 2021 00:15:07

US3142034

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (16)

Generated On: 11 Aug 2021 21:58:56

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:55:45
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:03:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 18:04:25
User entered '26 Dec 2020'	Shelby Pickle (b) (4) (b) (4)	22 Jan 2021 00:15:07

US3142034

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (16)

Generated On: 11 Aug 2021 21:58:56

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:55:45
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:03:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 18:04:25
User entered '1'	Shelby Pickle (b) (4) (b) (4)	22 Jan 2021 00:15:07

US3142034

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (16)

Generated On: 11 Aug 2021 21:58:56

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:55:45
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:03:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 18:04:25
User entered empty.	Shelby Pickle (b) (4) (b) (4)	22 Jan 2021 00:15:07

US3142034

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (16)

Generated On: 11 Aug 2021 21:58:56

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:55:45
User entered empty.	System	22 Jan 2021 00:15:07

US3142034

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (16)

Generated On: 11 Aug 2021 21:58:56

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:55:45
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:03:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 18:04:25
User entered empty.	Shelby Pickle (b) (4) (b) (4)	22 Jan 2021 00:15:07

US3142034

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (16)

Generated On: 11 Aug 2021 21:58:56

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:55:45
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:03:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 18:04:25
User entered empty.	Shelby Pickle (b) (4) (b) (4)	22 Jan 2021 00:15:07

US3142034

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (16)

Generated On: 11 Aug 2021 21:58:56

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:55:45
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:03:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 18:04:25
User entered empty.	Shelby Pickle (b) (4) (b) (4)	22 Jan 2021 00:15:07

US3142034

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (16)

Generated On: 11 Aug 2021 21:58:56

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:55:45
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:03:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 18:04:25
User entered empty.	Shelby Pickle (b) (4) (b) (4)	22 Jan 2021 00:15:07

US3142034

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (16)

Generated On: 11 Aug 2021 21:58:56

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:55:45
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:03:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 18:04:25
User entered empty.	Shelby Pickle (b) (4) (b) (4)	22 Jan 2021 00:15:07

US3142034

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (16)

Generated On: 11 Aug 2021 21:58:56

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:55:45
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:03:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 18:04:25
User entered empty.	Shelby Pickle (b) (4) (b) (4)	22 Jan 2021 00:15:07

US3142034

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (16)

Generated On: 11 Aug 2021 21:58:56

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:55:45
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:03:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 18:04:25
User entered empty.	Shelby Pickle (b) (4) (b) (4)	22 Jan 2021 00:15:07

US3142034

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (16)

Generated On: 11 Aug 2021 21:58:56

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:55:45
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:03:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 18:04:25
User entered empty.	Shelby Pickle (b) (4) (b) (4)	22 Jan 2021 00:15:07

US3142034

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (16)

Generated On: 11 Aug 2021 21:58:56

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:55:45
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:03:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 18:04:25
User entered empty.	Shelby Pickle (b) (4) (b) (4)	22 Jan 2021 00:15:07

US3142034

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (16)

Generated On: 11 Aug 2021 21:58:56

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:55:45
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:03:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 18:04:25
User entered empty.	Shelby Pickle (b) (4) (b) (4)	22 Jan 2021 00:15:07

US3142034

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (16)

Generated On: 11 Aug 2021 21:58:56

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:55:45
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:03:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 18:04:25
User entered empty.	Shelby Pickle (b) (4) (b) (4)	22 Jan 2021 00:15:07

US3142034

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (16)

Generated On: 11 Aug 2021 21:58:56

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:55:45
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:03:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 18:04:25
User entered empty.	Shelby Pickle (b) (4) (b) (4)	22 Jan 2021 00:15:07

US3142034

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (16)

Generated On: 11 Aug 2021 21:58:56

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:55:45
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:03:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 18:04:25
User entered empty.	Shelby Pickle (b) (4) (b) (4)	22 Jan 2021 00:15:07

US3142034

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (16)

Generated On: 11 Aug 2021 21:58:56

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:55:45
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:03:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 18:04:25
User entered empty.	Shelby Pickle (b) (4) (b) (4)	22 Jan 2021 00:15:07

US3142034

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (16)

Generated On: 11 Aug 2021 21:58:56

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:55:45
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:03:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 18:04:25
User entered empty.	Shelby Pickle (b) (4) (b) (4)	22 Jan 2021 00:15:07

US3142034

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (16)

Generated On: 11 Aug 2021 21:58:56

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:55:45
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:03:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 18:04:25
User entered empty.	Shelby Pickle (b) (4) (b) (4)	22 Jan 2021 00:15:07

US3142034

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (16)

Generated On: 11 Aug 2021 21:58:56

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:55:45
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:03:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 18:04:25
User entered empty.	Shelby Pickle (b) (4) (b) (4)	22 Jan 2021 00:15:07

US3142034

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (17)

Generated On: 11 Aug 2021 21:58:56

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:55:45
User closed query 'Per ETRTR: As per AE page, the end date of COVID infection is 28-Dec-2020. Please record Day 19 (28-Dec-2020) data. Thank You!' (Site from CRA).	(b) (4)	27 Apr 2021 19:31:03
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 19:03:31
Query 'Per ETRTR: As per AE page, the end date of COVID infection is 28-Dec-2020. Please record Day 19 (28-Dec-2020) data. Thank You!' answered with 'AS PER REQUEST DAY 19 IS IN SYMPTOM LOG FOR 28DEC2020. TY' (Site from CRA).	Lisa Jackson (b) (4) (b) (4)	07 Apr 2021 20:06:02
User opened query 'Per ETRTR: As per AE page, the end date of COVID infection is 28-Dec-2020. Please record Day 19 (28-Dec-2020) data. Thank You!' (Site from CRA).	(b) (4), (b) (6)	06 Apr 2021 10:42:53
User entered 'Day 18 (Day 18)'	Shelby Pickle (b) (4) (b) (4)	22 Jan 2021 00:15:21

US3142034

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (17)

Generated On: 11 Aug 2021 21:58:56

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:55:45
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:03:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 18:04:25
User entered '27 Dec 2020'	Shelby Pickle (b) (4) (b) (4)	22 Jan 2021 00:15:21

US3142034

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (17)

Generated On: 11 Aug 2021 21:58:56

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:55:45
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:03:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 18:04:25
User entered '1'	Shelby Pickle (b) (4) (b) (4)	22 Jan 2021 00:15:21

US3142034

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (17)

Generated On: 11 Aug 2021 21:58:56

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:55:45
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:03:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 18:04:25
User entered empty.	Shelby Pickle (b) (4) (b) (4)	22 Jan 2021 00:15:21

US3142034

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (17)

Generated On: 11 Aug 2021 21:58:56

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:55:45
User entered empty.	System	22 Jan 2021 00:15:21

US3142034

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (17)

Generated On: 11 Aug 2021 21:58:56

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:55:45
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:03:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 18:04:25
User entered empty.	Shelby Pickle (b) (4) (b) (4)	22 Jan 2021 00:15:21

US3142034

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (17)

Generated On: 11 Aug 2021 21:58:56

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:55:45
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:03:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 18:04:25
User entered empty.	Shelby Pickle (b) (4) (b) (4)	22 Jan 2021 00:15:21

US3142034

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (17)

Generated On: 11 Aug 2021 21:58:56

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:55:45
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:03:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 18:04:25
User entered empty.	Shelby Pickle (b) (4) (b) (4)	22 Jan 2021 00:15:21

US3142034

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (17)

Generated On: 11 Aug 2021 21:58:56

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:55:45
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:03:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 18:04:25
User entered empty.	Shelby Pickle (b) (4) (b) (4)	22 Jan 2021 00:15:21

US3142034

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (17)

Generated On: 11 Aug 2021 21:58:56

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:55:45
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:03:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 18:04:25
User entered empty.	Shelby Pickle (b) (4) (b) (4)	22 Jan 2021 00:15:21

US3142034

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (17)

Generated On: 11 Aug 2021 21:58:56

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:55:45
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:03:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 18:04:25
User entered empty.	Shelby Pickle (b) (4) (b) (4)	22 Jan 2021 00:15:21

US3142034

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (17)

Generated On: 11 Aug 2021 21:58:56

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:55:45
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:03:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 18:04:25
User entered empty.	Shelby Pickle (b) (4) (b) (4)	22 Jan 2021 00:15:21

US3142034

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (17)

Generated On: 11 Aug 2021 21:58:56

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:55:45
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:03:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 18:04:25
User entered empty.	Shelby Pickle (b) (4) (b) (4)	22 Jan 2021 00:15:21

US3142034

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (17)

Generated On: 11 Aug 2021 21:58:56

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:55:45
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:03:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 18:04:25
User entered empty.	Shelby Pickle (b) (4) (b) (4)	22 Jan 2021 00:15:21

US3142034

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (17)

Generated On: 11 Aug 2021 21:58:56

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:55:45
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:03:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 18:04:25
User entered empty.	Shelby Pickle (b) (4) (b) (4)	22 Jan 2021 00:15:21

US3142034

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (17)

Generated On: 11 Aug 2021 21:58:56

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:55:45
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:03:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 18:04:25
User entered empty.	Shelby Pickle (b) (4) (b) (4)	22 Jan 2021 00:15:21

US3142034

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (17)

Generated On: 11 Aug 2021 21:58:56

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:55:45
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:03:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 18:04:25
User entered empty.	Shelby Pickle (b) (4) (b) (4)	22 Jan 2021 00:15:21

US3142034

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (17)

Generated On: 11 Aug 2021 21:58:56

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:55:45
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:03:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 18:04:25
User entered empty.	Shelby Pickle (b) (4) (b) (4)	22 Jan 2021 00:15:21

US3142034

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (17)

Generated On: 11 Aug 2021 21:58:56

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:55:45
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:03:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 18:04:25
User entered empty.	Shelby Pickle (b) (4) (b) (4)	22 Jan 2021 00:15:21

US3142034

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (17)

Generated On: 11 Aug 2021 21:58:56

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:55:45
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:03:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 18:04:25
User entered empty.	Shelby Pickle (b) (4) (b) (4)	22 Jan 2021 00:15:21

US3142034

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (17)

Generated On: 11 Aug 2021 21:58:56

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:55:45
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:03:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 18:04:25
User entered empty.	Shelby Pickle (b) (4) (b) (4)	22 Jan 2021 00:15:21

US3142034

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (17)

Generated On: 11 Aug 2021 21:58:56

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:55:45
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:03:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 18:04:25
User entered empty.	Shelby Pickle (b) (4) (b) (4)	22 Jan 2021 00:15:21

US3142034

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (18)

Generated On: 11 Aug 2021 21:58:56

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:55:45
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 19:03:31
User entered 'Day 26 (Day 26)'	Shelby Pickle (b) (4) (b) (4)	22 Jan 2021 00:16:21

US3142034

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (18)

Generated On: 11 Aug 2021 21:58:56

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:55:45
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:03:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 18:04:25
User entered '04 Jan 2021'	Shelby Pickle (b) (4) (b) (4)	22 Jan 2021 00:16:21

US3142034

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (18)

Generated On: 11 Aug 2021 21:58:56

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:55:45
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:03:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 18:04:25
User entered '0'	Shelby Pickle (b) (4) (b) (4)	22 Jan 2021 00:16:21

US3142034

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (18)

Generated On: 11 Aug 2021 21:58:56

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:55:45
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:03:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 18:04:25
User entered '95'	Shelby Pickle (b) (4) (b) (4)	22 Jan 2021 00:16:21

US3142034

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (18)

Generated On: 11 Aug 2021 21:58:56

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:55:45
User entered '%'	System	22 Jan 2021 00:16:21

US3142034

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (18)

Generated On: 11 Aug 2021 21:58:56

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:55:45
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:03:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 18:04:25
User entered '98.0' F	Shelby Pickle (b) (4) (b) (4)	22 Jan 2021 00:16:21

US3142034

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (18)

Generated On: 11 Aug 2021 21:58:56

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:55:45
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:03:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 18:04:25
User entered 'None (None)'	Shelby Pickle (b) (4) (b) (4)	22 Jan 2021 00:16:21

US3142034

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (18)

Generated On: 11 Aug 2021 21:58:56

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:55:45
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:03:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 18:04:25
User entered 'None (None)'	Shelby Pickle (b) (4) (b) (4)	22 Jan 2021 00:16:21

US3142034

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (18)

Generated On: 11 Aug 2021 21:58:56

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:55:45
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:03:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 18:04:25
User entered 'None (None)'	Shelby Pickle (b) (4) (b) (4)	22 Jan 2021 00:16:21

US3142034

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (18)

Generated On: 11 Aug 2021 21:58:56

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:55:45
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:03:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 18:04:25
User entered 'None (None)'	Shelby Pickle (b) (4) (b) (4)	22 Jan 2021 00:16:21

US3142034

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (18)

Generated On: 11 Aug 2021 21:58:56

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:55:45
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:03:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 18:04:25
User entered 'None (None)'	Shelby Pickle (b) (4) (b) (4)	22 Jan 2021 00:16:21

US3142034

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (18)

Generated On: 11 Aug 2021 21:58:56

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:55:45
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:03:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 18:04:25
User entered 'None (None)'	Shelby Pickle (b) (4) (b) (4)	22 Jan 2021 00:16:21

US3142034

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (18)

Generated On: 11 Aug 2021 21:58:56

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:55:45
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:03:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 18:04:25
User entered 'None (None)'	Shelby Pickle (b) (4) (b) (4)	22 Jan 2021 00:16:21

US3142034

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (18)

Generated On: 11 Aug 2021 21:58:56

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:55:45
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:03:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 18:04:25
User entered 'None (None)'	Shelby Pickle (b) (4) (b) (4)	22 Jan 2021 00:16:21

US3142034

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (18)

Generated On: 11 Aug 2021 21:58:56

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:55:45
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:03:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 18:04:25
User entered 'None (None)'	Shelby Pickle (b) (4) (b) (4)	22 Jan 2021 00:16:21

US3142034

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (18)

Generated On: 11 Aug 2021 21:58:56

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:55:45
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:03:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 18:04:25
User entered 'None (None)'	Shelby Pickle (b) (4) (b) (4)	22 Jan 2021 00:16:21

US3142034

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (18)

Generated On: 11 Aug 2021 21:58:56

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:55:45
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:03:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 18:04:25
User entered 'None (None)'	Shelby Pickle (b) (4) (b) (4)	22 Jan 2021 00:16:21

US3142034

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (18)

Generated On: 11 Aug 2021 21:58:56

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:55:45
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:03:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 18:04:25
User entered 'None (None)'	Shelby Pickle (b) (4) (b) (4)	22 Jan 2021 00:16:21

US3142034

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (18)

Generated On: 11 Aug 2021 21:58:56

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:55:45
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:03:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 18:04:25
User entered 'None (None)'	Shelby Pickle (b) (4) (b) (4)	22 Jan 2021 00:16:21

US3142034

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (18)

Generated On: 11 Aug 2021 21:58:56

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:55:45
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:03:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 18:04:25
User entered 'None (None)'	Shelby Pickle (b) (4) (b) (4)	22 Jan 2021 00:16:21

US3142034

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (18)

Generated On: 11 Aug 2021 21:58:56

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:55:45
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:03:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 18:04:25
User entered 'None (None)'	Shelby Pickle (b) (4) (b) (4)	22 Jan 2021 00:16:21

US3142034

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (18)

Generated On: 11 Aug 2021 21:58:56

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:55:45
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:03:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 18:04:25
User entered 'None (None)'	Shelby Pickle (b) (4) (b) (4)	22 Jan 2021 00:16:21

US3142034

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (19)

Generated On: 11 Aug 2021 21:58:56

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:55:45
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 19:03:31
User entered 'Day 6 (Day 6)'	Shelby Pickle (b) (4) (b) (4)	04 Feb 2021 22:04:16

US3142034

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (19)

Generated On: 11 Aug 2021 21:58:56

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:55:45
DataPoint Verified.		21 Apr 2021 18:39:16
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 19:03:31
User entered '15 Dec 2020'	Shelby Pickle (b) (4) (b) (4)	04 Feb 2021 22:04:16

US3142034

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (19)

Generated On: 11 Aug 2021 21:58:56

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:55:45
DataPoint Verified.		21 Apr 2021 18:39:16
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:03:31
User entered '0'	(b) (4) Shelby Pickle (b) (4) (b) (4)	04 Feb 2021 22:04:16

US3142034

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (19)

Generated On: 11 Aug 2021 21:58:56

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:55:45
DataPoint Verified.		21 Apr 2021 18:39:16
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:03:31
User entered '94'	(b) (4) Shelby Pickle (b) (4) (b) (4)	04 Feb 2021 22:04:16

US3142034

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (19)

Generated On: 11 Aug 2021 21:58:56

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:55:45
User entered '%'	System	04 Feb 2021 22:04:16

US3142034

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (19)

Generated On: 11 Aug 2021 21:58:56

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:55:45
DataPoint Verified.		21 Apr 2021 18:39:16
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:03:31
User entered '98.0' F	(b) (4) Shelby Pickle (b) (4) (b) (4)	04 Feb 2021 22:04:16

US3142034

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (19)

Generated On: 11 Aug 2021 21:58:56

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:55:45
DataPoint Verified.		21 Apr 2021 18:39:16
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 19:03:31
User entered 'None (None)'	Shelby Pickle (b) (4) (b) (4)	04 Feb 2021 22:04:16

US3142034

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (19)

Generated On: 11 Aug 2021 21:58:56

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:55:45
DataPoint Verified.	(b) (4)	21 Apr 2021 18:39:16
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 19:03:31
User entered 'Mild (Mild)'	Shelby Pickle (b) (4) (b) (4)	04 Feb 2021 22:04:16

US3142034

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (19)

Generated On: 11 Aug 2021 21:58:56

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:55:45
DataPoint Verified.	(b) (4)	21 Apr 2021 18:39:16
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 19:03:31
User entered 'None (None)'	Shelby Pickle (b) (4) (b) (4)	04 Feb 2021 22:04:16

US3142034

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (19)

Generated On: 11 Aug 2021 21:58:56

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:55:45
DataPoint Verified.	(b) (4)	21 Apr 2021 18:39:16
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 19:03:31
User entered 'None (None)'	Shelby Pickle (b) (4) (b) (4)	04 Feb 2021 22:04:16

US3142034

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (19)

Generated On: 11 Aug 2021 21:58:56

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:55:45
DataPoint Verified.	(b) (4)	21 Apr 2021 18:39:16
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 19:03:31
User entered 'Mild (Mild)'	Shelby Pickle (b) (4) (b) (4)	04 Feb 2021 22:04:16

US3142034

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (19)

Generated On: 11 Aug 2021 21:58:56

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:55:45
DataPoint Verified.	(b) (4)	21 Apr 2021 18:39:16
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 19:03:31
User entered 'None (None)'	Shelby Pickle (b) (4) (b) (4)	04 Feb 2021 22:04:16

US3142034

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (19)

Generated On: 11 Aug 2021 21:58:56

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:55:45
DataPoint Verified.		21 Apr 2021 18:39:16
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 19:03:31
User entered 'None (None)'	Shelby Pickle (b) (4) (b) (4)	04 Feb 2021 22:04:16

US3142034

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (19)

Generated On: 11 Aug 2021 21:58:56

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:55:45
DataPoint Verified.		21 Apr 2021 18:39:16
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 19:03:31
User entered 'Mild (Mild)'	Shelby Pickle (b) (4) (b) (4)	04 Feb 2021 22:04:16

US3142034

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (19)

Generated On: 11 Aug 2021 21:58:56

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:55:45
DataPoint Verified.	(b) (4)	21 Apr 2021 18:39:16
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 19:03:31
User entered 'None (None)'	Shelby Pickle (b) (4) (b) (4)	04 Feb 2021 22:04:16

US3142034

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (19)

Generated On: 11 Aug 2021 21:58:56

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:55:45
DataPoint Verified.	(b) (4)	21 Apr 2021 18:39:16
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 19:03:31
User entered 'None (None)'	Shelby Pickle (b) (4) (b) (4)	04 Feb 2021 22:04:16

US3142034

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (19)

Generated On: 11 Aug 2021 21:58:56

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:55:45
DataPoint Verified.		21 Apr 2021 18:39:16
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 19:03:31
User entered 'Mild (Mild)'	Shelby Pickle (b) (4) (b) (4)	04 Feb 2021 22:04:16

US3142034

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (19)

Generated On: 11 Aug 2021 21:58:56

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:55:45
DataPoint Verified.		21 Apr 2021 18:39:16
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 19:03:31
User entered 'Mild (Mild)'	Shelby Pickle (b) (4) (b) (4)	04 Feb 2021 22:04:16

US3142034

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (19)

Generated On: 11 Aug 2021 21:58:56

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:55:45
DataPoint Verified.	(b) (4)	21 Apr 2021 18:39:16
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 19:03:31
User entered 'None (None)'	Shelby Pickle (b) (4) (b) (4)	04 Feb 2021 22:04:16

US3142034

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (19)

Generated On: 11 Aug 2021 21:58:56

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:55:45
DataPoint Verified.		21 Apr 2021 18:39:16
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 19:03:31
User entered 'None (None)'	Shelby Pickle (b) (4) (b) (4)	04 Feb 2021 22:04:16

US3142034

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (19)

Generated On: 11 Aug 2021 21:58:56

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:55:45
DataPoint Verified.	(b) (4)	21 Apr 2021 18:39:16
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 19:03:31
User entered 'None (None)'	Shelby Pickle (b) (4) (b) (4)	04 Feb 2021 22:04:16

US3142034

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (19)

Generated On: 11 Aug 2021 21:58:56

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:55:45
DataPoint Verified.		21 Apr 2021 18:39:16
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 19:03:31
User entered 'None (None)'	Shelby Pickle (b) (4) (b) (4)	04 Feb 2021 22:04:16

US3142034

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (20)

Generated On: 11 Aug 2021 21:58:56

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:55:45
User closed query 'Per CDM: Please note that there are symptoms that are blank/missing in the Covid-19 Assessment 14 Dec 2020 symptom log on log line 20. Please verify if the missing data is available, otherwise please indicate Not Done as per CCGs accordingly. ' (Site from DM).		26 Apr 2021 23:46:24
Query 'Per CDM: Please note that there are symptoms that are blank/missing in the Covid-19 Assessment 14 Dec 2020 symptom log on log line 20. Please verify if the missing data is available, otherwise please indicate Not Done as per CCGs accordingly. ' answered with 'oxygen and temperature were not recorded ' (Site from DM).	Jill York (b) (4)	21 Apr 2021 14:50:55
User opened query 'Per CDM: Please note that there are symptoms that are blank/missing in the Covid-19 Assessment 14 Dec 2020 symptom log on log line 20. Please verify if the missing data is available, otherwise please indicate Not Done as per CCGs accordingly. ' (Site from DM).	(b) (4), (b) (6)	20 Apr 2021 13:26:05
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 19:03:31
User entered 'Day 19 (Day 19)'	Lisa Jackson (b) (4) (b) (4)	07 Apr 2021 20:04:15

US3142034

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (20)

Generated On: 11 Aug 2021 21:58:56

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:55:45
DataPoint Verified.	(b) (4)	21 Apr 2021 18:39:16
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:03:31
User entered '28 Dec 2020'	(b) (4) Lisa Jackson (b) (4) (b) (4)	07 Apr 2021 20:04:15

US3142034

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (20)

Generated On: 11 Aug 2021 21:58:56

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:55:45
DataPoint Verified.		21 Apr 2021 18:39:16
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:03:31
User entered '0'	(b) (4) Lisa Jackson (b) (4) (b) (4)	07 Apr 2021 20:04:15

US3142034

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (20)

Generated On: 11 Aug 2021 21:58:56

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:55:45
Query 'Re-query Per CDM: in the Covid-19 Assessment 28DEC2020 symptom log on log line 20 O2 Saturation and Temperature are left blank. If not done, select Not Done for each symptom.' canceled (Site from DM).		30 Apr 2021 13:55:39
User opened query 'Re-query Per CDM: in the Covid-19 Assessment 28DEC2020 symptom log on log line 20, O2 Saturation and Temperature are left blank. If not done, select Not Done for each symptom.' (Site from DM).		26 Apr 2021 23:47:05
DataPoint Verified.		21 Apr 2021 18:39:16
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 19:03:31
User entered empty.	Lisa Jackson (b) (4) (b) (4)	07 Apr 2021 20:04:15

US3142034

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (20)

Generated On: 11 Aug 2021 21:58:56

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:55:45
User entered empty.	System	07 Apr 2021 20:04:15

US3142034

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (20)

Generated On: 11 Aug 2021 21:58:56

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:55:45
DataPoint Verified.		21 Apr 2021 18:39:16
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:03:31
User entered empty.	(b) (4) Lisa Jackson (b) (4) (b) (4)	07 Apr 2021 20:04:15

US3142034

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (20)

Generated On: 11 Aug 2021 21:58:56

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:55:45
DataPoint Verified.		21 Apr 2021 18:39:16
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:03:31
User entered 'None (None)'	(b) (4) Lisa Jackson (b) (4) (b) (4)	07 Apr 2021 20:04:15

US3142034

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (20)

Generated On: 11 Aug 2021 21:58:56

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:55:45
DataPoint Verified.	(b) (4)	21 Apr 2021 18:39:16
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:03:31
User entered 'None (None)'	(b) (4) Lisa Jackson (b) (4) (b) (4)	07 Apr 2021 20:04:15

US3142034

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (20)

Generated On: 11 Aug 2021 21:58:56

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:55:45
DataPoint Verified.		21 Apr 2021 18:39:16
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:03:31
User entered 'None (None)'	(b) (4) Lisa Jackson (b) (4) (b) (4)	07 Apr 2021 20:04:15

US3142034

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (20)

Generated On: 11 Aug 2021 21:58:56

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:55:45
DataPoint Verified.	(b) (4)	21 Apr 2021 18:39:16
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:03:31
User entered 'None (None)'	(b) (4) Lisa Jackson (b) (4) (b) (4)	07 Apr 2021 20:04:15

US3142034

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (20)

Generated On: 11 Aug 2021 21:58:56

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:55:45
DataPoint Verified.		21 Apr 2021 18:39:16
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:03:31
User entered 'None (None)'	(b) (4) Lisa Jackson (b) (4) (b) (4)	07 Apr 2021 20:04:15

US3142034

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (20)

Generated On: 11 Aug 2021 21:58:56

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:55:45
DataPoint Verified.	(b) (4)	21 Apr 2021 18:39:16
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:03:31
User entered 'None (None)'	(b) (4) Lisa Jackson (b) (4) (b) (4)	07 Apr 2021 20:04:15

US3142034

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (20)

Generated On: 11 Aug 2021 21:58:56

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:55:45
DataPoint Verified.	(b) (4)	21 Apr 2021 18:39:16
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:03:31
User entered 'None (None)'	(b) (4) Lisa Jackson (b) (4) (b) (4)	07 Apr 2021 20:04:15

US3142034

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (20)

Generated On: 11 Aug 2021 21:58:56

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:55:45
DataPoint Verified.	(b) (4)	21 Apr 2021 18:39:16
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:03:31
User entered 'None (None)'	(b) (4) Lisa Jackson (b) (4) (b) (4)	07 Apr 2021 20:04:15

US3142034

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (20)

Generated On: 11 Aug 2021 21:58:56

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:55:45
DataPoint Verified.	(b) (4)	21 Apr 2021 18:39:16
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:03:31
User entered 'None (None)'	(b) (4) Lisa Jackson (b) (4) (b) (4)	07 Apr 2021 20:04:15

US3142034

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (20)

Generated On: 11 Aug 2021 21:58:56

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:55:45
DataPoint Verified.	(b) (4)	21 Apr 2021 18:39:16
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:03:31
User entered 'None (None)'	(b) (4) Lisa Jackson (b) (4) (b) (4)	07 Apr 2021 20:04:15

US3142034

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (20)

Generated On: 11 Aug 2021 21:58:56

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:55:45
DataPoint Verified.	(b) (4)	21 Apr 2021 18:39:16
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:03:31
User entered 'None (None)'	(b) (4) Lisa Jackson (b) (4) (b) (4)	07 Apr 2021 20:04:15

US3142034

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (20)

Generated On: 11 Aug 2021 21:58:56

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:55:45
DataPoint Verified.		21 Apr 2021 18:39:16
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:03:31
User entered 'None (None)'	(b) (4) Lisa Jackson (b) (4) (b) (4)	07 Apr 2021 20:04:15

US3142034

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (20)

Generated On: 11 Aug 2021 21:58:56

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:55:45
DataPoint Verified.	(b) (4)	21 Apr 2021 18:39:16
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:03:31
User entered 'None (None)'	(b) (4) Lisa Jackson (b) (4) (b) (4)	07 Apr 2021 20:04:15

US3142034

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (20)

Generated On: 11 Aug 2021 21:58:56

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:55:45
DataPoint Verified.	(b) (4)	21 Apr 2021 18:39:16
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:03:31
User entered 'None (None)'	(b) (4) Lisa Jackson (b) (4) (b) (4)	07 Apr 2021 20:04:15

US3142034

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (20)

Generated On: 11 Aug 2021 21:58:56

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:55:45
DataPoint Verified.	(b) (4)	21 Apr 2021 18:39:16
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:03:31
User entered 'None (None)'	(b) (4) Lisa Jackson (b) (4) (b) (4)	07 Apr 2021 20:04:15

US3142034

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (20)

Generated On: 11 Aug 2021 21:58:56

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:55:45
DataPoint Verified.		21 Apr 2021 18:39:16
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:03:31
User entered 'None (None)'	(b) (4) Lisa Jackson (b) (4) (b) (4)	07 Apr 2021 20:04:15

US3142034

Folder: Covid-19 Assessment 14 Dec 2020

Form: COVID Diagnostic Test

Generated On: 11 Aug 2021 21:58:56

[Date of Visit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:55:53
DataPoint Verified.	(b) (4)	22 Apr 2021 16:27:12
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 19:03:31
User entered '14 Dec 2020'	Shelby Pickle (b) (4) (b) (4)	16 Dec 2020 19:53:56

US3142034

Folder: Covid-19 Assessment 14 Dec 2020

Form: COVID Diagnostic Test

Generated On: 11 Aug 2021 21:58:56

[Was the Subject Tested For SARS-CoV-2 by RT-PCR?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:55:53
DataPoint Verified.		22 Apr 2021 16:27:12
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 19:03:31
User entered 'Yes (Y)'	Shelby Pickle (b) (4) (b) (4)	16 Dec 2020 19:53:56

US3142034

Folder: Covid-19 Assessment 14 Dec 2020

Form: COVID Diagnostic Test

Generated On: 11 Aug 2021 21:58:56

[Did Subject Test Positive For SARS-CoV-2 by RT-PCR?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:55:53
DataPoint Verified.	(b) (4)	22 Apr 2021 16:27:12
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:03:31
User closed query 'Did Subject Test Positive For SARS-CoV-2 by RT-PCR is Yes. Please confirm test result was positive and enter COVID-19 diagnosis on the Adverse Events form.' (Site from System).	(b) (4) (b) (4), (b) (6)	09 Feb 2021 05:43:33
Query 'Did Subject Test Positive For SARS-CoV-2 by RT-PCR is Yes. Please confirm test result was positive and enter COVID-19 diagnosis on the Adverse Events form.' answered with 'subject tested possitive for SARS-CoV-2' (Site from System).	Meghan York (b) (4) (b) (4)	01 Feb 2021 16:49:33
User closed query 'Data is required. Please complete.' (Site from System).	System	18 Dec 2020 18:06:54
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	18 Dec 2020 18:06:54
User opened query 'Did Subject Test Positive For SARS-CoV-2 by RT-PCR is Yes. Please confirm test result was positive and enter COVID-19 diagnosis on the Adverse Events form.' (Site from System).	System	18 Dec 2020 18:06:54
User entered 'Yes (Y)' reason for change: Data Entry Error	Meghan York (b) (4) (b) (4)	18 Dec 2020 18:06:54
User opened query 'Data is required. Please complete.' (Site from System).	System	16 Dec 2020 19:53:56
User entered empty.	Shelby Pickle (b) (4) (b) (4)	16 Dec 2020 19:53:56

US3142034

Folder: Covid-19 Assessment 14 Dec 2020

Form: COVID Diagnostic Test

Generated On: 11 Aug 2021 21:58:56

[Date of Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:55:53
DataPoint Verified.	(b) (4)	22 Apr 2021 16:27:12
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 19:03:31
User entered '14 Dec 2020'	Shelby Pickle (b) (4) (b) (4)	16 Dec 2020 19:53:56

US3142034

Folder: Covid-19 Assessment 14 Dec 2020

Form: COVID Diagnostic Test

Generated On: 11 Aug 2021 21:58:56

[Type of Test Performed](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:55:53
DataPoint Verified.		22 Apr 2021 16:27:12
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 19:03:31
User entered 'Nasopharyngeal Swab (Nasopharyngeal Swab)'	Shelby Pickle (b) (4) (b) (4)	16 Dec 2020 19:53:56

US3142034

Folder: Covid-19 Assessment 14 Dec 2020

Form: COVID Diagnostic Test

Generated On: 11 Aug 2021 21:58:56

[Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:55:53
DataPoint Verified.		22 Apr 2021 16:27:12
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 19:03:31
User entered empty.	Shelby Pickle (b) (4) (b) (4)	16 Dec 2020 19:53:56

US3142034

Folder: Covid-19 Assessment 14 Dec 2020

Form: COVID Diagnostic Test

Generated On: 11 Aug 2021 21:58:56

[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)	30 Apr 2021 13:55:53
DataPoint Verified.		22 Apr 2021 16:27:12
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 19:03:31
User entered 'No (N)'	Shelby Pickle (b) (4) (b) (4)	16 Dec 2020 19:53:56

US3142034

Folder: Covid-19 Assessment 14 Dec 2020

Form: COVID Diagnostic Test

Generated On: 11 Aug 2021 21:58:56

[Lab/ Institution Test Performed](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:55:53
DataPoint Verified.		22 Apr 2021 16:27:12
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 19:03:31
User entered empty.	Shelby Pickle (b) (4) (b) (4)	16 Dec 2020 19:53:56

US3142034

Folder: Covid-19 Assessment 14 Dec 2020

Form: COVID Diagnostic Test

Generated On: 11 Aug 2021 21:58:56

[CLIA Certified?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:55:53
DataPoint Verified.		22 Apr 2021 16:27:12
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 19:03:31
User entered empty.	Shelby Pickle (b) (4) (b) (4)	16 Dec 2020 19:53:56

US3142034

Folder: Covid-19 Assessment 14 Dec 2020

Form: COVID Diagnostic Test

Generated On: 11 Aug 2021 21:58:56

[COVID-19 Positive \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:55:53
User entered '1'	System	18 Dec 2020 18:06:54

US3142034

Folder: Covid-19 Assessment 14 Dec 2020

Form: Covid-19 Severity Assessment

Generated On: 11 Aug 2021 21:58:56

Did the subject have Respiratory Rates \geq 30 per Minute?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:56:03
DataPoint Verified.		22 Apr 2021 16:22:29
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 19:03:31
User entered 'No (N)'	Shelby Pickle (b) (4) (b) (4)	23 Dec 2020 00:30:23

US3142034

Folder: Covid-19 Assessment 14 Dec 2020

Form: Covid-19 Severity Assessment

Generated On: 11 Aug 2021 21:58:56

[Start Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:56:03
DataPoint Verified.		22 Apr 2021 16:22:29
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 19:03:31
User entered empty.	Shelby Pickle (b) (4) (b) (4)	23 Dec 2020 00:30:23

US3142034

Folder: Covid-19 Assessment 14 Dec 2020

Form: Covid-19 Severity Assessment

Generated On: 11 Aug 2021 21:58:56

[End Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:56:03
DataPoint Verified.		22 Apr 2021 16:22:29
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 19:03:31
User entered empty.	Shelby Pickle (b) (4) (b) (4)	23 Dec 2020 00:30:23

US3142034

Folder: Covid-19 Assessment 14 Dec 2020

Form: Covid-19 Severity Assessment

Generated On: 11 Aug 2021 21:58:56

[Respiratory Rate](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:56:03
DataPoint Verified.	(b) (4)	22 Apr 2021 16:22:29
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 19:03:31
User entered empty.	Shelby Pickle (b) (4) (b) (4)	23 Dec 2020 00:30:23

US3142034

Folder: Covid-19 Assessment 14 Dec 2020

Form: Covid-19 Severity Assessment

Generated On: 11 Aug 2021 21:58:56

Did the subject have Heart Rate \geq 125 beats per minute

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:56:03
DataPoint Verified.		22 Apr 2021 16:22:29
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 19:03:31
User entered 'No (N)'	Shelby Pickle (b) (4) (b) (4)	23 Dec 2020 00:30:23

US3142034

Folder: Covid-19 Assessment 14 Dec 2020

Form: Covid-19 Severity Assessment

Generated On: 11 Aug 2021 21:58:56

[Start Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:56:03
DataPoint Verified.		22 Apr 2021 16:22:29
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 19:03:31
User entered empty.	Shelby Pickle (b) (4) (b) (4)	23 Dec 2020 00:30:23

US3142034

Folder: Covid-19 Assessment 14 Dec 2020

Form: Covid-19 Severity Assessment

Generated On: 11 Aug 2021 21:58:56

[End Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:56:03
DataPoint Verified.		22 Apr 2021 16:22:29
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:03:31
User entered empty.	(b) (4) Shelby Pickle (b) (4) (b) (4)	23 Dec 2020 00:30:23

US3142034

Folder: Covid-19 Assessment 14 Dec 2020

Form: Covid-19 Severity Assessment

Generated On: 11 Aug 2021 21:58:56

[Heart Rate](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:56:03
DataPoint Verified.		22 Apr 2021 16:22:29
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 19:03:31
User entered empty.	Shelby Pickle (b) (4) (b) (4)	23 Dec 2020 00:30:23

US3142034

Folder: Covid-19 Assessment 14 Dec 2020

Form: Covid-19 Severity Assessment

Generated On: 11 Aug 2021 21:58:56

Did the subject have Oxygen Saturation of SpO2 ≤ 93% on room air at sea level?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:56:03
DataPoint Verified.		22 Apr 2021 16:22:29
User closed query 'Information is not correct per symptom log entries. If the subject has any O2 93% or less it is to be recorded on severity page. Please update to Yes, start date = 14Dec2020; end date = 21Dec2020 and O2 = 93%' (Site from CRA). User signature succeeded.		19 Apr 2021 12:21:13
User closed query 'Per DM CLR: Please note that there is no corresponding AE recorded for this COVID-19 Assessment data. Please reconcile and update to record the AE as applicable. Otherwise, provide clarification. ' (Site from DM).	Ripley Hollister (b) (4)	18 Apr 2021 19:03:31
User closed query 'Per DM CLR: Please note that there is no corresponding AE recorded for this COVID-19 Assessment data. Please reconcile and update to record the AE as applicable. Otherwise, provide clarification. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	30 Mar 2021 02:58:26
Query 'Per DM CLR: Please note that there is no corresponding AE recorded for this COVID-19 Assessment data. Please reconcile and update to record the AE as applicable. Otherwise, provide clarification. ' answered with 'AE now entered ' (Site from DM).	Jill York (b) (4)	26 Mar 2021 02:37:11
User opened query 'Per DM CLR: Please note that there is no corresponding AE recorded for this COVID-19 Assessment data. Please reconcile and update to record the AE as applicable. Otherwise, provide clarification. ' (Site from DM).	(b) (4), (b) (6)	18 Mar 2021 11:49:03
Query 'Information is not correct per symptom log entries. If the subject has any O2 93% or less it is to be recorded on severity page. Please update to Yes, start date = 14Dec2020; end date = 21Dec2020 and O2 = 93%' answered with 'corrected ' (Site from CRA).	Jill York (b) (4)	01 Mar 2021 20:16:44
User entered 'Yes (Y)' reason for change: Data Entry Error	Jill York (b) (4)	01 Mar 2021 20:16:33
User opened query 'Information is not correct per symptom log entries. If the subject has any O2 93% or less it is to be recorded on severity page. Please update to Yes, start date = 14Dec2020; end date = 21Dec2020 and O2 = 93%' (Site from CRA).	(b) (4), (b) (6)	01 Feb 2021 23:43:33

US3142034

Folder: Covid-19 Assessment 14 Dec 2020

Form: Covid-19 Severity Assessment

Generated On: 11 Aug 2021 21:58:56

[Did the subject have Oxygen Saturation of SpO2 ≤ 93% on room air at sea level?](#)

Audit	User	Time (GMT)
User closed query 'Please confirm response as O2 saturation of 93% is noted on 14Dec2020, 16Dec2020 and 21Dec2020.' (Site from CRA).	(b) (4), (b) (6)	01 Feb 2021 23:43:33
Query 'Please confirm response as O2 saturation of 93% is noted on 14Dec2020, 16Dec2020 and 21Dec2020.' answered with 'information is correct ' (Site from CRA).	Meghan York (b) (4) (b) (4)	01 Feb 2021 16:48:42
User opened query 'Please confirm response as O2 saturation of 93% is noted on 14Dec2020, 16Dec2020 and 21Dec2020.' (Site from CRA).	(b) (4), (b) (6)	26 Jan 2021 20:57:39
User entered 'No (N)'	Shelby Pickle (b) (4) (b) (4)	23 Dec 2020 00:30:23

US3142034

Folder: Covid-19 Assessment 14 Dec 2020

Form: Covid-19 Severity Assessment

Generated On: 11 Aug 2021 21:58:56

[Start Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:56:03
DataPoint Verified.	(b) (4)	22 Apr 2021 16:22:29
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 19:03:31
User entered '14 Dec 2020' reason for change: Data Entry Error	Jill York (b) (4)	01 Mar 2021 20:16:33
User entered empty.	Shelby Pickle (b) (4) (b) (4)	23 Dec 2020 00:30:23

US3142034

Folder: Covid-19 Assessment 14 Dec 2020

Form: Covid-19 Severity Assessment

Generated On: 11 Aug 2021 21:58:56

[End Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:56:03
DataPoint Verified.	(b) (4)	22 Apr 2021 16:22:29
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 19:03:31
User entered '21 Dec 2020' reason for change: Data Entry Error	Jill York (b) (4)	01 Mar 2021 20:16:33
User entered empty.	Shelby Pickle (b) (4) (b) (4)	23 Dec 2020 00:30:23

US3142034

Folder: Covid-19 Assessment 14 Dec 2020

Form: Covid-19 Severity Assessment

Generated On: 11 Aug 2021 21:58:56

[Oxygen Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:56:03
DataPoint Verified.	(b) (4)	22 Apr 2021 16:22:29
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 19:03:31
User entered '93' reason for change: Data Entry Error	Jill York (b) (4)	01 Mar 2021 20:16:33
User entered empty.	Shelby Pickle (b) (4) (b) (4)	23 Dec 2020 00:30:23

US3142034

Folder: Covid-19 Assessment 14 Dec 2020

Form: Covid-19 Severity Assessment

Generated On: 11 Aug 2021 21:58:56

Did the subject have PaO2/FIO2 Ratio < 300 mm Hg?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:56:03
DataPoint Verified.		22 Apr 2021 16:22:29
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 19:03:31
User entered 'No (N)'	Shelby Pickle (b) (4) (b) (4)	23 Dec 2020 00:30:23

US3142034

Folder: Covid-19 Assessment 14 Dec 2020

Form: Covid-19 Severity Assessment

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[Start Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:56:03
DataPoint Verified.		22 Apr 2021 16:22:29
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 19:03:31
User entered empty.	Shelby Pickle (b) (4) (b) (4)	23 Dec 2020 00:30:23

US3142034

Folder: Covid-19 Assessment 14 Dec 2020

Form: Covid-19 Severity Assessment

Generated On: 11 Aug 2021 21:58:56

[End Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:56:03
DataPoint Verified.		22 Apr 2021 16:22:29
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 19:03:31
User entered empty.	Shelby Pickle (b) (4) (b) (4)	23 Dec 2020 00:30:23

US3142034

Folder: Covid-19 Assessment 14 Dec 2020

Form: Covid-19 Severity Assessment

Generated On: 11 Aug 2021 21:58:56

[PaO2](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:56:03
DataPoint Verified.		22 Apr 2021 16:22:29
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:03:31
User entered empty.	(b) (4) Shelby Pickle (b) (4) (b) (4)	23 Dec 2020 00:30:23

US3142034

Folder: Covid-19 Assessment 14 Dec 2020

Form: Covid-19 Severity Assessment

Generated On: 11 Aug 2021 21:58:56

[Did the subject have Respiratory failure?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:56:03
DataPoint Verified.		22 Apr 2021 16:22:29
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 19:03:31
User entered 'No (N)'	Shelby Pickle (b) (4) (b) (4)	23 Dec 2020 00:30:23

US3142034

Folder: Covid-19 Assessment 14 Dec 2020

Form: Covid-19 Severity Assessment

Generated On: 11 Aug 2021 21:58:56

[Start Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:56:03
DataPoint Verified.	(b) (4)	22 Apr 2021 16:22:29
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:03:31
User entered empty.	(b) (4) Shelby Pickle (b) (4) (b) (4)	23 Dec 2020 00:30:23

US3142034

Folder: Covid-19 Assessment 14 Dec 2020

Form: Covid-19 Severity Assessment

Generated On: 11 Aug 2021 21:58:56

Did the subject have Acute Respiratory Distress Syndrome (ARDS)?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:56:03
DataPoint Verified.		22 Apr 2021 16:22:29
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 19:03:31
User entered 'No (N)'	Shelby Pickle (b) (4) (b) (4)	23 Dec 2020 00:30:23

US3142034

Folder: Covid-19 Assessment 14 Dec 2020

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[Start Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:56:03
DataPoint Verified.		22 Apr 2021 16:22:29
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:03:31
User entered empty.	(b) (4) Shelby Pickle (b) (4) (b) (4)	23 Dec 2020 00:30:23

US3142034

Folder: Covid-19 Assessment 14 Dec 2020

Form: Covid-19 Severity Assessment

Generated On: 11 Aug 2021 21:58:56

[High-Flow Oxygen?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:56:03
DataPoint Verified.		22 Apr 2021 16:22:29
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 19:03:31
User entered 'No (N)'	Shelby Pickle (b) (4) (b) (4)	23 Dec 2020 00:30:23

US3142034

Folder: Covid-19 Assessment 14 Dec 2020

Form: Covid-19 Severity Assessment

Generated On: 11 Aug 2021 21:58:56

[Start Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:56:03
DataPoint Verified.		22 Apr 2021 16:22:29
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 19:03:31
User entered empty.	Shelby Pickle (b) (4) (b) (4)	23 Dec 2020 00:30:23

US3142034

Folder: Covid-19 Assessment 14 Dec 2020

Form: Covid-19 Severity Assessment

Generated On: 11 Aug 2021 21:58:56

[End Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:56:03
DataPoint Verified.		22 Apr 2021 16:22:29
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:03:31
User entered empty.	(b) (4) Shelby Pickle (b) (4) (b) (4)	23 Dec 2020 00:30:23

US3142034

Folder: Covid-19 Assessment 14 Dec 2020

Form: Covid-19 Severity Assessment

Generated On: 11 Aug 2021 21:58:56

[Non-Invasive Ventilation?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:56:03
DataPoint Verified.		22 Apr 2021 16:22:29
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 19:03:31
User entered 'No (N)'	Shelby Pickle (b) (4) (b) (4)	23 Dec 2020 00:30:23

US3142034

Folder: Covid-19 Assessment 14 Dec 2020

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Generated On: 11 Aug 2021 21:58:56

[Start Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:56:03
DataPoint Verified.		22 Apr 2021 16:22:29
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 19:03:31
User entered empty.	Shelby Pickle (b) (4) (b) (4)	23 Dec 2020 00:30:23

US3142034

Folder: Covid-19 Assessment 14 Dec 2020

Form: Covid-19 Severity Assessment

Generated On: 11 Aug 2021 21:58:56

[End Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:56:03
DataPoint Verified.		22 Apr 2021 16:22:29
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:03:31
User entered empty.	(b) (4) Shelby Pickle (b) (4) (b) (4)	23 Dec 2020 00:30:23

US3142034

Folder: Covid-19 Assessment 14 Dec 2020

Form: Covid-19 Severity Assessment

Generated On: 11 Aug 2021 21:58:56

[Mechanical Ventilation?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:56:03
DataPoint Verified.		22 Apr 2021 16:22:29
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 19:03:31
User entered 'No (N)'	Shelby Pickle (b) (4) (b) (4)	23 Dec 2020 00:30:23

US3142034

Folder: Covid-19 Assessment 14 Dec 2020

Form: Covid-19 Severity Assessment

Generated On: 11 Aug 2021 21:58:56

[Start Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:56:03
DataPoint Verified.		22 Apr 2021 16:22:29
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 19:03:31
User entered empty.	Shelby Pickle (b) (4) (b) (4)	23 Dec 2020 00:30:23

US3142034

Folder: Covid-19 Assessment 14 Dec 2020

Form: Covid-19 Severity Assessment

Generated On: 11 Aug 2021 21:58:56

[End Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:56:03
DataPoint Verified.		22 Apr 2021 16:22:29
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:03:31
User entered empty.	(b) (4) Shelby Pickle (b) (4) (b) (4)	23 Dec 2020 00:30:23

US3142034

Folder: Covid-19 Assessment 14 Dec 2020

Form: Covid-19 Severity Assessment

Generated On: 11 Aug 2021 21:58:56

[ECMO?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:56:03
DataPoint Verified.		22 Apr 2021 16:22:29
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 19:03:31
User entered 'No (N)'	Shelby Pickle (b) (4) (b) (4)	23 Dec 2020 00:30:23

US3142034

Folder: Covid-19 Assessment 14 Dec 2020

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[Start Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:56:03
DataPoint Verified.		22 Apr 2021 16:22:29
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 19:03:31
User entered empty.	Shelby Pickle (b) (4) (b) (4)	23 Dec 2020 00:30:23

US3142034

Folder: Covid-19 Assessment 14 Dec 2020

Form: Covid-19 Severity Assessment

Generated On: 11 Aug 2021 21:58:56

[End Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:56:03
DataPoint Verified.		22 Apr 2021 16:22:29
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 19:03:31
User entered empty.	Shelby Pickle (b) (4) (b) (4)	23 Dec 2020 00:30:23

US3142034

Folder: Covid-19 Assessment 14 Dec 2020

Form: Covid-19 Severity Assessment

Generated On: 11 Aug 2021 21:58:56

Systolic Blood Pressure < 90 mmHg, Diastolic Blood Pressure < 60 mmHg

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:56:03
DataPoint Verified.		22 Apr 2021 16:22:29
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 19:03:31
User entered 'No (N)'	Shelby Pickle (b) (4) (b) (4)	23 Dec 2020 00:30:23

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[Start Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:56:03
DataPoint Verified.		22 Apr 2021 16:22:29
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:03:31
User entered empty.	(b) (4) Shelby Pickle (b) (4) (b) (4)	23 Dec 2020 00:30:23

US3142034

Folder: Covid-19 Assessment 14 Dec 2020

Form: Covid-19 Severity Assessment

Generated On: 11 Aug 2021 21:58:56

[End Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:56:03
DataPoint Verified.	(b) (4)	22 Apr 2021 16:22:29
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 19:03:31
User entered empty.	Shelby Pickle (b) (4) (b) (4)	23 Dec 2020 00:30:23

US3142034

Folder: Covid-19 Assessment 14 Dec 2020

Form: Covid-19 Severity Assessment

Generated On: 11 Aug 2021 21:58:56

[Evidence of Shock Requires Vasopressors](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:56:03
DataPoint Verified.	(b) (4)	22 Apr 2021 16:22:29
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:03:31
User entered 'No (N)'	(b) (4) Shelby Pickle (b) (4) (b) (4)	23 Dec 2020 00:30:23

US3142034

Folder: Covid-19 Assessment 14 Dec 2020

Form: Covid-19 Severity Assessment

Generated On: 11 Aug 2021 21:58:56

[Start Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:56:03
DataPoint Verified.		22 Apr 2021 16:22:29
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:03:31
User entered empty.	(b) (4) Shelby Pickle (b) (4) (b) (4)	23 Dec 2020 00:30:23

US3142034

Folder: Covid-19 Assessment 14 Dec 2020

Form: Covid-19 Severity Assessment

Generated On: 11 Aug 2021 21:58:56

[End Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:56:03
DataPoint Verified.	(b) (4)	22 Apr 2021 16:22:29
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 19:03:31
User entered empty.	Shelby Pickle (b) (4) (b) (4)	23 Dec 2020 00:30:23

US3142034

Folder: Covid-19 Assessment 14 Dec 2020

Form: Covid-19 Severity Assessment

Generated On: 11 Aug 2021 21:58:56

[Acute Renal Dysfunction?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:56:03
DataPoint Verified.		22 Apr 2021 16:22:29
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 19:03:31
User entered 'No (N)'	Shelby Pickle (b) (4) (b) (4)	23 Dec 2020 00:30:23

US3142034

Folder: Covid-19 Assessment 14 Dec 2020

Form: Covid-19 Severity Assessment

Generated On: 11 Aug 2021 21:58:56

[Start Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:56:03
DataPoint Verified.		22 Apr 2021 16:22:29
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 19:03:31
User entered empty.	Shelby Pickle (b) (4) (b) (4)	23 Dec 2020 00:30:23

US3142034

Folder: Covid-19 Assessment 14 Dec 2020

Form: Covid-19 Severity Assessment

Generated On: 11 Aug 2021 21:58:56

[Hepatic Dysfunction?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:56:03
DataPoint Verified.	(b) (4)	22 Apr 2021 16:22:29
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 19:03:31
User entered 'No (N)'	Shelby Pickle (b) (4) (b) (4)	23 Dec 2020 00:30:23

US3142034

Folder: Covid-19 Assessment 14 Dec 2020

Form: Covid-19 Severity Assessment

Generated On: 11 Aug 2021 21:58:56

[Start Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:56:03
DataPoint Verified.		22 Apr 2021 16:22:29
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 19:03:31
User entered empty.	Shelby Pickle (b) (4) (b) (4)	23 Dec 2020 00:30:23

US3142034

Folder: Covid-19 Assessment 14 Dec 2020

Form: Covid-19 Severity Assessment

Generated On: 11 Aug 2021 21:58:56

[Neurologic Dysfunction?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:56:03
DataPoint Verified.	(b) (4)	22 Apr 2021 16:22:29
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 19:03:31
User entered 'No (N)'	Shelby Pickle (b) (4) (b) (4)	23 Dec 2020 00:30:23

US3142034

Folder: Covid-19 Assessment 14 Dec 2020

Form: Covid-19 Severity Assessment

Generated On: 11 Aug 2021 21:58:56

[Start Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:56:03
DataPoint Verified.		22 Apr 2021 16:22:29
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 19:03:31
User entered empty.	Shelby Pickle (b) (4) (b) (4)	23 Dec 2020 00:30:23

US3142034

Folder: Covid-19 Assessment 14 Dec 2020

Form: Covid-19 Severity Assessment

Generated On: 11 Aug 2021 21:58:56

[Clinical Evidence](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:56:03
DataPoint Verified.	(b) (4)	22 Apr 2021 16:22:29
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 19:03:31
User entered 'No (N)'	Shelby Pickle (b) (4) (b) (4)	23 Dec 2020 00:30:23

US3142034

Folder: Covid-19 Assessment 14 Dec 2020

Form: Covid-19 Severity Assessment

Generated On: 11 Aug 2021 21:58:56

[Date of Assessment](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:56:03
DataPoint Verified.		22 Apr 2021 16:22:29
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 19:03:31
User entered empty.	Shelby Pickle (b) (4) (b) (4)	23 Dec 2020 00:30:23

US3142034

Folder: Covid-19 Assessment 14 Dec 2020

Form: Covid-19 Severity Assessment

Generated On: 11 Aug 2021 21:58:56

[Radiographical Evidence](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:56:03
DataPoint Verified.		22 Apr 2021 16:22:29
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 19:03:31
User entered 'No (N)'	Shelby Pickle (b) (4) (b) (4)	23 Dec 2020 00:30:23

US3142034

Folder: Covid-19 Assessment 14 Dec 2020

Form: Covid-19 Severity Assessment

Generated On: 11 Aug 2021 21:58:56

[Date of Assessment](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:56:03
DataPoint Verified.		22 Apr 2021 16:22:29
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 19:03:31
User entered empty.	Shelby Pickle (b) (4) (b) (4)	23 Dec 2020 00:30:23

US3142034

Folder: Covid-19 Assessment 14 Dec 2020

Form: Covid-19 Severity Assessment

Generated On: 11 Aug 2021 21:58:56

[Admission to an intensive care unit due to SARS-CoV-2](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:56:03
DataPoint Verified.		22 Apr 2021 16:22:29
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 19:03:31
User entered 'No (N)'	Shelby Pickle (b) (4) (b) (4)	23 Dec 2020 00:30:23

US3142034

Folder: Covid-19 Assessment 14 Dec 2020

Form: Covid-19 Severity Assessment

Generated On: 11 Aug 2021 21:58:56

[Start Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:56:03
DataPoint Verified.		22 Apr 2021 16:22:29
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 19:03:31
User entered empty.	Shelby Pickle (b) (4) (b) (4)	23 Dec 2020 00:30:23

US3142034

Folder: Covid-19 Assessment 14 Dec 2020

Form: Covid-19 Severity Assessment

Generated On: 11 Aug 2021 21:58:56

[End Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:56:03
DataPoint Verified.		22 Apr 2021 16:22:29
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 19:03:31
User entered empty.	Shelby Pickle (b) (4) (b) (4)	23 Dec 2020 00:30:23

US3142034

Folder: Covid-19 Assessment 14 Dec 2020

Form: Generate Next COVID-19 Assessment

Generated On: 11 Aug 2021 21:58:56

[Generate Next COVID-19 Assessment](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:56:22
DataPoint Verified.		22 Apr 2021 16:22:48
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 19:03:31
User entered 'No (N)'	Shelby Pickle (b) (4) (b) (4)	16 Dec 2020 19:54:02

US3142034

Folder: Illness Visit (1)

Form: Saliva Collection (1)

Generated On: 11 Aug 2021 21:58:56

[Visit](#)

Audit	User	Time (GMT)
User closed query 'Per GCL Lab Reconciliation: Saliva: PPD Central Lab reported results reported from Day 3 to Day 21 with the same date 12JAN2021. However, from Day 3 to Day 21 in EDC are reported with different dates. Hence please review the dates recorded on the Saliva collection form and confirm the "EDC dates are correct" from Day 3 to Day 21 to be updated in the Preclarus report.' (Site from DM).	(b) (4), (b) (6)	09 Apr 2021 09:09:24
Query 'Per GCL Lab Reconciliation: Saliva: PPD Central Lab reported results reported from Day 3 to Day 21 with the same date 12JAN2021. However, from Day 3 to Day 21 in EDC are reported with different dates. Hence please review the dates recorded on the Saliva collection form and confirm the "EDC dates are correct" from Day 3 to Day 21 to be updated in the Preclarus report.' answered with 'this should be queried in the Preclarus portal' (Site from DM).	Jill York (b) (4)	07 Apr 2021 21:55:37
User opened query 'Per GCL Lab Reconciliation: Saliva: PPD Central Lab reported results reported from Day 3 to Day 21 with the same date 12JAN2021. However, from Day 3 to Day 21 in EDC are reported with different dates. Hence please review the dates recorded on the Saliva collection form and confirm the "EDC dates are correct" from Day 3 to Day 21 to be updated in the Preclarus report.' (Site from DM).	(b) (4), (b) (6)	07 Apr 2021 11:00:35
User accepted default value 'Day 3 (Day 3)'	Lisa Jackson (b) (4) (b) (4)	30 Mar 2021 16:45:41

US3142034

Folder: Illness Visit (1)

Form: Saliva Collection (1)

Generated On: 11 Aug 2021 21:58:56

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 16:26:39
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:03:50
User closed query 'Per GCL Lab Reconciliation: Saliva Re-query : PPD Central Lab reported results reported from Day 3 to Day 21 with the same date 12JAN2021. However, from Day 3 to Day 21 in EDC are reported with different dates. Hence please review the dates recorded on the Saliva collection form and confirm the "EDC dates are correct" from Day 3 to Day 21 to be updated in the Preclarus report.' (Site from DM).	(b) (4) (b) (4), (b) (6)	16 Apr 2021 05:21:24
Query 'Per GCL Lab Reconciliation: Saliva Re-query Jill York : PPD Central Lab reported results reported from Day 3 to Day 21 with the same date 12JAN2021. However, from Day 3 to Day 21 in EDC are reported with different dates. Hence please review the dates recorded on the Saliva collection form and confirm the "EDC dates are correct" from Day 3 to Day 21 to be updated in the Preclarus report.' answered with 'EDC dates are correct ' (Site from DM).	(b) (4)	13 Apr 2021 14:54:30
User opened query 'Per GCL Lab Reconciliation: Saliva Re-query : PPD Central Lab reported results reported from Day 3 to Day 21 with the same date 12JAN2021. However, from Day 3 to Day 21 in EDC are reported with different dates. Hence please review the dates recorded on the Saliva collection form and confirm the "EDC dates are correct" from Day 3 to Day 21 to be updated in the Preclarus report.' (Site from DM).	(b) (4), (b) (6)	09 Apr 2021 09:09:22
User entered 'Yes (Y)'	Lisa Jackson (b) (4) (b) (4)	30 Mar 2021 16:45:41

US3142034

Folder: Illness Visit (1)

Form: Saliva Collection (1)

Generated On: 11 Aug 2021 21:58:56

[Date of Collection](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 16:26:39
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:03:50
User entered '17 Dec 2020'	Lisa Jackson (b) (4)	30 Mar 2021 16:45:41

US3142034

Folder: Illness Visit (1)

Form: Saliva Collection (2)

Generated On: 11 Aug 2021 21:58:56

[Visit](#)

Audit	User	Time (GMT)
User accepted default value 'Day 5 (Day 5)'	Lisa Jackson (b) (4) (b) (4)	30 Mar 2021 16:46:33

US3142034

Folder: Illness Visit (1)

Form: Saliva Collection (2)

Generated On: 11 Aug 2021 21:58:56

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 16:26:39
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 19:03:50
User entered 'Yes (Y)'	Lisa Jackson (b) (4) (b) (4)	30 Mar 2021 16:46:33

US3142034

Folder: Illness Visit (1)

Form: Saliva Collection (2)

Generated On: 11 Aug 2021 21:58:56

[Date of Collection](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 16:26:39
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:03:50
User entered '19 Dec 2020'	Lisa Jackson (b) (4)	30 Mar 2021 16:46:33

US3142034

Folder: Illness Visit (1)

Form: Saliva Collection (3)

Generated On: 11 Aug 2021 21:58:56

[Visit](#)

Audit	User	Time (GMT)
User accepted default value 'Day 7 (Day 7)'	Lisa Jackson (b) (4) (b) (4)	30 Mar 2021 16:47:04

US3142034

Folder: Illness Visit (1)

Form: Saliva Collection (3)

Generated On: 11 Aug 2021 21:58:56

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 16:26:39
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:03:50
User entered 'Yes (Y)'	Lisa Jackson (b) (4)	30 Mar 2021 16:47:04

US3142034

Folder: Illness Visit (1)

Form: Saliva Collection (3)

Generated On: 11 Aug 2021 21:58:56

[Date of Collection](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 16:26:39
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:03:50
User entered '21 Dec 2020'	Lisa Jackson (b) (4)	30 Mar 2021 16:47:04

US3142034

Folder: Illness Visit (1)

Form: Saliva Collection (4)

Generated On: 11 Aug 2021 21:58:56

[Visit](#)

Audit	User	Time (GMT)
User accepted default value 'Day 9 (Day 9)'	Lisa Jackson (b) (4) (b) (4)	30 Mar 2021 16:47:39

US3142034

Folder: Illness Visit (1)

Form: Saliva Collection (4)

Generated On: 11 Aug 2021 21:58:56

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 16:26:39
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 19:03:50
User entered 'Yes (Y)'	Lisa Jackson (b) (4) (b) (4)	30 Mar 2021 16:47:39

US3142034

Folder: Illness Visit (1)

Form: Saliva Collection (4)

Generated On: 11 Aug 2021 21:58:56

[Date of Collection](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 16:26:39
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:03:50
User entered '23 Dec 2020'	Lisa Jackson (b) (4)	30 Mar 2021 16:47:39

US3142034

Folder: Illness Visit (1)

Form: Saliva Collection (5)

Generated On: 11 Aug 2021 21:58:56

[Visit](#)

Audit	User	Time (GMT)
User accepted default value 'Day 14 (Day 14)'	Lisa Jackson (b) (4) (b) (4)	30 Mar 2021 16:48:20

US3142034

Folder: Illness Visit (1)

Form: Saliva Collection (5)

Generated On: 11 Aug 2021 21:58:56

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 16:26:39
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 19:03:50
User entered 'Yes (Y)'	Lisa Jackson (b) (4) (b) (4)	30 Mar 2021 16:48:20

US3142034

Folder: Illness Visit (1)

Form: Saliva Collection (5)

Generated On: 11 Aug 2021 21:58:56

[Date of Collection](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 16:26:39
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 19:03:50
User entered '28 Dec 2020'	Lisa Jackson (b) (4) (b) (4)	30 Mar 2021 16:48:20

US3142034

Folder: Illness Visit (1)

Form: Saliva Collection (6)

Generated On: 11 Aug 2021 21:58:56

[Visit](#)

Audit	User	Time (GMT)
User closed query 'Per CDM: Per sponsor review, please confirm if saliva sample was taken for Day 28 and update saliva log. Thank you.' (Site from DM).	(b) (4), (b) (6)	14 Apr 2021 09:40:12
Query 'Per CDM: Per sponsor review, please confirm if saliva sample was taken for Day 28 and update saliva log. Thank you.' answered with 'SALIVA WAS TAKEN ON 04JAN2021. ACCORDING TO 15DEC2020 LOG FROM THE LAB.' (Site from DM).	Lisa Jackson (b) (4) (b) (4)	07 Apr 2021 20:40:46
User opened query 'Per CDM: Per sponsor review, please confirm if saliva sample was taken for Day 28 and update saliva log. Thank you.' (Site from DM).	(b) (4), (b) (6)	05 Apr 2021 15:46:03
User accepted default value 'Day 21 (Day 21)'	Lisa Jackson (b) (4) (b) (4)	30 Mar 2021 16:48:59

US3142034

Folder: Illness Visit (1)

Form: Saliva Collection (6)

Generated On: 11 Aug 2021 21:58:56

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 16:26:39
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 19:03:50
User entered 'Yes (Y)'	Lisa Jackson (b) (4) (b) (4)	30 Mar 2021 16:48:59

US3142034

Folder: Illness Visit (1)

Form: Saliva Collection (6)

Generated On: 11 Aug 2021 21:58:56

[Date of Collection](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 16:26:39
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 19:03:50
User entered '04 Jan 2021'	Lisa Jackson (b) (4) (b) (4)	30 Mar 2021 16:48:59

US3142034

Folder: Illness Visit (1)

Form: Saliva Collection (7)

Generated On: 11 Aug 2021 21:58:56

[Visit](#)

Audit	User	Time (GMT)
User accepted default value 'Day 28 (Day 28)'	Lisa Jackson (b) (4) (b) (4)	07 Apr 2021 20:41:12

US3142034

Folder: Illness Visit (1)

Form: Saliva Collection (7)

Generated On: 11 Aug 2021 21:58:56

Was Saliva Collected?

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 16:26:39
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 19:03:50
User closed query 'Data is required. Please complete.' (Site from System).	System	07 Apr 2021 20:41:51
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	07 Apr 2021 20:41:51
User entered 'No (N)' reason for change: Data Entry Error	Lisa Jackson (b) (4) (b) (4)	07 Apr 2021 20:41:51
User opened query 'Data is required. Please complete.' (Site from System).	System	07 Apr 2021 20:41:12
User entered empty.	Lisa Jackson (b) (4) (b) (4)	07 Apr 2021 20:41:12

US3142034

Folder: Illness Visit (1)

Form: Saliva Collection (7)

Generated On: 11 Aug 2021 21:58:56

[Date of Collection](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 16:26:39
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 19:03:50
User entered empty.	Lisa Jackson (b) (4) (b) (4)	07 Apr 2021 20:41:12

US3142034

Folder: Illness Visit Day 1 (1)

Form: Visit Date

Generated On: 11 Aug 2021 21:58:56

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:16:02
DataPoint Verified.		22 Apr 2021 16:23:16
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 19:03:50
User entered 'Yes (Y)'	Shelby Pickle (b) (4) (b) (4)	16 Dec 2020 19:57:55

US3142034

Folder: Illness Visit Day 1 (1)

Form: Visit Date

Generated On: 11 Aug 2021 21:58:56

Visit date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:16:02
DataPoint Verified.		22 Apr 2021 16:23:16
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:03:50
User entered '14 Dec 2020'	(b) (4) Shelby Pickle (b) (4) (b) (4)	16 Dec 2020 19:57:55

US3142034

Folder: Illness Visit Day 1 (1)

Form: Visit Date

Generated On: 11 Aug 2021 21:58:56

[Was visit performed at the participant's home or at the clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:16:02
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 16:23:16
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:03:50
User closed query 'Per ETRTR: Please consider updating answer to "Clinic Visit - Unscheduled" because Illness Visit did not occur during a Protocol Scheduled Visit. Thank You! ' (Site from CRA).	(b) (4) (b) (4), (b) (6)	08 Apr 2021 21:03:07
Query 'Per ETRTR: Please consider updating answer to "Clinic Visit - Unscheduled" because Illness Visit did not occur during a Protocol Scheduled Visit. Thank You! ' answered with 'Vist was preformed in the clinic ' (Site from CRA).	Jami Wagner (b) (4) (b) (4)	07 Apr 2021 16:28:08
User opened query 'Per ETRTR: Please consider updating answer to "Clinic Visit - Unscheduled" because Illness Visit did not occur during a Protocol Scheduled Visit. Thank You! ' (Site from CRA).	(b) (4), (b) (6)	06 Apr 2021 10:27:32
User entered 'Clinic (Clinic)'	Shelby Pickle (b) (4) (b) (4)	16 Dec 2020 19:57:55

US3142034

Folder: Illness Visit Day 1 (1)

Form: Visit Date

Generated On: 11 Aug 2021 21:58:56

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:16:02
User entered 'SICKD1'	System	16 Dec 2020 19:57:55

US3142034

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 21:58:56

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:16:02
DataPoint Verified.		22 Apr 2021 16:23:32
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:03:50
User entered 'Yes (Y)'	(b) (4) Shelby Pickle (b) (4) (b) (4)	16 Dec 2020 19:58:50

US3142034

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 21:58:56

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:16:02
DataPoint Verified.		22 Apr 2021 16:23:32
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:03:50
User entered '14 Dec 2020'	(b) (4) Shelby Pickle (b) (4) (b) (4)	16 Dec 2020 19:58:50

US3142034

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 21:58:56

Time of assessment (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:16:02
DataPoint Verified.		22 Apr 2021 16:23:32
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:03:50
User entered '09:47'	(b) (4) Shelby Pickle (b) (4) (b) (4)	16 Dec 2020 19:58:50

US3142034

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 21:58:56

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:16:02
User entered '14 Dec 2020 09:47'	System	16 Dec 2020 19:58:50

US3142034

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 21:58:56

[Height \(xxx.x\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:16:02
DataPoint Verified.		22 Apr 2021 16:23:32
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:03:50
User entered missing code ND - Not Done.	(b) (4) Shelby Pickle (b) (4)	16 Dec 2020 19:58:50
DataPoint set to visible.	(b) (4) System	16 Dec 2020 19:57:55

US3142034

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 21:58:56

[Weight \(xxx.x\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:16:02
DataPoint Verified.		22 Apr 2021 16:23:32
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:03:50
User entered missing code ND - Not Done.	(b) (4) Shelby Pickle (b) (4)	16 Dec 2020 19:58:50
DataPoint set to visible.	(b) (4) System	16 Dec 2020 19:57:55

US3142034

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 21:58:56

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:16:02
DataPoint Verified.		22 Apr 2021 16:23:32
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:03:50
User entered '97.8' F	(b) (4) Shelby Pickle (b) (4) (b) (4)	16 Dec 2020 19:58:50

US3142034

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 21:58:56

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:16:02
DataPoint Verified.		22 Apr 2021 16:23:32
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 19:03:50
User entered 'Other (Other)'	Shelby Pickle (b) (4) (b) (4)	16 Dec 2020 19:58:50

US3142034

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 21:58:56

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:16:02
DataPoint Verified.		22 Apr 2021 16:23:32
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 19:03:50
User entered 'Temporal'	Shelby Pickle (b) (4) (b) (4)	16 Dec 2020 19:58:50

US3142034

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 21:58:56

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:16:02
DataPoint Verified.		22 Apr 2021 16:23:32
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:03:50
User entered '75'	(b) (4) Shelby Pickle (b) (4) (b) (4)	16 Dec 2020 19:58:50

US3142034

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 21:58:56

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:16:02
User entered 'bpm'	System	16 Dec 2020 19:58:50

US3142034

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 21:58:56

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:16:02
DataPoint Verified.		22 Apr 2021 16:23:32
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 19:03:50
User entered '14'	Shelby Pickle (b) (4) (b) (4)	16 Dec 2020 19:58:50

US3142034

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 21:58:56

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:16:02
User entered 'breaths/min'	System	16 Dec 2020 19:58:50

US3142034

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 21:58:56

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:16:02
DataPoint Verified.		22 Apr 2021 16:23:32
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 19:03:50
User entered '127'	Shelby Pickle (b) (4) (b) (4)	16 Dec 2020 19:58:50

US3142034

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 21:58:56

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:16:02
User entered 'mmHg'	System	16 Dec 2020 19:58:50

US3142034

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 21:58:56

[Diastolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:16:02
DataPoint Verified.		22 Apr 2021 16:23:32
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:03:50
User entered '83'	(b) (4) Shelby Pickle (b) (4) (b) (4)	16 Dec 2020 19:58:50

US3142034

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 21:58:56

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:16:02
User entered 'mmHg'	System	16 Dec 2020 19:58:50

US3142034

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 21:58:56

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:16:02

US3142034

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 21:58:56

[Weight \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:16:02

US3142034

Folder: Illness Visit Day 1 (1)

Form: Physical Examination

Generated On: 11 Aug 2021 21:58:56

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:16:02
DataPoint Verified.		22 Apr 2021 16:24:09
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 19:03:50
User entered 'Yes (Y)'	Shelby Pickle (b) (4) (b) (4)	16 Dec 2020 19:58:58

US3142034

Folder: Illness Visit Day 1 (1)

Form: Physical Examination

Generated On: 11 Aug 2021 21:58:56

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:16:02
DataPoint Verified.		22 Apr 2021 16:24:09
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 19:03:50
User entered '14 Dec 2020'	Shelby Pickle (b) (4) (b) (4)	16 Dec 2020 19:58:58

US3142034

Folder: Illness Visit Day 1 (1)

Form: Blood Sample Collection for Immunologic Assessment of SARS-CoV-2 Infection

Generated On: 11 Aug 2021 21:58:56

[Was Blood Sample Taken for Immunologic Assessment of SARS_COV-2 Infection?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:16:02
DataPoint Verified.		22 Apr 2021 16:24:26
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:03:50
User entered 'Yes (Y)'	(b) (4) Shelby Pickle (b) (4) (b) (4)	16 Dec 2020 19:59:10

US3142034

Folder: Illness Visit Day 1 (1)

Form: Blood Sample Collection for Immunologic Assessment of SARS-CoV-2 Infection

Generated On: 11 Aug 2021 21:58:56

[Date of Collection](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:16:02
DataPoint Verified.	(b) (4)	22 Apr 2021 16:24:26
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:03:50
User entered '14 Dec 2020'	(b) (4) Shelby Pickle (b) (4) (b) (4)	16 Dec 2020 19:59:10

US3142034

Folder: Convalescence Visit Day 28 (1)

Form: Visit Date

Generated On: 11 Aug 2021 21:58:56

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:23:19
DataPoint Verified.		22 Apr 2021 16:24:51
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 19:03:31
User entered 'Yes (Y)'	Shelby Pickle (b) (4) (b) (4)	18 Jan 2021 16:16:19

US3142034

Folder: Convalescence Visit Day 28 (1)

Form: Visit Date

Generated On: 11 Aug 2021 21:58:56

Visit date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:23:19
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 16:24:51
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:03:31
User closed query 'Per GCL LAB reconciliation: Saliva: PPD Central lab reports sample dated 12JAN2021 labelled as Illness Visit which is missing in EDC. Please confirm if the sample was collected then initiate an illness visit and record the data on the Saliva collection form. Thank you' (Site from DM).	(b) (4)	(b) (4), (b) (6)
Query 'Per GCL LAB reconciliation: Saliva: PPD Central lab reports sample dated 12JAN2021 labelled as Illness Visit which is missing in EDC. Please confirm if the sample was collected then initiate an illness visit and record the data on the Saliva collection form. Thank you' answered with '12Jan2021 is a convalescence visit day 28 to an illness visit for this patient, not an initial illness visit. Information provided in EDC already.' (Site from DM).	Shelby Pickle (b) (4)	31 Mar 2021 20:23:13
User opened query 'Per GCL LAB reconciliation: Saliva: PPD Central lab reports sample dated 12JAN2021 labelled as Illness Visit which is missing in EDC. Please confirm if the sample was collected then initiate an illness visit and record the data on the Saliva collection form. Thank you' (Site from DM).	(b) (4), (b) (6)	09 Feb 2021 16:44:35
User entered '12 Jan 2021'	Shelby Pickle (b) (4)	18 Jan 2021 16:16:19

US3142034

Folder: Convalescence Visit Day 28 (1)

Form: Visit Date

Generated On: 11 Aug 2021 21:58:56

[Was visit performed at the participant's home or at the clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:23:19
DataPoint Verified.		22 Apr 2021 16:24:51
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 19:03:31
User entered 'Clinic (Clinic)'	Shelby Pickle (b) (4) (b) (4)	18 Jan 2021 16:16:19

US3142034

Folder: Convalescence Visit Day 28 (1)

Form: Visit Date

Generated On: 11 Aug 2021 21:58:56

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:23:19
User entered 'SICKD28'	System	18 Jan 2021 16:16:19

US3142034

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 21:58:56

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:23:19
DataPoint Verified.		22 Apr 2021 16:25:20
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:03:31
User entered 'Yes (Y)'	(b) (4) Shelby Pickle (b) (4) (b) (4)	18 Jan 2021 16:16:56

US3142034

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 21:58:56

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:23:19
DataPoint Verified.		22 Apr 2021 16:25:20
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:03:31
User entered '12 Jan 2021'	(b) (4) Shelby Pickle (b) (4) (b) (4)	18 Jan 2021 16:16:56

US3142034

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 21:58:56

Time of assessment (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:23:19
DataPoint Verified.		22 Apr 2021 16:25:20
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 19:03:31
User entered '10:09'	Shelby Pickle (b) (4) (b) (4)	18 Jan 2021 16:16:56

US3142034

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 21:58:56

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:23:19
User entered '12 Jan 2021 10:09'	System	18 Jan 2021 16:16:56

US3142034

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 21:58:56

[Height \(xxx.x\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:23:19
DataPoint Verified.	(b) (4)	22 Apr 2021 16:25:20
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:03:31
User entered missing code ND - Not Done.	(b) (4) Shelby Pickle (b) (4)	18 Jan 2021 16:16:56
DataPoint set to visible.	(b) (4) System	18 Jan 2021 16:16:19

US3142034

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 21:58:56

[Weight \(xxx.x\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:23:19
DataPoint Verified.		22 Apr 2021 16:25:20
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:03:31
User entered missing code ND - Not Done.	(b) (4) Shelby Pickle (b) (4)	18 Jan 2021 16:16:56
DataPoint set to visible.	(b) (4) System	18 Jan 2021 16:16:19

US3142034

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 21:58:56

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:23:19
DataPoint Verified.		22 Apr 2021 16:25:20
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:03:31
User entered '97.8' F	(b) (4) Shelby Pickle (b) (4) (b) (4)	18 Jan 2021 16:16:56

US3142034

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 21:58:56

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:23:19
DataPoint Verified.	(b) (4)	22 Apr 2021 16:25:20
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 19:03:31
User entered 'Other (Other)'	Shelby Pickle (b) (4) (b) (4)	18 Jan 2021 16:16:56

US3142034

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 21:58:56

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:23:19
DataPoint Verified.		22 Apr 2021 16:25:20
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:03:31
User entered 'Temporal'	(b) (4) Shelby Pickle (b) (4) (b) (4)	18 Jan 2021 16:16:56

US3142034

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 21:58:56

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:23:19
DataPoint Verified.		22 Apr 2021 16:25:20
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:03:31
User entered '82'	(b) (4) Shelby Pickle (b) (4) (b) (4)	18 Jan 2021 16:16:56

US3142034

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 21:58:56

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:23:19
User entered 'bpm'	System	18 Jan 2021 16:16:56

US3142034

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 21:58:56

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:23:19
DataPoint Verified.		22 Apr 2021 16:25:20
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:03:31
User entered '12'	(b) (4) Shelby Pickle (b) (4) (b) (4)	18 Jan 2021 16:16:56

US3142034

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 21:58:56

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:23:19
User entered 'breaths/min'	System	18 Jan 2021 16:16:56

US3142034

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 21:58:56

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:23:19
DataPoint Verified.		22 Apr 2021 16:25:20
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 19:03:31
User entered '112'	Shelby Pickle (b) (4) (b) (4)	18 Jan 2021 16:16:56

US3142034

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 21:58:56

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:23:19
User entered 'mmHg'	System	18 Jan 2021 16:16:56

US3142034

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 21:58:56

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:23:19
DataPoint Verified.		22 Apr 2021 16:25:20
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:03:31
User entered '77'	(b) (4) Shelby Pickle (b) (4) (b) (4)	18 Jan 2021 16:16:56

US3142034

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 21:58:56

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:23:19
User entered 'mmHg'	System	18 Jan 2021 16:16:56

US3142034

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 21:58:56

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:23:19

US3142034

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 21:58:56

[Weight \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:23:19

US3142034

Folder: Convalescence Visit Day 28 (1)

Form: Physical Examination

Generated On: 11 Aug 2021 21:58:56

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:23:19
DataPoint Verified.		22 Apr 2021 16:26:06
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 19:03:31
User entered 'Yes (Y)'	Shelby Pickle (b) (4) (b) (4)	18 Jan 2021 16:17:05

US3142034

Folder: Convalescence Visit Day 28 (1)

Form: Physical Examination

Generated On: 11 Aug 2021 21:58:56

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:23:19
DataPoint Verified.		22 Apr 2021 16:26:06
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:03:31
User entered '12 Jan 2021'	(b) (4) Shelby Pickle (b) (4) (b) (4)	18 Jan 2021 16:17:05

US3142034

Folder: Convalescence Visit Day 28 (1)

Form: Blood Sample Collection for Immunologic Assessment of SARS-CoV-2 Infection

Generated On: 11 Aug 2021 21:58:56

[Was Blood Sample Taken for Immunologic Assessment of SARS_COV-2 Infection?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:23:19
DataPoint Verified.		22 Apr 2021 16:26:19
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 19:03:31
User entered 'Yes (Y)'	Shelby Pickle (b) (4) (b) (4)	18 Jan 2021 16:17:15

US3142034

Folder: Convalescence Visit Day 28 (1)

Form: Blood Sample Collection for Immunologic Assessment of SARS-CoV-2 Infection

Generated On: 11 Aug 2021 21:58:56

[Date of Collection](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:23:19
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 16:26:19
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:03:31
User closed query 'Per GCL Lab Reconciliation: SARS-CoV-2 serum sample: Re-Query: Thank you for response, please provide the Accession number and Tracking number with the shipping date for the 12 JAN 2021 SARS-CoV-2 serum sample reported under Convalescence Visit Day 28 in EDC, to track the sample in PPD central lab as the sample is still missing in PPD central lab.' (Site from DM).	(b) (4) (b) (4), (b) (6)	17 Feb 2021 10:49:09
Query 'Per GCL Lab Reconciliation: SARS-CoV-2 serum sample: Re-Query: Thank you for response, please provide the Accession number and Tracking number with the shipping date for the 12 JAN 2021 SARS-CoV-2 serum sample reported under Convalescence Visit Day 28 in EDC, to track the sample in PPD central lab as the sample is still missing in PPD central lab.' answered with 'Accession and tracking numbers cannot be provided ' (Site from DM).	Jill York (b) (4)	16 Feb 2021 17:46:57
User opened query 'Per GCL Lab Reconciliation: SARS-CoV-2 serum sample: Re-Query: Thank you for response, please provide the Accession number and Tracking number with the shipping date for the 12 JAN 2021 SARS-CoV-2 serum sample reported under Convalescence Visit Day 28 in EDC, to track the sample in PPD central lab as the sample is still missing in PPD central lab.' (Site from DM).	(b) (4), (b) (6)	08 Feb 2021 08:17:52

US3142034

Folder: Convalescence Visit Day 28 (1)

Form: Blood Sample Collection for Immunologic Assessment of SARS-CoV-2 Infection

Generated On: 11 Aug 2021 21:58:56

[Date of Collection](#)

Audit	User	Time (GMT)
User closed query 'Per Lab Recon: SARS-COV2: Sample dated 12 JAN 2021 is missing in PPD GCL records, please kindly review the preclarus and update the PPD GCL with missing sample data. Please review if the sample has been shipped by providing in response the Accession number, Tracking number & shipping date, as this helps to track the sample with the details provided. Please kindly also review if site has to scan in barcodes through preclarus, so that the data reflects in PPD GCL records. Thank you.' (Site from DM).	(b) (4), (b) (6)	08 Feb 2021 08:15:41
Query 'Per Lab Recon: SARS-COV2: Sample dated 12 JAN 2021 is missing in PPD GCL records, please kindly review the preclarus and update the PPD GCL with missing sample data. Please review if the sample has been shipped by providing in response the Accession number, Tracking number & shipping date, as this helps to track the sample with the details provided. Please kindly also review if site has to scan in barcodes through preclarus, so that the data reflects in PPD GCL records. Thank you.' answered with 'Sample was shipped. Tracking and accession number can not be provided.' (Site from DM).	Meghan York (b) (4) (b) (4)	01 Feb 2021 16:47:46
User opened query 'Per Lab Recon: SARS-COV2: Sample dated 12 JAN 2021 is missing in PPD GCL records, please kindly review the preclarus and update the PPD GCL with missing sample data. Please review if the sample has been shipped by providing in response the Accession number, Tracking number & shipping date, as this helps to track the sample with the details provided. Please kindly also review if site has to scan in barcodes through preclarus, so that the data reflects in PPD GCL records. Thank you.' (Site from DM).	(b) (4), (b) (6)	29 Jan 2021 04:14:58
User entered '12 Jan 2021'	Shelby Pickle (b) (4) (b) (4)	18 Jan 2021 16:17:15

US3142034

Folder: Participant Decision Visit / OL-D1 (1)

Form: Visit Date

Generated On: 11 Aug 2021 21:58:56

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:11:10
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:03:50
User closed query 'Per GCL Lab Reconciliation: Immunogenicity Assessment: Per GCL, there is an Immunogenicity Assessment sample collected on 12JAN2021 for the Participant Decision Visit / OL-D1, however, there is no data recorded on the Immunogenicity Assessment form within this folder. Please clarify and update as appropriate.' (Site from DM).	(b) (4), (b) (6)	30 Mar 2021 12:07:19
Query 'Per GCL Lab Reconciliation: Immunogenicity Assessment: Per GCL, there is an Immunogenicity Assessment sample collected on 12JAN2021 for the Participant Decision Visit / OL-D1, however, there is no data recorded on the Immunogenicity Assessment form within this folder. Please clarify and update as appropriate.' answered with 'data now entered ' (Site from DM).	Jill York (b) (4)	23 Mar 2021 16:27:16
User opened query 'Per GCL Lab Reconciliation: Immunogenicity Assessment: Per GCL, there is an Immunogenicity Assessment sample collected on 12JAN2021 for the Participant Decision Visit / OL-D1, however, there is no data recorded on the Immunogenicity Assessment form within this folder. Please clarify and update as appropriate.' (Site from DM).	(b) (4), (b) (6)	11 Feb 2021 16:30:45
User entered 'Yes (Y)'	Shelby Pickle (b) (4)	18 Jan 2021 16:18:27

US3142034

Folder: Participant Decision Visit / OL-D1 (1)

Form: Visit Date

Generated On: 11 Aug 2021 21:58:56

[Visit date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:11:10
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:03:50
User closed query 'Per GCL Lab Reconciliation: Swab: Sample dated 12-JAN-2021 is reported under OL-1 visit in PPD portal; however, the same is missing in EDC. Kindly review if the sample was collected, if yes, update the data as appropriate in Central Laboratory - Nasopharyngeal Swab (Single) eCRF initiated under Participant Decision Visit / OL-D1 eCRF, else clarify.' (Site from DM).	(b) (4) (b) (4), (b) (6)	30 Mar 2021 12:07:24
Query 'Per GCL Lab Reconciliation: Swab: Sample dated 12-JAN-2021 is reported under OL-1 visit in PPD portal; however, the same is missing in EDC. Kindly review if the sample was collected, if yes, update the data as appropriate in Central Laboratory - Nasopharyngeal Swab (Single) eCRF initiated under Participant Decision Visit / OL-D1 eCRF, else clarify.' answered with 'data now entered for this visit' (Site from DM).	Jill York (b) (4)	23 Mar 2021 16:26:13
User entered '2 Mar 2021' reason for change: Data Entry Error	Jill York (b) (4)	23 Mar 2021 16:19:47
User opened query 'Per GCL Lab Reconciliation: Swab: Sample dated 12-JAN-2021 is reported under OL-1 visit in PPD portal; however, the same is missing in EDC. Kindly review if the sample was collected, if yes, update the data as appropriate in Central Laboratory - Nasopharyngeal Swab (Single) eCRF initiated under Participant Decision Visit / OL-D1 eCRF, else clarify.' (Site from DM).	(b) (4), (b) (6)	23 Mar 2021 11:29:07
User entered '12 Jan 2021'	Shelby Pickle (b) (4) (b) (4)	18 Jan 2021 16:18:27

US3142034

Folder: Participant Decision Visit / OL-D1 (1)

Form: Visit Date

Generated On: 11 Aug 2021 21:58:56

[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 20:11:10
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:03:50
User entered 'Clinic (Clinic)'	(b) (4) Shelby Pickle (b) (4) (b) (4)	18 Jan 2021 16:18:27

US3142034

Folder: Participant Decision Visit / OL-D1 (1)

Form: Visit Date

Generated On: 11 Aug 2021 21:58:56

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:11:10
User entered 'UNBLND_DECIDE'	System	18 Jan 2021 16:18:27

US3142034

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 11 Aug 2021 21:58:56

Date of updated informed consent (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:11:10
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 19:03:50
User entered '12 Jan 2021'	Shelby Pickle (b) (4) (b) (4)	18 Jan 2021 16:19:39

US3142034

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 11 Aug 2021 21:58:56

[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 20:11:10
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:03:50
User entered '0'	(b) (4)	23 Mar 2021 16:20:44
Amendment Manager inserted this DataPoint.	Jill York (b) (4)	06 Mar 2021 11:00:12
	System	

US3142034

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 11 Aug 2021 21:58:56

[Was the participant unblinded?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:11:10
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 19:03:50
User entered 'Yes (Y)'	Shelby Pickle (b) (4) (b) (4)	18 Jan 2021 16:19:39

US3142034

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 11 Aug 2021 21:58:56

[Under what version of the Protocol was the Participant unblinded?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:11:10
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:03:50
User entered 'Amendment 6 or later (Amendment 6 or later)'	(b) (4)	
Amendment Manager inserted this DataPoint.	Jill York (b) (4)	23 Mar 2021 16:20:44
	System	06 Mar 2021 11:00:12

US3142034

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 11 Aug 2021 21:58:56

Date of unblinding (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:11:10
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 19:03:50
User entered '12 Jan 2021'	Shelby Pickle (b) (4) (b) (4)	18 Jan 2021 16:19:39

US3142034

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 11 Aug 2021 21:58:56

[Participant randomization assignment](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:11:10
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 19:03:50
User entered 'Placebo (Placebo)'	Shelby Pickle (b) (4) (b) (4)	18 Jan 2021 16:19:39

US3142034

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 11 Aug 2021 21:58:56

[Actual Dose 1](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:11:10
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 19:03:50
Amendment Manager: User entered 'Placebo (Placebo)'	System	20 Jan 2021 05:52:12
User entered 'Placebo (Placebo)'	Shelby Pickle (b) (4) (b) (4)	18 Jan 2021 16:19:39

US3142034

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 11 Aug 2021 21:58:56

[Actual Dose 2](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:11:10
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 19:03:50
Amendment Manager: User entered 'Placebo (Placebo)'	System	20 Jan 2021 05:52:12
User entered 'Placebo (Placebo)'	Shelby Pickle (b) (4) (b) (4)	18 Jan 2021 16:19:39

US3142034

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 11 Aug 2021 21:58:56

[Will participant receive mRNA-1273?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:11:10
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 19:03:50
User entered 'Yes (Y)'	Shelby Pickle (b) (4) (b) (4)	18 Jan 2021 16:19:39

US3142034

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 11 Aug 2021 21:58:56

[Placebo Only Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:11:10
User entered '1'	System	18 Jan 2021 16:19:39

US3142034

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 11 Aug 2021 21:58:56

[Continuing with mRNA-1273](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:11:10
User entered '1'	System	18 Jan 2021 16:19:39

US3142034

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing

Generated On: 11 Aug 2021 21:58:56

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:11:10
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:03:50
User entered missing code ND - Not Done.	Jill York (b) (4)	23 Mar 2021 16:22:39

US3142034

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing

Generated On: 11 Aug 2021 21:58:56

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:11:10
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:03:50
User entered missing code ND - Not Done.	Jill York (b) (4)	23 Mar 2021 16:22:39

US3142034

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing

Generated On: 11 Aug 2021 21:58:56

BMI (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:11:10
User entered empty.	System	23 Mar 2021 16:22:39
DataPoint set to visible.	System	18 Jan 2021 16:19:39

US3142034

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing

Generated On: 11 Aug 2021 21:58:56

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:11:10
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:03:50
User entered missing code ND - Not Done.	Jill York (b) (4)	23 Mar 2021 16:22:39

US3142034

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing

Generated On: 11 Aug 2021 21:58:56

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:11:10
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:03:50
User entered missing code ND - Not Done.	Jill York (b) (4)	23 Mar 2021 16:22:39

US3142034

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing

Generated On: 11 Aug 2021 21:58:56

BMI (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:11:10
User entered empty.	System	23 Mar 2021 16:22:39
DataPoint set to visible.	System	18 Jan 2021 16:19:39

US3142034

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 21:58:56

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:11:10
User accepted default value 'Pre-Dose (PREDOSE)'	Jill York (b) (4)	23 Mar 2021 16:22:39

US3142034

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 21:58:56

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:11:10
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:03:50
User entered 'Yes (Y)'	Jill York (b) (4)	23 Mar 2021 16:22:39

US3142034

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 21:58:56

Date of assessment (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:11:10
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:03:50
User entered '2 Mar 2021'	Jill York (b) (4)	23 Mar 2021 16:22:39

US3142034

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 21:58:56

Time of assessment (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:11:10
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:03:50
User entered '10:16'	Jill York (b) (4)	23 Mar 2021 16:22:39

US3142034

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 21:58:56

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:11:10
User entered '2 Mar 2021 10:16'	System	23 Mar 2021 16:22:39

US3142034

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 21:58:56

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:11:10
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:03:50
User entered '97.8' F	Jill York (b) (4)	23 Mar 2021 16:22:39

US3142034

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 21:58:56

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:11:10
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:03:50
User entered 'Other (Other)'	Jill York (b) (4)	23 Mar 2021 16:22:39

US3142034

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 21:58:56

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:11:10
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:03:50
User entered 'temporal'	Jill York (b) (4)	23 Mar 2021 16:22:39

US3142034

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 21:58:56

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:11:10
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:03:50
User entered '64'	Jill York (b) (4)	23 Mar 2021 16:22:39

US3142034

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 21:58:56

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:11:10
User entered 'bpm'	System	23 Mar 2021 16:22:39

US3142034

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 21:58:56

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:11:10
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:03:50
User entered '10'	Jill York (b) (4)	23 Mar 2021 16:22:39

US3142034

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 21:58:56

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:11:10
User entered 'breaths/min'	System	23 Mar 2021 16:22:39

US3142034

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 21:58:56

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:11:10
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:03:50
User entered '113'	Jill York (b) (4)	23 Mar 2021 16:22:39

US3142034

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 21:58:56

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:11:10
User entered 'mmHg'	System	23 Mar 2021 16:22:39

US3142034

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 21:58:56

[Diastolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:11:10
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:03:50
User entered '70'	Jill York (b) (4)	23 Mar 2021 16:22:39

US3142034

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 21:58:56

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:11:10
User entered 'mmHg'	System	23 Mar 2021 16:22:39

US3142034

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing

Generated On: 11 Aug 2021 21:58:56

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:11:10
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:03:50
User entered missing code ND - Not Done.	Jill York (b) (4)	23 Mar 2021 16:22:39

US3142034

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing

Generated On: 11 Aug 2021 21:58:56

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:11:10
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:03:50
User entered missing code ND - Not Done.	Jill York (b) (4)	23 Mar 2021 16:22:39

US3142034

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing

Generated On: 11 Aug 2021 21:58:56

BMI (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:11:10
User entered empty.	System	23 Mar 2021 16:22:39
DataPoint set to visible.	System	18 Jan 2021 16:19:39

US3142034

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 21:58:56

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:11:10
User accepted default value 'Post-Dose (POSTDOSE)'	Jill York (b) (4)	23 Mar 2021 16:22:39

US3142034

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 21:58:56

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:11:10
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:03:50
User entered 'Yes (Y)'	Jill York (b) (4)	23 Mar 2021 16:22:39

US3142034

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 21:58:56

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:11:10
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:03:50
User entered '2 Mar 2021'	Jill York (b) (4)	23 Mar 2021 16:22:39

US3142034

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 21:58:56

Time of assessment (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:11:10
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:03:50
User entered '11:40'	Jill York (b) (4)	23 Mar 2021 16:22:39

US3142034

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 21:58:56

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:11:10
User entered '2 Mar 2021 11:40'	System	23 Mar 2021 16:22:39

US3142034

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 21:58:56

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:11:10
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:03:50
User entered '97.3' F	Jill York (b) (4)	23 Mar 2021 16:22:39

US3142034

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 21:58:56

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:11:10
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:03:50
User entered 'Other (Other)'	Jill York (b) (4)	23 Mar 2021 16:22:39

US3142034

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 21:58:56

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:11:10
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:03:50
User entered 'temporal'	Jill York (b) (4)	23 Mar 2021 16:22:39

US3142034

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 21:58:56

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:11:10
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:03:50
User entered '64'	Jill York (b) (4)	23 Mar 2021 16:22:39

US3142034

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 21:58:56

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:11:10
User entered 'bpm'	System	23 Mar 2021 16:22:39

US3142034

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 21:58:56

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:11:10
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:03:50
User entered '10'	Jill York (b) (4)	23 Mar 2021 16:22:39

US3142034

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 21:58:56

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:11:10
User entered 'breaths/min'	System	23 Mar 2021 16:22:39

US3142034

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 21:58:56

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:11:10
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:03:50
User entered '136'	Jill York (b) (4)	23 Mar 2021 16:22:39

US3142034

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 21:58:56

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:11:10
User entered 'mmHg'	System	23 Mar 2021 16:22:39

US3142034

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 21:58:56

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:11:10
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:03:50
User entered '66'	Jill York (b) (4)	23 Mar 2021 16:22:39

US3142034

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 21:58:56

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:11:10
User entered 'mmHg'	System	23 Mar 2021 16:22:39

US3142034

Folder: Participant Decision Visit / OL-D1 (1)

Form: Physical Examination

Generated On: 11 Aug 2021 21:58:56

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:11:10
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:03:50
User entered 'Yes (Y)'	Jill York (b) (4)	23 Mar 2021 16:23:01

US3142034

Folder: Participant Decision Visit / OL-D1 (1)

Form: Physical Examination

Generated On: 11 Aug 2021 21:58:56

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:11:10
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:03:50
User entered '2 Mar 2021'	Jill York (b) (4)	23 Mar 2021 16:23:01

US3142034

Folder: Participant Decision Visit / OL-D1 (1)

Form: Exposure

Generated On: 11 Aug 2021 21:58:56

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:11:10
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:03:50
User entered 'Yes (Y)'	Jill York (b) (4)	23 Mar 2021 16:23:37

US3142034

Folder: Participant Decision Visit / OL-D1 (1)

Form: Exposure

Generated On: 11 Aug 2021 21:58:56

[If No, reason not given](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:11:10
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:03:50
User entered empty.	Jill York (b) (4)	23 Mar 2021 16:23:37

US3142034

Folder: Participant Decision Visit / OL-D1 (1)

Form: Exposure

Generated On: 11 Aug 2021 21:58:56

If reason is Physician Decision, Withdrawal of Consent by Participant, Protocol Deviation, or Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:11:10
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:03:50
User entered empty.	Jill York (b) (4)	23 Mar 2021 16:23:37

US3142034

Folder: Participant Decision Visit / OL-D1 (1)

Form: Exposure

Generated On: 11 Aug 2021 21:58:56

[What was the study treatment? \(Unblinded\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:11:10
User entered 'mRNA-1273'	System	23 Mar 2021 16:23:37
DataPoint set to visible.	System	18 Jan 2021 16:19:39

US3142034

Folder: Participant Decision Visit / OL-D1 (1)

Form: Exposure

Generated On: 11 Aug 2021 21:58:56

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:11:10
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:03:50
User entered '2 Mar 2021'	Jill York (b) (4)	23 Mar 2021 16:23:37

US3142034

Folder: Participant Decision Visit / OL-D1 (1)

Form: Exposure

Generated On: 11 Aug 2021 21:58:56

[What was the treatment time? \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:11:10
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:03:50
User entered '11:10'	Jill York (b) (4)	23 Mar 2021 16:23:37

US3142034

Folder: Participant Decision Visit / OL-D1 (1)

Form: Exposure

Generated On: 11 Aug 2021 21:58:56

[Treatment Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:11:10
User entered '2 Mar 2021 11:10'	System	23 Mar 2021 16:23:37

US3142034

Folder: Participant Decision Visit / OL-D1 (1)

Form: Exposure

Generated On: 11 Aug 2021 21:58:56

[Which arm was used to give treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:11:10
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:03:50
User entered 'Left Arm (LEFT ARM)'	Jill York (b) (4)	23 Mar 2021 16:23:37

US3142034

Folder: Participant Decision Visit / OL-D1 (1)

Form: Exposure

Generated On: 11 Aug 2021 21:58:56

[What was the frequency of the study treatment dosing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:11:10
User entered 'ONCE'	System	23 Mar 2021 16:23:37

US3142034

Folder: Participant Decision Visit / OL-D1 (1)

Form: Exposure

Generated On: 11 Aug 2021 21:58:56

[What was the route of administration for the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:11:10
User entered 'INTRAMUSCULAR'	System	23 Mar 2021 16:23:37

US3142034

Folder: Participant Decision Visit / OL-D1 (1)

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 21:58:56

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:11:10
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:03:50
User entered 'Yes (Y)'	Jill York (b) (4)	23 Mar 2021 16:23:59

US3142034

Folder: Participant Decision Visit / OL-D1 (1)

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 21:58:56

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:11:10
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:03:50
User entered '2 Mar 2021'	Jill York (b) (4)	23 Mar 2021 16:23:59

US3142034

Folder: Participant Decision Visit / OL-D1 (1)

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 21:58:56

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:11:10
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:03:50
User entered '10:56'	Jill York (b) (4)	23 Mar 2021 16:23:59

US3142034

Folder: Participant Decision Visit / OL-D1 (1)

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 21:58:56

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:11:10
User entered '2 Mar 2021 10:56'	System	23 Mar 2021 16:23:59

US3142034

Folder: Participant Decision Visit / OL-D1 (1)

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 11 Aug 2021 21:58:56

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:11:10
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:03:50
User entered 'Yes (Y)'	Jill York (b) (4)	23 Mar 2021 16:24:27

US3142034

Folder: Participant Decision Visit / OL-D1 (1)

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 11 Aug 2021 21:58:56

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:11:10
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:03:50
User closed query 'Per GCL Lab Reconciliation: Swab: Sample dated "02-MAR-2021" is recorded under Participant Decision Visit / OL-D1 visit in EDC; however, in PPD portal, it is recorded as "12-JAN-2021" for OL-1 visit. Kindly review and confirm in site response the collection date and update EDC or Preclarus portal as appropriate, else clarify.' (Site from DM).	(b) (4) (b) (4), (b) (6)	13 Apr 2021 09:36:36
Query 'Per GCL Lab Reconciliation: Swab: Sample dated "02-MAR-2021" is recorded under Participant Decision Visit / OL-D1 visit in EDC; however, in PPD portal, it is recorded as "12-JAN-2021" for OL-1 visit. Kindly review and confirm in site response the collection date and update EDC or Preclarus portal as appropriate, else clarify.' answered with 'OL-D1/OL-1 IS OFFICIALLY ON 01MAR2021. 12JAN2021 IS A DAY 28 VISIT IN THE CLINIC. THE LATER VISIT WAS MARKEC WRONG. ACCORDINGTO CLINICAL CONDUCTOR.' (Site from DM).	Lisa Jackson (b) (4) (b) (4)	07 Apr 2021 20:38:56
User entered '01 Mar 2021' reason for change: Data Entry Error	Lisa Jackson (b) (4) (b) (4)	07 Apr 2021 20:36:57
User opened query 'Per GCL Lab Reconciliation: Swab: Sample dated "02-MAR-2021" is recorded under Participant Decision Visit / OL-D1 visit in EDC; however, in PPD portal, it is recorded as "12-JAN-2021" for OL-1 visit. Kindly review and confirm in site response the collection date and update EDC or Preclarus portal as appropriate, else clarify.' (Site from DM).	(b) (4), (b) (6)	07 Apr 2021 07:45:45
User entered '2 Mar 2021'	Jill York (b) (4)	23 Mar 2021 16:24:27

US3142034

Folder: Participant Decision Visit / OL-D1 (1)

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 11 Aug 2021 21:58:56

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:11:10
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:03:50
User entered '10:54'	Jill York (b) (4)	23 Mar 2021 16:24:27

US3142034

Folder: Participant Decision Visit / OL-D1 (1)

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 11 Aug 2021 21:58:56

[Collection Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:11:10
User entered '01 Mar 2021 10:54'	System	07 Apr 2021 20:36:57
User entered '2 Mar 2021 10:54'	System	23 Mar 2021 16:24:27

US3142034

Folder: Participant Decision Visit / OL-D1 (1)

Form: Continuing

Generated On: 11 Aug 2021 21:58:56

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:11:10
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 19:03:50
User entered 'Yes (Y)'	Shelby Pickle (b) (4) (b) (4)	18 Jan 2021 16:19:52

US3142034

Folder: Participant Decision Visit / OL-D1 (1)

Form: Continuing

Generated On: 11 Aug 2021 21:58:56

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:11:10
User entered '1'	System	18 Jan 2021 16:19:52

US3142034

Folder: Safety Call OL-D8 (1)

Form: Safety Call

Generated On: 11 Aug 2021 21:58:56

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:36:05
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 19:03:50
User entered 'Yes (Y)'	Shelby Pickle (b) (4) (b) (4)	31 Mar 2021 21:12:16

US3142034

Folder: Safety Call OL-D8 (1)

Form: Safety Call

Generated On: 11 Aug 2021 21:58:56

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:36:05
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:03:50
User entered '09 Mar 2021'	(b) (4) Shelby Pickle (b) (4)	31 Mar 2021 21:12:16

US3142034

Folder: Safety Call OL-D8 (1)

Form: Safety Call

Generated On: 11 Aug 2021 21:58:56

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:36:05
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 19:03:50
User entered 'Contact Made (CONTACT MADE)'	Shelby Pickle (b) (4) (b) (4)	31 Mar 2021 21:12:16

US3142034

Folder: Safety Call OL-D8 (1)

Form: Safety Call

Generated On: 11 Aug 2021 21:58:56

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:36:05
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:03:50
User entered empty.	(b) (4) Shelby Pickle (b) (4)	31 Mar 2021 21:12:16

US3142034

Folder: Safety Call OL-D8 (1)

Form: Continuing

Generated On: 11 Aug 2021 21:58:56

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:36:05
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:03:50
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	02 Mar 2021 18:39:04

US3142034

Folder: Safety Call OL-D8 (1)

Form: Continuing

Generated On: 11 Aug 2021 21:58:56

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:36:05
User entered '1'	System	02 Mar 2021 18:39:04

US3142034

Folder: Safety Call OL-D8 (1)

Form: Continuing

Generated On: 11 Aug 2021 21:58:56

[OLD29 Placebo Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:36:05
User entered '1'	System	02 Mar 2021 18:39:04
DataPoint set to visible.	System	02 Mar 2021 18:39:04

US3142034

Folder: OL-D29 (1)

Form: Visit Date

Generated On: 11 Aug 2021 21:58:56

[Was this visit performed?](#)

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 19:03:50
User entered 'Yes (Y)' reason for change: Data Entry Error	Lisa Jackson (b) (4) (b) (4)	01 Apr 2021 18:51:55
Query 'Data is required. Please complete.' canceled (Site from System).	(b) (4), (b) (6)	30 Mar 2021 22:00:20
User opened query 'Data is required. Please complete.' (Site from System).	System	24 Mar 2021 14:10:36
User entered empty; reason for change Data Entry Error	Jill York (b) (4)	24 Mar 2021 14:10:36
User entered 'Yes (Y)'	(b) (4), (b) (6)	02 Mar 2021 18:39:17

US3142034

Folder: OL-D29 (1)

Form: Visit Date

Generated On: 11 Aug 2021 21:58:56

Visit date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:03:50
User entered '01 Apr 2021' reason for change: Data Entry Error	(b) (4)	
User entered '01 Apr 2021' reason for change: Data Entry Error	Lisa Jackson (b) (4)	01 Apr 2021 18:51:55
User closed query 'OL-D29 Visit Date is < 25 days or > 42 days after the Participant Decision visit vaccination. Please reconcile or confirm dates.' (Site from System).	System	24 Mar 2021 14:10:36
Query 'OL-D29 Visit Date is < 25 days or > 42 days after the Participant Decision visit vaccination. Please reconcile or confirm dates.' answered by data change (Site from System).	System	24 Mar 2021 14:10:36
User entered empty; reason for change Data Entry Error	Jill York (b) (4)	24 Mar 2021 14:10:36
User opened query 'OL-D29 Visit Date is < 25 days or > 42 days after the Participant Decision visit vaccination. Please reconcile or confirm dates.' (Site from System).	System	23 Mar 2021 16:23:37
User entered '02 Mar 2021' reason for change: Data Entry Error	Shelby Pickle (b) (4)	02 Mar 2021 20:41:42
User entered '02 Mar 2021' reason for change: Data Entry Error	(b) (4)	
User entered '1 Mar 2021' reason for change: Data Entry Error	(b) (4), (b) (6)	02 Mar 2021 18:41:15
User entered '2 Mar 2021'		02 Mar 2021 18:39:17

US3142034

Folder: OL-D29 (1)

Form: Visit Date

Generated On: 11 Aug 2021 21:58:56

[Was visit performed at the participant's home or at the clinic?](#)

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 19:03:50
User entered 'Clinic (Clinic)' reason for change: Data Entry Error	Lisa Jackson (b) (4) (b) (4)	01 Apr 2021 18:51:55
User entered empty; reason for change Data Entry Error	Jill York (b) (4)	24 Mar 2021 14:10:36
User entered 'Clinic (Clinic)'	(b) (4), (b) (6)	02 Mar 2021 18:39:17

US3142034

Folder: OL-D29 (1)

Form: Visit Date

Generated On: 11 Aug 2021 21:58:56

[Folder OID](#)

Audit	User	Time (GMT)
User entered 'OLD29'	System	01 Apr 2021 18:51:55
User entered empty.	System	24 Mar 2021 14:10:36
User entered 'OLD29'	System	02 Mar 2021 18:39:17

US3142034

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 21:58:56

[Timepoint](#)

Audit	User	Time (GMT)
User accepted default value 'Pre-Dose (PREDOSE)'	(b) (4), (b) (6)	02 Mar 2021 18:42:03

US3142034

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 21:58:56

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 19:03:50
User entered 'Yes (Y)' reason for change: Data Entry Error	Lisa Jackson (b) (4) (b) (4)	01 Apr 2021 18:53:34
Query 'Data is required. Please complete.' canceled (Site from System).	(b) (4), (b) (6)	30 Mar 2021 22:00:34
User opened query 'Data is required. Please complete.' (Site from System).	System	24 Mar 2021 14:12:48
User entered empty; reason for change Data Entry Error	Jill York (b) (4)	24 Mar 2021 14:12:48
User entered 'Yes (Y)'	(b) (4), (b) (6)	02 Mar 2021 18:42:03

US3142034

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 21:58:56

Date of assessment (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:03:50
	(b) (4)	
User entered '01 Apr 2021' reason for change: Data Entry Error	Lisa Jackson (b) (4)	01 Apr 2021 18:53:34
	(b) (4)	
User entered empty; reason for change Data Entry Error	Jill York (b) (4)	24 Mar 2021 14:12:48
User closed query 'The Collection Date is not equal to Visit Date. Please review and reconcile.' (Site from System).	System	02 Mar 2021 20:43:08
User entered '02 Mar 2021' reason for change: Data Entry Error	Shelby Pickle (b) (4)	02 Mar 2021 20:43:08
	(b) (4)	
User opened query 'The Collection Date is not equal to Visit Date. Please review and reconcile.' (Site from System).	System	02 Mar 2021 20:41:42
User entered '1 Mar 2021'	(b) (4), (b) (6)	02 Mar 2021 18:42:03

US3142034

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 21:58:56

Time of assessment (00:00-23:59)

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 19:03:50
User entered '12:11' reason for change: Data Entry Error	Lisa Jackson (b) (4) (b) (4)	01 Apr 2021 18:53:34
User entered empty; reason for change Data Entry Error	Jill York (b) (4)	24 Mar 2021 14:12:48
User entered '10:33' reason for change: Data Entry Error	Shelby Pickle (b) (4) (b) (4)	02 Mar 2021 20:43:08
User entered '10:16'	(b) (4), (b) (6)	02 Mar 2021 18:42:03

US3142034

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 21:58:56

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered '01 Apr 2021 12:11'	System	01 Apr 2021 18:53:34
User entered empty.	System	24 Mar 2021 14:12:48
User entered '02 Mar 2021 10:33'	System	02 Mar 2021 20:43:08
User entered '1 Mar 2021 10:16'	System	02 Mar 2021 18:42:03

US3142034

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 21:58:56

Temperature (xxx.x)

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:03:50
	(b) (4)	
User entered '97.9' F reason for change: Data Entry Error	Lisa Jackson (b) (4)	01 Apr 2021 18:53:34
	(b) (4)	
User entered empty; reason for change Data Entry Error	Jill York (b) (4)	24 Mar 2021 14:12:48
User entered '97.6' F reason for change: Data Entry Error	Shelby Pickle (b) (4)	02 Mar 2021 20:43:08
	(b) (4)	
User entered '97.8' F	(b) (4), (b) (6)	02 Mar 2021 18:42:03

US3142034

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 21:58:56

[Route of measurement](#)

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 19:03:50
User entered 'Other (Other)' reason for change: Data Entry Error	Lisa Jackson (b) (4) (b) (4)	01 Apr 2021 18:53:34
User entered empty; reason for change Data Entry Error	Jill York (b) (4)	24 Mar 2021 14:12:48
User entered 'Other (Other)'	(b) (4), (b) (6)	02 Mar 2021 18:42:03

US3142034

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 21:58:56

[If Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 19:03:50
User entered 'temporal' reason for change: Data Entry Error	Lisa Jackson (b) (4) (b) (4)	01 Apr 2021 18:53:34
User entered empty; reason for change Data Entry Error	Jill York (b) (4)	24 Mar 2021 14:12:48
User entered 'temporal'	(b) (4), (b) (6)	02 Mar 2021 18:42:03

US3142034

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 21:58:56

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:03:50
	(b) (4)	
User entered '67' reason for change: Data Entry Error	Lisa Jackson (b) (4)	01 Apr 2021 18:53:34
	(b) (4)	
User entered empty; reason for change Data Entry Error	Jill York (b) (4)	24 Mar 2021 14:12:48
User entered '66' reason for change: Data Entry Error	Shelby Pickle (b) (4)	02 Mar 2021 20:43:08
	(b) (4)	
User entered '64'	(b) (4), (b) (6)	02 Mar 2021 18:42:03

US3142034

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 21:58:56

[Pulse units](#)

Audit	User	Time (GMT)
User entered 'bpm'	System	01 Apr 2021 18:53:34
User entered empty.	System	24 Mar 2021 14:12:48
User entered 'bpm'	System	02 Mar 2021 18:42:03

US3142034

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 21:58:56

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 19:03:50
User entered '14' reason for change: Data Entry Error	Lisa Jackson (b) (4) (b) (4)	01 Apr 2021 18:53:34
User entered empty; reason for change Data Entry Error	Jill York (b) (4)	24 Mar 2021 14:12:48
User entered '12' reason for change: Data Entry Error	Shelby Pickle (b) (4) (b) (4)	02 Mar 2021 20:43:08
User entered '10'	(b) (4), (b) (6)	02 Mar 2021 18:42:03

US3142034

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 21:58:56

[Respiratory Rate units](#)

Audit	User	Time (GMT)
User entered 'breaths/min'	System	01 Apr 2021 18:53:34
User entered empty.	System	24 Mar 2021 14:12:48
User entered 'breaths/min'	System	02 Mar 2021 18:42:03

US3142034

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 21:58:56

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 19:03:50
User entered '132' reason for change: Data Entry Error	Lisa Jackson (b) (4) (b) (4)	01 Apr 2021 18:53:34
User entered empty; reason for change Data Entry Error	Jill York (b) (4)	24 Mar 2021 14:12:48
User entered '123' reason for change: Data Entry Error	Shelby Pickle (b) (4) (b) (4)	02 Mar 2021 20:43:08
User entered '113'	(b) (4), (b) (6)	02 Mar 2021 18:42:03

US3142034

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 21:58:56

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	01 Apr 2021 18:53:34
User entered empty.	System	24 Mar 2021 14:12:48
User entered 'mmHg'	System	02 Mar 2021 18:42:03

US3142034

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 21:58:56

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 19:03:50
User entered '73' reason for change: Data Entry Error	Lisa Jackson (b) (4) (b) (4)	01 Apr 2021 18:53:34
User entered empty; reason for change Data Entry Error	Jill York (b) (4)	24 Mar 2021 14:12:48
User entered '73' reason for change: Data Entry Error	Shelby Pickle (b) (4) (b) (4)	02 Mar 2021 20:43:08
User entered '70'	(b) (4), (b) (6)	02 Mar 2021 18:42:03

US3142034

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 21:58:56

Diastolic Blood Pressure units

Audit	User	Time (GMT)
User entered 'mmHg'	System	01 Apr 2021 18:53:34
User entered empty.	System	24 Mar 2021 14:12:48
User entered 'mmHg'	System	02 Mar 2021 18:42:03

US3142034

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 21:58:56

[Timepoint](#)

Audit	User	Time (GMT)
User accepted default value 'Post-Dose (POSTDOSE)'	Shelby Pickle (b) (4) (b) (4)	02 Mar 2021 20:43:08

US3142034

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 21:58:56

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:03:50
Query 'Data is required. Please complete.' canceled (Site from System).	(b) (4) (b) (4), (b) (6)	30 Mar 2021 22:00:38
User opened query 'Data is required. Please complete.' (Site from System).	System	24 Mar 2021 14:12:48
User entered empty; reason for change Data Entry Error	Jill York (b) (4)	24 Mar 2021 14:12:48
User entered 'Yes (Y)'	Shelby Pickle (b) (4) (b) (4)	02 Mar 2021 20:43:08

US3142034

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 21:58:56

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 19:03:50
User entered empty; reason for change Data Entry Error	Jill York (b) (4)	24 Mar 2021 14:12:48
User entered '02 Mar 2021'	Shelby Pickle (b) (4) (b) (4)	02 Mar 2021 20:43:08

US3142034

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 21:58:56

Time of assessment (00:00-23:59)

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 19:03:50
User entered empty; reason for change Data Entry Error	Jill York (b) (4)	24 Mar 2021 14:12:48
User entered '11:40'	Shelby Pickle (b) (4) (b) (4)	02 Mar 2021 20:43:08

US3142034

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 21:58:56

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	24 Mar 2021 14:12:48
User entered '02 Mar 2021 11:40'	System	02 Mar 2021 20:43:08

US3142034

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 21:58:56

Temperature (xxx.x)

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:03:50
	(b) (4)	
User entered empty; reason for change Data Entry Error	Jill York (b) (4)	24 Mar 2021 14:12:48
User entered '97.3' F	Shelby Pickle (b) (4)	02 Mar 2021 20:43:08
	(b) (4)	

US3142034

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 21:58:56

[Route of measurement](#)

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:03:50
	(b) (4)	
User entered empty; reason for change Data Entry Error	Jill York (b) (4)	24 Mar 2021 14:12:48
User entered 'Other (Other)'	Shelby Pickle (b) (4)	02 Mar 2021 20:43:08
	(b) (4)	

US3142034

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 21:58:56

[If Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 19:03:50
User entered empty; reason for change Data Entry Error	Jill York (b) (4)	24 Mar 2021 14:12:48
User entered 'Temporal'	Shelby Pickle (b) (4) (b) (4)	02 Mar 2021 20:43:08

US3142034

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 21:58:56

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:03:50
	(b) (4)	
User entered empty; reason for change Data Entry Error	Jill York (b) (4)	24 Mar 2021 14:12:48
User entered '64'	Shelby Pickle (b) (4)	02 Mar 2021 20:43:08
	(b) (4)	

US3142034

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 21:58:56

[Pulse units](#)

Audit	User	Time (GMT)
User entered empty.	System	24 Mar 2021 14:12:48
User entered 'bpm'	System	02 Mar 2021 20:43:08

US3142034

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 21:58:56

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:03:50
	(b) (4)	
User entered empty; reason for change Data Entry Error	Jill York (b) (4)	24 Mar 2021 14:12:48
User entered missing code ND - Not Done.	Shelby Pickle (b) (4)	02 Mar 2021 20:43:08
	(b) (4)	

US3142034

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 21:58:56

[Respiratory Rate units](#)

Audit	User	Time (GMT)
User entered empty.	System	24 Mar 2021 14:12:48
User entered 'breaths/min'	System	02 Mar 2021 20:43:08

US3142034

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 21:58:56

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 19:03:50
User entered empty; reason for change Data Entry Error	Jill York (b) (4)	24 Mar 2021 14:12:48
User entered '136'	Shelby Pickle (b) (4) (b) (4)	02 Mar 2021 20:43:08

US3142034

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 21:58:56

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered empty.	System	24 Mar 2021 14:12:48
User entered 'mmHg'	System	02 Mar 2021 20:43:08

US3142034

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 21:58:56

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:03:50
	(b) (4)	
User entered empty; reason for change Data Entry Error	Jill York (b) (4)	24 Mar 2021 14:12:48
User entered '66'	Shelby Pickle (b) (4)	02 Mar 2021 20:43:08
	(b) (4)	

US3142034

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 21:58:56

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered empty.	System	24 Mar 2021 14:12:48
User entered 'mmHg'	System	02 Mar 2021 20:43:08

US3142034

Folder: OL-D29 (1)

Form: Physical Examination

Generated On: 11 Aug 2021 21:58:56

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:03:50
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4) (b) (4), (b) (6)	05 Apr 2021 11:16:53
User entered 'Yes (Y)' reason for change: Data Entry Error	Lisa Jackson (b) (4) (b) (4)	01 Apr 2021 18:54:05
Query 'Data is required. Please complete.' answered with 'data will be entered 29March' (Site from System).	Jill York (b) (4)	24 Mar 2021 14:15:05
User opened query 'Data is required. Please complete.' (Site from System).	System	24 Mar 2021 14:12:58
User entered empty; reason for change Data Entry Error	Jill York (b) (4)	24 Mar 2021 14:12:58
User entered 'Yes (Y)'	(b) (4), (b) (6)	02 Mar 2021 18:39:28

US3142034

Folder: OL-D29 (1)

Form: Physical Examination

Generated On: 11 Aug 2021 21:58:56

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:03:50
	(b) (4)	
User entered '01 Apr 2021' reason for change: Data Entry Error	Lisa Jackson (b) (4)	01 Apr 2021 18:54:05
	(b) (4)	
User entered empty; reason for change Data Entry Error	Jill York (b) (4)	24 Mar 2021 14:12:58
User closed query 'The Physical Examination Date is not equal to Visit Date. Please review and reconcile.' (Site from System).	System	02 Mar 2021 20:43:15
User entered '02 Mar 2021' reason for change: Data Entry Error	Shelby Pickle (b) (4)	02 Mar 2021 20:43:15
	(b) (4)	
User opened query 'The Physical Examination Date is not equal to Visit Date. Please review and reconcile.' (Site from System).	System	02 Mar 2021 20:41:42
User closed query 'The Physical Examination Date is not equal to Visit Date. Please review and reconcile.' (Site from System).	System	02 Mar 2021 18:42:14
User entered '1 Mar 2021' reason for change: Data Entry Error	(b) (4), (b) (6)	02 Mar 2021 18:42:14
User opened query 'The Physical Examination Date is not equal to Visit Date. Please review and reconcile.' (Site from System).	System	02 Mar 2021 18:41:15
User entered '2 Mar 2021'	(b) (4), (b) (6)	02 Mar 2021 18:39:28

US3142034

Folder: OL-D29 (1)

Form: Exposure

Generated On: 11 Aug 2021 21:58:56

[Was study treatment given?](#)

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:03:50
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4) (b) (4), (b) (6)	05 Apr 2021 11:16:43
User entered 'Yes (Y)' reason for change: Data Entry Error	Lisa Jackson (b) (4) (b) (4)	01 Apr 2021 18:55:12
Query 'Data is required. Please complete.' answered with 'data will be entered for this visit on 29 March' (Site from System).	Jill York (b) (4)	24 Mar 2021 14:14:41
User opened query 'Data is required. Please complete.' (Site from System).	System	24 Mar 2021 14:13:20
User entered empty; reason for change Data Entry Error	Jill York (b) (4)	24 Mar 2021 14:13:20
User entered 'Yes (Y)'	(b) (4), (b) (6)	02 Mar 2021 18:39:53

US3142034

Folder: OL-D29 (1)

Form: Exposure

Generated On: 11 Aug 2021 21:58:56

[If No, reason not given](#)

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:03:50
User entered empty.	(b) (4) (b) (4), (b) (6)	02 Mar 2021 18:39:53

US3142034

Folder: OL-D29 (1)

Form: Exposure

Generated On: 11 Aug 2021 21:58:56

If reason is Physician Decision, Withdrawal of Consent by Participant, Protocol Deviation, or Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:03:50
User entered empty.	(b) (4) (b) (4), (b) (6)	02 Mar 2021 18:39:53

US3142034

Folder: OL-D29 (1)

Form: Exposure

Generated On: 11 Aug 2021 21:58:56

[What was the study treatment? \(Unblinded\)](#)

Audit	User	Time (GMT)
User entered 'mRNA-1273'	System	01 Apr 2021 18:55:12
User entered empty.	System	24 Mar 2021 14:13:20
User entered 'mRNA-1273'	System	02 Mar 2021 18:39:53
DataPoint set to visible.	System	02 Mar 2021 18:39:04

US3142034

Folder: OL-D29 (1)

Form: Exposure

Generated On: 11 Aug 2021 21:58:56

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 19:03:50
User entered '01 Apr 2021' reason for change: Data Entry Error	Lisa Jackson (b) (4) (b) (4)	01 Apr 2021 18:55:12
User entered empty; reason for change Data Entry Error	Jill York (b) (4)	24 Mar 2021 14:13:20
User closed query 'The Treatment Date is not equal to the Visit Date. Please review and reconcile.' (Site from System).	(b) (4), (b) (6)	09 Mar 2021 08:40:43
User entered '02 Mar 2021' reason for change: Data Entry Error	Shelby Pickle (b) (4) (b) (4)	02 Mar 2021 20:43:27
Query 'The Treatment Date is not equal to the Visit Date. Please review and reconcile.' answered with 'Pt. not dosed same day due to mammogram testing' (Site from System).	(b) (4), (b) (6)	02 Mar 2021 18:43:58
User opened query 'The Treatment Date is not equal to the Visit Date. Please review and reconcile.' (Site from System).	System	02 Mar 2021 18:42:49
User entered '2 Mar 2021' reason for change: Data Entry Error	(b) (4), (b) (6)	02 Mar 2021 18:42:49
User closed query 'The Treatment Date is not equal to the Visit Date. Please review and reconcile.' (Site from System).	System	02 Mar 2021 18:42:25
Query 'The Treatment Date is not equal to the Visit Date. Please review and reconcile.' answered by data change (Site from System).	System	02 Mar 2021 18:42:25
User entered '1 Mar 2021' reason for change: Data Entry Error	(b) (4), (b) (6)	02 Mar 2021 18:42:25
User opened query 'The Treatment Date is not equal to the Visit Date. Please review and reconcile.' (Site from System).	System	02 Mar 2021 18:41:15
User entered '2 Mar 2021'	(b) (4), (b) (6)	02 Mar 2021 18:39:53

US3142034

Folder: OL-D29 (1)

Form: Exposure

Generated On: 11 Aug 2021 21:58:56

[What was the treatment time? \(00:00-23:59\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 19:03:50
User entered '12:42' reason for change: Data Entry Error	Lisa Jackson (b) (4) (b) (4)	01 Apr 2021 18:55:12
User entered empty; reason for change Data Entry Error	Jill York (b) (4)	24 Mar 2021 14:13:20
User entered '11:10'	(b) (4), (b) (6)	02 Mar 2021 18:39:53

US3142034

Folder: OL-D29 (1)

Form: Exposure

Generated On: 11 Aug 2021 21:58:56

[Treatment Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered '01 Apr 2021 12:42'	System	01 Apr 2021 18:55:12
User entered empty.	System	24 Mar 2021 14:13:20
User entered '02 Mar 2021 11:10'	System	02 Mar 2021 20:43:27
User entered '2 Mar 2021 11:10'	System	02 Mar 2021 18:42:49
User entered '1 Mar 2021 11:10'	System	02 Mar 2021 18:42:25
User entered '2 Mar 2021 11:10'	System	02 Mar 2021 18:39:53

US3142034

Folder: OL-D29 (1)

Form: Exposure

Generated On: 11 Aug 2021 21:58:56

[Which arm was used to give treatment?](#)

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 19:03:50
User entered 'Left Arm (LEFT ARM)' reason for change: Data Entry Error	Lisa Jackson (b) (4) (b) (4)	01 Apr 2021 18:55:12
User entered empty; reason for change Data Entry Error	Jill York (b) (4)	24 Mar 2021 14:13:20
User entered 'Left Arm (LEFT ARM)'	(b) (4), (b) (6)	02 Mar 2021 18:39:53

US3142034

Folder: OL-D29 (1)

Form: Exposure

Generated On: 11 Aug 2021 21:58:56

[What was the frequency of the study treatment dosing?](#)

Audit	User	Time (GMT)
User entered 'ONCE'	System	01 Apr 2021 18:55:12
User entered empty.	System	24 Mar 2021 14:13:20
User entered 'ONCE'	System	02 Mar 2021 18:39:53

US3142034

Folder: OL-D29 (1)

Form: Exposure

Generated On: 11 Aug 2021 21:58:56

[What was the route of administration for the study treatment?](#)

Audit	User	Time (GMT)
User entered 'INTRAMUSCULAR'	System	01 Apr 2021 18:55:12
User entered empty.	System	24 Mar 2021 14:13:20
User entered 'INTRAMUSCULAR'	System	02 Mar 2021 18:39:53

US3142034

Folder: OL-D29 (1)

Form: Continuing

Generated On: 11 Aug 2021 21:58:56

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:03:50
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	02 Mar 2021 18:39:57

US3142034

Folder: OL-D29 (1)

Form: Continuing

Generated On: 11 Aug 2021 21:58:56

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered '1'	System	02 Mar 2021 18:39:57

US3142034

Folder: Safety Call OL-D36 (1)

Form: Safety Call

Generated On: 11 Aug 2021 21:58:56

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:03:50
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	13 Apr 2021 16:52:23

US3142034

Folder: Safety Call OL-D36 (1)

Form: Safety Call

Generated On: 11 Aug 2021 21:58:56

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
User closed query 'OL Safety Call Day 36 'Date of Contact or Contact Attempt' is less than 7 days or greater than 10 days after OL-D29 Treatment Date on the Exposure Form. Please review and reconcile, or clarify.' (Site from System). User signature succeeded.	(b) (4), (b) (6)	19 Apr 2021 14:06:10
Query 'OL Safety Call Day 36 'Date of Contact or Contact Attempt' is less than 7 days or greater than 10 days after OL-D29 Treatment Date on the Exposure Form. Please review and reconcile, or clarify.' answered with 'Call attempted on 09 APR 2021 no answer.' (Site from System). User opened query 'OL Safety Call Day 36 'Date of Contact or Contact Attempt' is less than 7 days or greater than 10 days after OL-D29 Treatment Date on the Exposure Form. Please review and reconcile, or clarify.' (Site from System). User entered '12 Apr 2021'	Ripley Hollister (b) (4) (b) (4) (b) (4), (b) (6)	18 Apr 2021 19:03:50 13 Apr 2021 16:53:05 13 Apr 2021 16:52:23
	System	13 Apr 2021 16:52:23
	(b) (4), (b) (6)	13 Apr 2021 16:52:23

US3142034

Folder: Safety Call OL-D36 (1)

Form: Safety Call

Generated On: 11 Aug 2021 21:58:56

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:03:50
User entered 'Contact Made (CONTACT MADE)'	(b) (4) (b) (4), (b) (6)	13 Apr 2021 16:52:23

US3142034

Folder: Safety Call OL-D36 (1)

Form: Safety Call

Generated On: 11 Aug 2021 21:58:56

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:03:50
User entered empty.	(b) (4) (b) (4), (b) (6)	13 Apr 2021 16:52:23

US3142034

Folder: Safety Call OL-D36 (1)

Form: Continuing

Generated On: 11 Aug 2021 21:58:56

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:03:50
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	13 Apr 2021 16:53:17

US3142034

Folder: Safety Call OL-D36 (1)

Form: Continuing

Generated On: 11 Aug 2021 21:58:56

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered '1'	System	13 Apr 2021 16:53:17

US3142034

Folder: OL-D57 (1)

Form: Visit Date

Generated On: 11 Aug 2021 21:58:56

[Was this visit performed?](#)

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	03 May 2021 15:03:28
User entered 'Yes (Y)'	Jami Wagner (b) (4) (b) (4)	26 Apr 2021 17:39:36

US3142034

Folder: OL-D57 (1)

Form: Visit Date

Generated On: 11 Aug 2021 21:58:56

[Visit date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	03 May 2021 15:03:28
User entered '26 Apr 2021'	Jami Wagner (b) (4) (b) (4)	26 Apr 2021 17:39:36

US3142034

Folder: OL-D57 (1)

Form: Visit Date

Generated On: 11 Aug 2021 21:58:56

[Was visit performed at the participant's home or at the clinic?](#)

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	03 May 2021 15:03:28
User entered 'Clinic (Clinic)'	Jami Wagner (b) (4) (b) (4)	26 Apr 2021 17:39:36

US3142034

Folder: OL-D57 (1)

Form: Visit Date

Generated On: 11 Aug 2021 21:58:56

[Folder OID](#)

Audit	User	Time (GMT)
User entered 'OLD57'	System	26 Apr 2021 17:39:36

US3142034

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 21:58:56

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	03 May 2021 15:03:28
User entered 'Yes (Y)'	Jami Wagner (b) (4) (b) (4)	26 Apr 2021 17:40:41

US3142034

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 21:58:56

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	03 May 2021 15:03:28
User entered '26 Apr 2021'	Jami Wagner (b) (4) (b) (4)	26 Apr 2021 17:40:41

US3142034

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 21:58:56

Time of assessment (00:00-23:59)

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	03 May 2021 15:03:28
User entered '10:00'	Jami Wagner (b) (4) (b) (4)	26 Apr 2021 17:40:41

US3142034

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 21:58:56

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered '26 Apr 2021 10:00'	System	26 Apr 2021 17:40:41

US3142034

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 21:58:56

Temperature (xxx.x)

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	03 May 2021 15:03:28
User entered '98.0' F	Jami Wagner (b) (4) (b) (4)	26 Apr 2021 17:40:41

US3142034

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 21:58:56

[Route of measurement](#)

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	03 May 2021 15:03:28
User entered 'Other (Other)'	Jami Wagner (b) (4) (b) (4)	26 Apr 2021 17:40:41

US3142034

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 21:58:56

[If Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	03 May 2021 15:03:28
User entered 'temporal'	Jami Wagner (b) (4) (b) (4)	26 Apr 2021 17:40:41

US3142034

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 21:58:56

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	03 May 2021 15:03:28
User entered '80'	Jami Wagner (b) (4) (b) (4)	26 Apr 2021 17:40:41

US3142034

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 21:58:56

[Pulse units](#)

Audit	User	Time (GMT)
User entered 'bpm'	System	26 Apr 2021 17:40:41

US3142034

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 21:58:56

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	03 May 2021 15:03:28
User entered '14'	Jami Wagner (b) (4) (b) (4)	26 Apr 2021 17:40:41

US3142034

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 21:58:56

[Respiratory Rate units](#)

Audit	User	Time (GMT)
User entered 'breaths/min'	System	26 Apr 2021 17:40:41

US3142034

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 21:58:56

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	03 May 2021 15:03:28
User entered '115'	Jami Wagner (b) (4) (b) (4)	26 Apr 2021 17:40:41

US3142034

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 21:58:56

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	26 Apr 2021 17:40:41

US3142034

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 21:58:56

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	03 May 2021 15:03:28
User entered '76'	Jami Wagner (b) (4) (b) (4)	26 Apr 2021 17:40:41

US3142034

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 21:58:56

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	26 Apr 2021 17:40:41

US3142034

Folder: OL-D57 (1)

Form: Physical Examination

Generated On: 11 Aug 2021 21:58:56

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	03 May 2021 15:03:28
User entered 'No (N)'	Jami Wagner (b) (4) (b) (4)	26 Apr 2021 17:41:12

US3142034

Folder: OL-D57 (1)

Form: Physical Examination

Generated On: 11 Aug 2021 21:58:56

Date of examination (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	03 May 2021 15:03:28
User entered empty.	Jami Wagner (b) (4) (b) (4)	26 Apr 2021 17:41:12

US3142034

Folder: OL-D57 (1)

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 21:58:56

[Was the sample collected?](#)

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	03 May 2021 15:03:28
User entered 'Yes (Y)'	Jami Wagner (b) (4) (b) (4)	26 Apr 2021 17:41:29

US3142034

Folder: OL-D57 (1)

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 21:58:56

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	03 May 2021 15:03:28
User entered '26 Apr 2021'	Jami Wagner (b) (4) (b) (4)	26 Apr 2021 17:41:29

US3142034

Folder: OL-D57 (1)

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 21:58:56

Collection time (00:00-23:59)

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	03 May 2021 15:03:28
User entered '10:05'	Jami Wagner (b) (4) (b) (4)	26 Apr 2021 17:41:29

US3142034

Folder: OL-D57 (1)

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 21:58:56

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered '26 Apr 2021 10:05'	System	26 Apr 2021 17:41:29

US3142034

Folder: Adverse Events

Form: Adverse Events Summary

Generated On: 11 Aug 2021 21:58:56

[Did the participant experience any adverse events?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:39:22
DataPoint Verified.	(b) (4)	27 Apr 2021 18:30:56
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 19:03:31
User entered 'Yes (Y)' reason for change: Data Entry Error	Jill York (b) (4)	26 Mar 2021 02:10:53
User entered 'No (N)' reason for change: Data Entry Error	Shelby Pickle (b) (4) (b) (4)	18 Mar 2021 20:31:43
User entered 'Yes (Y)'	Meghan York (b) (4) (b) (4)	18 Dec 2020 18:07:41

US3142034

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 21:58:56

[AEID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	27 Apr 2021 18:31:06
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:03:31
User entered 'USA-US064-2021-mRNA-1273-P301000007'	(b) (4) System	26 Mar 2021 18:56:31
User entered 'New'	(b) (4), (b) (6)	26 Mar 2021 18:56:31

US3142034

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 21:58:56

[Adverse event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	27 Apr 2021 18:31:06
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:03:31
User coded data point as SOC: Infections and infestations, HLGT: Viral infectious disorders, HLT: Coronavirus infections, PT: COVID-19, LLT: COVID-19 - version MedDRA\\23.0.	Coder Import (b) (4)	29 Mar 2021 18:17:06
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4)	29 Mar 2021 18:17:06
Data point term sent to Coder	System	26 Mar 2021 02:17:47
User entered 'Positive COVID-19 diagnosis'	Jill York (b) (4)	26 Mar 2021 02:17:02

US3142034

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 21:58:56

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	27 Apr 2021 18:31:06
User closed query 'Per CDM, Per Sponsor review: Covid-19 AE present but Was this a medically-attended AE? Is marked NO. Please review and reconcile. Else clarify' (Site from DM). User signature succeeded.	(b) (4)	20 Apr 2021 10:40:59
Query 'Per CDM, Per Sponsor review: Covid-19 AE present but Was this a medically-attended AE? Is marked NO. Please review and reconcile. Else clarify' answered with 'Data has been corrected' (Site from DM).	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 19:03:31
User entered 'Yes (Y)' reason for change: Data Entry Error	Jami Wagner (b) (4) (b) (4)	09 Apr 2021 15:53:19
User opened query 'Per CDM, Per Sponsor review: Covid-19 AE present but Was this a medically-attended AE? Is marked NO. Please review and reconcile. Else clarify' (Site from DM).	(b) (4), (b) (6)	09 Apr 2021 08:58:13
User entered 'No (N)'	Jill York (b) (4)	26 Mar 2021 02:17:02

US3142034

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 21:58:56

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	27 Apr 2021 18:31:06
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:03:31
User entered 'No (N)'	Jill York (b) (4)	26 Mar 2021 02:17:02

US3142034

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 21:58:56

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	27 Apr 2021 18:31:06
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:03:31
User entered 'Yes (Y)'	Jill York (b) (4)	26 Mar 2021 02:17:02

US3142034

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 21:58:56

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	27 Apr 2021 18:31:06
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:03:31
User entered '14 Dec 2020'	Jill York (b) (4)	26 Mar 2021 02:17:02

US3142034

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 21:58:56

Start time (00:00-23:59)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	27 Apr 2021 18:31:06
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:03:31
User entered empty.	Jill York (b) (4)	26 Mar 2021 02:17:02

US3142034

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 21:58:56

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	26 Mar 2021 02:17:02

US3142034

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 21:58:56

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	27 Apr 2021 18:31:06
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:03:31
User entered 'No (N)'	Jill York (b) (4)	26 Mar 2021 02:17:02

US3142034

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 21:58:56

If not Ongoing, end date (*dd MMM yyyy*)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	27 Apr 2021 18:31:06
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:03:31
User entered '28 Dec 2020'	Jill York (b) (4)	26 Mar 2021 02:17:02

US3142034

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 21:58:56

End time (00:00-23:59)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	27 Apr 2021 18:31:06
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:03:31
User entered empty.	Jill York (b) (4)	26 Mar 2021 02:17:02

US3142034

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 21:58:56

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	26 Mar 2021 02:17:02

US3142034

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 21:58:56

[Severity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	27 Apr 2021 18:31:06
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 19:03:31
User entered 'Grade 2/Moderate (Grade 2/Moderate)'	Jill York (b) (4)	26 Mar 2021 02:17:02

US3142034

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 21:58:56

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	27 Apr 2021 18:31:06
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:03:31
User entered 'No (N)'	Jill York (b) (4)	26 Mar 2021 02:17:02

US3142034

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 21:58:56

Death

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	27 Apr 2021 18:31:06
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:03:31
User entered '0'	Jill York (b) (4)	26 Mar 2021 02:17:02

US3142034

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 21:58:56

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	27 Apr 2021 18:31:06
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:03:31
User entered '0'	Jill York (b) (4)	26 Mar 2021 02:17:02

US3142034

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 21:58:56

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	27 Apr 2021 18:31:06
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:03:31
User entered '0'	Jill York (b) (4)	26 Mar 2021 02:17:02

US3142034

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 21:58:56

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	27 Apr 2021 18:31:06
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:03:31
User entered empty.	Jill York (b) (4)	26 Mar 2021 02:17:02

US3142034

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 21:58:56

Hospital Discharge Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	27 Apr 2021 18:31:06
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:03:31
User entered empty.	Jill York (b) (4)	26 Mar 2021 02:17:02

US3142034

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 21:58:56

[Admitted to ICU?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	27 Apr 2021 18:31:06
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:03:31
User entered empty.	Jill York (b) (4)	26 Mar 2021 02:17:02

US3142034

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 21:58:56

[Number of Days in ICU](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	27 Apr 2021 18:31:06
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:03:31
User entered empty.	Jill York (b) (4)	26 Mar 2021 02:17:02

US3142034

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 21:58:56

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	27 Apr 2021 18:31:06
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:03:31
User entered '0'	Jill York (b) (4)	26 Mar 2021 02:17:02

US3142034

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 21:58:56

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	27 Apr 2021 18:31:06
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:03:31
User entered '0'	Jill York (b) (4)	26 Mar 2021 02:17:02

US3142034

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 21:58:56

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	27 Apr 2021 18:31:06
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:03:31
User entered '0'	Jill York (b) (4)	26 Mar 2021 02:17:02

US3142034

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 21:58:56

[Relationship to investigational product](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	27 Apr 2021 18:31:06
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:03:31
User entered 'Not Related (NOT RELATED)'	Jill York (b) (4)	26 Mar 2021 02:17:02

US3142034

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 21:58:56

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	27 Apr 2021 18:31:06
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:03:31
User entered 'Not Applicable (NOT APPLICABLE)'	Jill York (b) (4)	26 Mar 2021 02:17:02

US3142034

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 21:58:56

Action taken with investigational product

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	27 Apr 2021 18:31:06
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:03:31
User entered 'Not Applicable (NOT APPLICABLE)'	Jill York (b) (4)	26 Mar 2021 02:17:02

US3142034

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 21:58:56

[None](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	27 Apr 2021 18:31:06
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:03:31
User entered '1'	Jill York (b) (4)	26 Mar 2021 02:17:02

US3142034

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 21:58:56

[Concomitant Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	27 Apr 2021 18:31:06
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:03:31
User entered '0'	Jill York (b) (4)	26 Mar 2021 02:17:02

US3142034

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 21:58:56

[Concomitant Procedure](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	27 Apr 2021 18:31:06
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:03:31
User entered '0'	Jill York (b) (4)	26 Mar 2021 02:17:02

US3142034

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 21:58:56

[Outcome](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	27 Apr 2021 18:31:06
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 19:03:31
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)'	Jill York (b) (4)	26 Mar 2021 02:17:02

US3142034

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 21:58:56

If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	27 Apr 2021 18:31:06
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:03:31
User entered empty.	Jill York (b) (4)	26 Mar 2021 02:17:02

US3142034

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 21:58:56

[Narrative](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	27 Apr 2021 18:31:06
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:03:31
User entered empty.	Jill York (b) (4)	26 Mar 2021 02:17:02

US3142034

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 21:58:56

Serious Adverse Event Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
User entered '0'	System	26 Mar 2021 02:17:02

US3142034

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 21:58:56

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '1'	System	09 Apr 2021 15:52:28
User entered '0'	System	26 Mar 2021 02:17:02

US3142034

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Generated On: 11 Aug 2021 21:58:56

[Were any prior/concomitant medications and/or vaccinations taken?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:39:22
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:03:31
User closed query 'Per CDM: 'Were any prior/concomitant medications and/or vaccinations taken?' is recorded as "Yes" however, no medication has been found to be listed in the ConMed page. Please review and update the data as appropriate, else clarify. Thank you.' (Site from DM).	(b) (4) (b) (4), (b) (6)	05 Oct 2020 14:22:30
Query 'Per CDM: 'Were any prior/concomitant medications and/or vaccinations taken?' is recorded as "Yes" however, no medication has been found to be listed in the ConMed page. Please review and update the data as appropriate, else clarify. Thank you.' answered with 'con med page is now entered ' (Site from DM).	Meghan York (b) (4) (b) (4)	01 Oct 2020 15:15:05
User opened query 'Per CDM: 'Were any prior/concomitant medications and/or vaccinations taken?' is recorded as "Yes" however, no medication has been found to be listed in the ConMed page. Please review and update the data as appropriate, else clarify. Thank you.' (Site from DM).	(b) (4), (b) (6)	17 Sep 2020 03:39:48
User entered 'Yes (Y)'	Shelby Pickle (b) (4) (b) (4)	10 Aug 2020 19:30:05

US3142034

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 21:58:56

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:03:31
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: AGENTS ACTING ON THE RENIN-ANGIOTENSIN SYSTEM, ATC: ACE INHIBITORS, PLAIN, ATC: ACE INHIBITORS, PLAIN, PRODUCT: LISINOPRIL - version WHODrug-Global-B3\202003.	(b) (4) Coder Import (b) (4) (b) (4)	01 Oct 2020 15:16:48
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	01 Oct 2020 15:16:48
Data point term sent to Coder	System	01 Oct 2020 15:15:54
User entered 'lisinopril'	Meghan York (b) (4) (b) (4)	01 Oct 2020 15:15:43

US3142034

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 21:58:56

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 19:03:31
User entered 'No (N)'	Meghan York (b) (4) (b) (4)	01 Oct 2020 15:15:43

US3142034

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 21:58:56

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 19:03:31
User entered 'hypertension'	Meghan York (b) (4) (b) (4)	01 Oct 2020 15:15:43

US3142034

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 21:58:56

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 19:03:31
User entered '40'	Meghan York (b) (4) (b) (4)	01 Oct 2020 15:15:43

US3142034

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 21:58:56

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 19:03:31
User entered 'mg (mg)'	Meghan York (b) (4) (b) (4)	01 Oct 2020 15:15:43

US3142034

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 21:58:56

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 19:03:31
User entered empty.	Meghan York (b) (4) (b) (4)	01 Oct 2020 15:15:43

US3142034

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 21:58:56

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 19:03:31
User entered 'once daily (QD)'	Meghan York (b) (4) (b) (4)	01 Oct 2020 15:15:43

US3142034

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 21:58:56

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 19:03:31
User entered empty.	Meghan York (b) (4) (b) (4)	01 Oct 2020 15:15:43

US3142034

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 21:58:56

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 19:03:31
User entered 'Oral (ORAL)'	Meghan York (b) (4) (b) (4)	01 Oct 2020 15:15:43

US3142034

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 21:58:56

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 19:03:31
User entered empty.	Meghan York (b) (4) (b) (4)	01 Oct 2020 15:15:43

US3142034

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 21:58:56

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 19:03:31
User entered 'un UNK 2000'	Meghan York (b) (4) (b) (4)	01 Oct 2020 15:15:43

US3142034

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 21:58:56

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 19:03:31
User entered '0'	Meghan York (b) (4) (b) (4)	01 Oct 2020 15:15:43

US3142034

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 21:58:56

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 19:03:31
User entered 'Yes (Y)'	Meghan York (b) (4) (b) (4)	01 Oct 2020 15:15:43

US3142034

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 21:58:56

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 19:03:31
User entered empty.	Meghan York (b) (4) (b) (4)	01 Oct 2020 15:15:43

US3142034

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 21:58:56

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 19:03:31
User entered 'No (N)'	Meghan York (b) (4) (b) (4)	01 Oct 2020 15:15:43

US3142034

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 21:58:56

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	01 Oct 2020 15:15:43

US3142034

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 21:58:56

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	01 Oct 2020 15:15:43

US3142034

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 21:58:56

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	01 Oct 2020 15:15:43

US3142034

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 21:58:56

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:03:31
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: CALCIUM CHANNEL BLOCKERS, ATC: SELECTIVE CALCIUM CHANNEL BLOCKERS WITH DIRECT CARDIAC EFFECTS, ATC: BENZOTHIAZEPINE DERIVATIVES, PRODUCT: DILTIAZEM - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4) (b) (4)	01 Oct 2020 15:17:49
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	01 Oct 2020 15:17:49
Data point term sent to Coder	System	01 Oct 2020 15:16:58
User entered 'diltiazem'	Meghan York (b) (4) (b) (4)	01 Oct 2020 15:16:28

US3142034

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 21:58:56

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 19:03:31
User entered 'No (N)'	Meghan York (b) (4) (b) (4)	01 Oct 2020 15:16:28

US3142034

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 21:58:56

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 19:03:31
User entered 'hypertension'	Meghan York (b) (4) (b) (4)	01 Oct 2020 15:16:28

US3142034

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 21:58:56

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 19:03:31
User entered '240'	Meghan York (b) (4) (b) (4)	01 Oct 2020 15:16:28

US3142034

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 21:58:56

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 19:03:31
User entered 'mg (mg)'	Meghan York (b) (4) (b) (4)	01 Oct 2020 15:16:28

US3142034

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 21:58:56

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 19:03:31
User entered empty.	Meghan York (b) (4) (b) (4)	01 Oct 2020 15:16:28

US3142034

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 21:58:56

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 19:03:31
User entered 'once daily (QD)'	Meghan York (b) (4) (b) (4)	01 Oct 2020 15:16:28

US3142034

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 21:58:56

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 19:03:31
User entered empty.	Meghan York (b) (4) (b) (4)	01 Oct 2020 15:16:28

US3142034

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 21:58:56

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 19:03:31
User entered 'Oral (ORAL)'	Meghan York (b) (4) (b) (4)	01 Oct 2020 15:16:28

US3142034

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 21:58:56

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 19:03:31
User entered empty.	Meghan York (b) (4) (b) (4)	01 Oct 2020 15:16:28

US3142034

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 21:58:56

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 19:03:31
User entered 'un UNK 2000'	Meghan York (b) (4) (b) (4)	01 Oct 2020 15:16:28

US3142034

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 21:58:56

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 19:03:31
User entered '0'	Meghan York (b) (4) (b) (4)	01 Oct 2020 15:16:28

US3142034

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 21:58:56

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 19:03:31
User entered 'Yes (Y)'	Meghan York (b) (4) (b) (4)	01 Oct 2020 15:16:28

US3142034

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 21:58:56

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 19:03:31
User entered empty.	Meghan York (b) (4) (b) (4)	01 Oct 2020 15:16:28

US3142034

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 21:58:56

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 19:03:31
User entered 'No (N)'	Meghan York (b) (4) (b) (4)	01 Oct 2020 15:16:28

US3142034

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 21:58:56

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	01 Oct 2020 15:16:28

US3142034

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 21:58:56

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	01 Oct 2020 15:16:28

US3142034

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 21:58:56

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	01 Oct 2020 15:16:28

US3142034

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 11 Aug 2021 21:58:56

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:03:31
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: LIPID MODIFYING AGENTS, ATC: LIPID MODIFYING AGENTS, PLAIN, ATC: HMG COA REDUCTASE INHIBITORS, PRODUCT: SIMVASTATIN - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4) (b) (4)	01 Oct 2020 15:18:54
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	01 Oct 2020 15:18:54
Data point term sent to Coder	System	01 Oct 2020 15:17:59
User entered 'simvastatin'	Meghan York (b) (4) (b) (4)	01 Oct 2020 15:17:08

US3142034

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 11 Aug 2021 21:58:56

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 19:03:31
User entered 'No (N)'	Meghan York (b) (4) (b) (4)	01 Oct 2020 15:17:08

US3142034

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 11 Aug 2021 21:58:56

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 19:03:31
User entered 'hypercholesterolemia'	Meghan York (b) (4) (b) (4)	01 Oct 2020 15:17:08

US3142034

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 11 Aug 2021 21:58:56

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 19:03:31
User entered '40'	Meghan York (b) (4) (b) (4)	01 Oct 2020 15:17:08

US3142034

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 11 Aug 2021 21:58:56

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 19:03:31
User entered 'mg (mg)'	Meghan York (b) (4) (b) (4)	01 Oct 2020 15:17:08

US3142034

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 11 Aug 2021 21:58:56

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 19:03:31
User entered empty.	Meghan York (b) (4) (b) (4)	01 Oct 2020 15:17:08

US3142034

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 11 Aug 2021 21:58:56

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 19:03:31
User entered 'once daily (QD)'	Meghan York (b) (4) (b) (4)	01 Oct 2020 15:17:08

US3142034

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 11 Aug 2021 21:58:56

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 19:03:31
User entered empty.	Meghan York (b) (4) (b) (4)	01 Oct 2020 15:17:08

US3142034

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 11 Aug 2021 21:58:56

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 19:03:31
User entered 'Oral (ORAL)'	Meghan York (b) (4) (b) (4)	01 Oct 2020 15:17:08

US3142034

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 11 Aug 2021 21:58:56

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 19:03:31
User entered empty.	Meghan York (b) (4) (b) (4)	01 Oct 2020 15:17:08

US3142034

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 11 Aug 2021 21:58:56

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 19:03:31
User entered 'un UNK 2000'	Meghan York (b) (4) (b) (4)	01 Oct 2020 15:17:08

US3142034

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 11 Aug 2021 21:58:56

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 19:03:31
User entered '0'	Meghan York (b) (4) (b) (4)	01 Oct 2020 15:17:08

US3142034

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 11 Aug 2021 21:58:56

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 19:03:31
User entered 'Yes (Y)'	Meghan York (b) (4) (b) (4)	01 Oct 2020 15:17:08

US3142034

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 11 Aug 2021 21:58:56

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 19:03:31
User entered empty.	Meghan York (b) (4) (b) (4)	01 Oct 2020 15:17:08

US3142034

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 11 Aug 2021 21:58:56

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 19:03:31
User entered 'No (N)'	Meghan York (b) (4) (b) (4)	01 Oct 2020 15:17:08

US3142034

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 11 Aug 2021 21:58:56

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	01 Oct 2020 15:17:08

US3142034

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 11 Aug 2021 21:58:56

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	01 Oct 2020 15:17:08

US3142034

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 11 Aug 2021 21:58:56

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	01 Oct 2020 15:17:08

US3142034

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 11 Aug 2021 21:58:56

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:03:31
User coded data point as ATC: GENITO URINARY SYSTEM AND SEX HORMONES, ATC: SEX HORMONES AND MODULATORS OF THE GENITAL SYSTEM, ATC: ESTROGENS, ATC: NATURAL AND SEMISYNTHETIC ESTROGENS, PLAIN, PRODUCT: ESTRADIOL, PRODUCTSYNONYM: VIVELLE DOT - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	01 Oct 2020 15:19:46
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	01 Oct 2020 15:19:46
Data point term sent to Coder	System	01 Oct 2020 15:19:04
User entered 'vivelle dot'	Meghan York (b) (4)	01 Oct 2020 15:18:25

US3142034

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 11 Aug 2021 21:58:56

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 19:03:31
User entered 'No (N)'	Meghan York (b) (4) (b) (4)	01 Oct 2020 15:18:25

US3142034

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 11 Aug 2021 21:58:56

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 19:03:31
User entered 'menopause'	Meghan York (b) (4) (b) (4)	01 Oct 2020 15:18:25

US3142034

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 11 Aug 2021 21:58:56

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 19:03:31
User entered '0.025'	Meghan York (b) (4) (b) (4)	01 Oct 2020 15:18:25

US3142034

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 11 Aug 2021 21:58:56

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 19:03:31
User entered 'mg (mg)'	Meghan York (b) (4) (b) (4)	01 Oct 2020 15:18:25

US3142034

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 11 Aug 2021 21:58:56

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 19:03:31
User entered empty.	Meghan York (b) (4) (b) (4)	01 Oct 2020 15:18:25

US3142034

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 11 Aug 2021 21:58:56

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 19:03:31
User entered 'other (OTHER)'	Meghan York (b) (4) (b) (4)	01 Oct 2020 15:18:25

US3142034

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 11 Aug 2021 21:58:56

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 19:03:31
User entered 'twice a week'	Meghan York (b) (4) (b) (4)	01 Oct 2020 15:18:25

US3142034

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 11 Aug 2021 21:58:56

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 19:03:31
User entered 'Oral (ORAL)'	Meghan York (b) (4) (b) (4)	01 Oct 2020 15:18:25

US3142034

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 11 Aug 2021 21:58:56

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 19:03:31
User entered empty.	Meghan York (b) (4) (b) (4)	01 Oct 2020 15:18:25

US3142034

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 11 Aug 2021 21:58:56

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 19:03:31
User entered 'un UNK 2000'	Meghan York (b) (4) (b) (4)	01 Oct 2020 15:18:25

US3142034

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 11 Aug 2021 21:58:56

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 19:03:31
User entered '0'	Meghan York (b) (4) (b) (4)	01 Oct 2020 15:18:25

US3142034

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 11 Aug 2021 21:58:56

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 19:03:31
User entered 'Yes (Y)'	Meghan York (b) (4) (b) (4)	01 Oct 2020 15:18:25

US3142034

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 11 Aug 2021 21:58:56

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 19:03:31
User entered empty.	Meghan York (b) (4) (b) (4)	01 Oct 2020 15:18:25

US3142034

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 11 Aug 2021 21:58:56

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 19:03:31
User entered 'No (N)'	Meghan York (b) (4) (b) (4)	01 Oct 2020 15:18:25

US3142034

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 11 Aug 2021 21:58:56

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	01 Oct 2020 15:18:25

US3142034

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 11 Aug 2021 21:58:56

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	01 Oct 2020 15:18:25

US3142034

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 11 Aug 2021 21:58:56

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	01 Oct 2020 15:18:25

US3142034

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 11 Aug 2021 21:58:56

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:03:31
User coded data point as ATC: GENITO URINARY SYSTEM AND SEX HORMONES, ATC: SEX HORMONES AND MODULATORS OF THE GENITAL SYSTEM, ATC: HORMONAL CONTRACEPTIVES FOR SYSTEMIC USE, ATC: PROGESTOGENS, PRODUCT: MEDROXYPROGESTERONE ACETATE, PRODUCTSYNONYM: MEDROXY - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	01 Oct 2020 15:20:50
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	01 Oct 2020 15:20:50
Data point term sent to Coder	System	01 Oct 2020 15:20:06
User entered 'medroxy progesterone'	Meghan York (b) (4)	01 Oct 2020 15:19:47

US3142034

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 11 Aug 2021 21:58:56

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 19:03:31
User entered 'No (N)'	Meghan York (b) (4) (b) (4)	01 Oct 2020 15:19:47

US3142034

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 11 Aug 2021 21:58:56

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 19:03:31
User entered 'menopause'	Meghan York (b) (4) (b) (4)	01 Oct 2020 15:19:47

US3142034

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 11 Aug 2021 21:58:56

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 19:03:31
User entered '10'	Meghan York (b) (4) (b) (4)	01 Oct 2020 15:19:47

US3142034

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 11 Aug 2021 21:58:56

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 19:03:31
User entered 'mg (mg)'	Meghan York (b) (4) (b) (4)	01 Oct 2020 15:19:47

US3142034

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 11 Aug 2021 21:58:56

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 19:03:31
User entered empty.	Meghan York (b) (4) (b) (4)	01 Oct 2020 15:19:47

US3142034

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 11 Aug 2021 21:58:56

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 19:03:31
User entered 'other (OTHER)'	Meghan York (b) (4) (b) (4)	01 Oct 2020 15:19:47

US3142034

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 11 Aug 2021 21:58:56

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 19:03:31
User entered 'every 3 months'	Meghan York (b) (4) (b) (4)	01 Oct 2020 15:19:47

US3142034

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 11 Aug 2021 21:58:56

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 19:03:31
User entered 'Oral (ORAL)'	Meghan York (b) (4) (b) (4)	01 Oct 2020 15:19:47

US3142034

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 11 Aug 2021 21:58:56

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 19:03:31
User entered empty.	Meghan York (b) (4) (b) (4)	01 Oct 2020 15:19:47

US3142034

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 11 Aug 2021 21:58:56

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 19:03:31
User entered 'un UNK 2000'	Meghan York (b) (4) (b) (4)	01 Oct 2020 15:19:47

US3142034

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 11 Aug 2021 21:58:56

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 19:03:31
User entered '0'	Meghan York (b) (4) (b) (4)	01 Oct 2020 15:19:47

US3142034

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 11 Aug 2021 21:58:56

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 19:03:31
User entered 'Yes (Y)'	Meghan York (b) (4) (b) (4)	01 Oct 2020 15:19:47

US3142034

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 11 Aug 2021 21:58:56

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 19:03:31
User entered empty.	Meghan York (b) (4) (b) (4)	01 Oct 2020 15:19:47

US3142034

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 11 Aug 2021 21:58:56

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 19:03:31
User entered 'No (N)'	Meghan York (b) (4) (b) (4)	01 Oct 2020 15:19:47

US3142034

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 11 Aug 2021 21:58:56

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	01 Oct 2020 15:19:47

US3142034

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 11 Aug 2021 21:58:56

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	01 Oct 2020 15:19:47

US3142034

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 11 Aug 2021 21:58:56

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	01 Oct 2020 15:19:47

US3142034

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 11 Aug 2021 21:58:56

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:03:31
User coded data point as ATC: MUSCULO-SKELETAL SYSTEM, ATC: DRUGS FOR TREATMENT OF BONE DISEASES, ATC: DRUGS AFFECTING BONE STRUCTURE AND MINERALIZATION, ATC: BISPHOSPHONATES, PRODUCT: ALENDRONATE SODIUM, PRODUCTSYNONYM: FOSAMAX - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4)	01 Oct 2020 15:21:45
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	01 Oct 2020 15:21:45
Data point term sent to Coder	System	01 Oct 2020 15:21:07
User entered 'Fosamax'	Meghan York (b) (4) (b) (4)	01 Oct 2020 15:21:00

US3142034

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 11 Aug 2021 21:58:56

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 19:03:31
User entered 'No (N)'	Meghan York (b) (4) (b) (4)	01 Oct 2020 15:21:00

US3142034

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 11 Aug 2021 21:58:56

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 19:03:31
User entered 'osteoporosis'	Meghan York (b) (4) (b) (4)	01 Oct 2020 15:21:00

US3142034

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 11 Aug 2021 21:58:56

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 19:03:31
User entered '70'	Meghan York (b) (4) (b) (4)	01 Oct 2020 15:21:00

US3142034

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 11 Aug 2021 21:58:56

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 19:03:31
User entered 'mg (mg)'	Meghan York (b) (4) (b) (4)	01 Oct 2020 15:21:00

US3142034

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 11 Aug 2021 21:58:56

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 19:03:31
User entered empty.	Meghan York (b) (4) (b) (4)	01 Oct 2020 15:21:00

US3142034

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 11 Aug 2021 21:58:56

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 19:03:31
User entered 'every week (QS)'	Meghan York (b) (4) (b) (4)	01 Oct 2020 15:21:00

US3142034

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 11 Aug 2021 21:58:56

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 19:03:31
User entered empty.	Meghan York (b) (4) (b) (4)	01 Oct 2020 15:21:00

US3142034

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 11 Aug 2021 21:58:56

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 19:03:31
User entered 'Oral (ORAL)'	Meghan York (b) (4) (b) (4)	01 Oct 2020 15:21:00

US3142034

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 11 Aug 2021 21:58:56

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 19:03:31
User entered empty.	Meghan York (b) (4) (b) (4)	01 Oct 2020 15:21:00

US3142034

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 11 Aug 2021 21:58:56

Start date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 19:03:31
User entered 'un UNK 2016'	Meghan York (b) (4) (b) (4)	01 Oct 2020 15:21:00

US3142034

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 11 Aug 2021 21:58:56

Start date completely unknown

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 19:03:31
User entered '0'	Meghan York (b) (4) (b) (4)	01 Oct 2020 15:21:00

US3142034

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 11 Aug 2021 21:58:56

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 19:03:31
User entered 'Yes (Y)'	Meghan York (b) (4) (b) (4)	01 Oct 2020 15:21:00

US3142034

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 11 Aug 2021 21:58:56

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 19:03:31
User entered empty.	Meghan York (b) (4) (b) (4)	01 Oct 2020 15:21:00

US3142034

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 11 Aug 2021 21:58:56

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 19:03:31
User entered 'No (N)'	Meghan York (b) (4) (b) (4)	01 Oct 2020 15:21:00

US3142034

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 11 Aug 2021 21:58:56

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	01 Oct 2020 15:21:00

US3142034

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 11 Aug 2021 21:58:56

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	01 Oct 2020 15:21:00

US3142034

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 11 Aug 2021 21:58:56

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '803 (803)'	System	01 Oct 2020 15:21:00

US3142034

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 11 Aug 2021 21:58:56

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:03:31
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: VITAMINS, ATC: VITAMIN A AND D, INCL. COMBINATIONS OF THE TWO, ATC: VITAMIN D AND ANALOGUES, PRODUCT: COLECALCIFEROL, PRODUCTSYNONYM: VITAMIN D3 - version WHODrug-Global-B3\202003.	(b) (4) Coder Import (b) (4)	01 Oct 2020 15:22:53
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	01 Oct 2020 15:22:53
Data point term sent to Coder	System	01 Oct 2020 15:22:08
User entered 'vitamin d3'	Meghan York (b) (4) (b) (4)	01 Oct 2020 15:21:40

US3142034

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 11 Aug 2021 21:58:56

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:03:31
User closed query 'Per DM CLR: Please review the response as this medication appears to be given as prophylaxis. Note that supplements, vitamins, contraceptives/birth control, prophylactically indicated drugs, & heart health medications are examples of it. Update response as appropriate. Otherwise, clarify. '(Site from DM).	(b) (4) (b) (4), (b) (6)	11 Nov 2020 16:44:29
Query 'Per DM CLR: Please review the response as this medication appears to be given as prophylaxis. Note that supplements, vitamins, contraceptives/birth control, prophylactically indicated drugs, & heart health medications are examples of it. Update response as appropriate. Otherwise, clarify. ' answered with 'now corrected ' (Site from DM).	Meghan York (b) (4) (b) (4)	05 Nov 2020 21:43:13
User entered 'Yes (Y)' reason for change: Data Entry Error	Meghan York (b) (4) (b) (4)	05 Nov 2020 21:43:01
User opened query 'Per DM CLR: Please review the response as this medication appears to be given as prophylaxis. Note that supplements, vitamins, contraceptives/birth control, prophylactically indicated drugs, & heart health medications are examples of it. Update response as appropriate. Otherwise, clarify. '(Site from DM).	(b) (4), (b) (6)	05 Nov 2020 18:46:30
User entered 'No (N)'	Meghan York (b) (4) (b) (4)	01 Oct 2020 15:21:40

US3142034

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 11 Aug 2021 21:58:56

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 19:03:31
User entered 'general health'	Meghan York (b) (4) (b) (4)	01 Oct 2020 15:21:40

US3142034

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 11 Aug 2021 21:58:56

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 19:03:31
User entered '1000'	Meghan York (b) (4) (b) (4)	01 Oct 2020 15:21:40

US3142034

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 11 Aug 2021 21:58:56

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 19:03:31
User entered 'IU (IU)'	Meghan York (b) (4) (b) (4)	01 Oct 2020 15:21:40

US3142034

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 11 Aug 2021 21:58:56

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 19:03:31
User entered empty.	Meghan York (b) (4) (b) (4)	01 Oct 2020 15:21:40

US3142034

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 11 Aug 2021 21:58:56

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 19:03:31
User entered 'once daily (QD)'	Meghan York (b) (4) (b) (4)	01 Oct 2020 15:21:40

US3142034

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 11 Aug 2021 21:58:56

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 19:03:31
User entered empty.	Meghan York (b) (4) (b) (4)	01 Oct 2020 15:21:40

US3142034

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 11 Aug 2021 21:58:56

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 19:03:31
User entered 'Oral (ORAL)'	Meghan York (b) (4) (b) (4)	01 Oct 2020 15:21:40

US3142034

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 11 Aug 2021 21:58:56

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 19:03:31
User entered empty.	Meghan York (b) (4) (b) (4)	01 Oct 2020 15:21:40

US3142034

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 11 Aug 2021 21:58:56

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 19:03:31
User entered 'un UNK 2000'	Meghan York (b) (4) (b) (4)	01 Oct 2020 15:21:40

US3142034

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 11 Aug 2021 21:58:56

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 19:03:31
User entered '0'	Meghan York (b) (4) (b) (4)	01 Oct 2020 15:21:40

US3142034

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 11 Aug 2021 21:58:56

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 19:03:31
User entered 'Yes (Y)'	Meghan York (b) (4) (b) (4)	01 Oct 2020 15:21:40

US3142034

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 11 Aug 2021 21:58:56

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 19:03:31
User entered empty.	Meghan York (b) (4) (b) (4)	01 Oct 2020 15:21:40

US3142034

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 11 Aug 2021 21:58:56

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 19:03:31
User entered 'No (N)'	Meghan York (b) (4) (b) (4)	01 Oct 2020 15:21:40

US3142034

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 11 Aug 2021 21:58:56

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	01 Oct 2020 15:21:40

US3142034

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 11 Aug 2021 21:58:56

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	01 Oct 2020 15:21:40

US3142034

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 11 Aug 2021 21:58:56

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	01 Oct 2020 15:21:40

US3142034

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 11 Aug 2021 21:58:56

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:03:31
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: MINERAL SUPPLEMENTS, ATC: CALCIUM, ATC: CALCIUM, PRODUCT: CALCIUM CITRATE, PRODUCTSYNONYM: CITRACAL [CALCIUM CITRATE] - version WHODrug-Global-B3\202003.	(b) (4) Coder Import (b) (4)	01 Oct 2020 20:24:48
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	01 Oct 2020 20:24:48
Data point term sent to Coder	System	01 Oct 2020 15:23:11
User entered 'citracal'	Meghan York (b) (4) (b) (4)	01 Oct 2020 15:22:27

US3142034

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 11 Aug 2021 21:58:56

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:03:31
User closed query 'Per DM CLR: Please review the response as this medication appears to be given as prophylaxis. Note that supplements, vitamins, contraceptives/birth control, prophylactically indicated drugs, & heart health medications are examples of it. Update response as appropriate. Otherwise, clarify. '(Site from DM).	(b) (4) (b) (4), (b) (6)	11 Nov 2020 16:45:50
Query 'Per DM CLR: Please review the response as this medication appears to be given as prophylaxis. Note that supplements, vitamins, contraceptives/birth control, prophylactically indicated drugs, & heart health medications are examples of it. Update response as appropriate. Otherwise, clarify. ' answered with 'now corrected ' (Site from DM).	Meghan York (b) (4) (b) (4)	05 Nov 2020 21:52:37
User entered 'Yes (Y)' reason for change: Data Entry Error	Meghan York (b) (4) (b) (4)	05 Nov 2020 21:43:23
User opened query 'Per DM CLR: Please review the response as this medication appears to be given as prophylaxis. Note that supplements, vitamins, contraceptives/birth control, prophylactically indicated drugs, & heart health medications are examples of it. Update response as appropriate. Otherwise, clarify. '(Site from DM).	(b) (4), (b) (6)	05 Nov 2020 18:48:44
User entered 'No (N)'	Meghan York (b) (4) (b) (4)	01 Oct 2020 15:22:27

US3142034

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 11 Aug 2021 21:58:56

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 19:03:31
User entered 'general health'	Meghan York (b) (4) (b) (4)	01 Oct 2020 15:22:27

US3142034

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 11 Aug 2021 21:58:56

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 19:03:31
User entered '400'	Meghan York (b) (4) (b) (4)	01 Oct 2020 15:22:27

US3142034

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 11 Aug 2021 21:58:56

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 19:03:31
User entered 'mg (mg)'	Meghan York (b) (4) (b) (4)	01 Oct 2020 15:22:27

US3142034

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 11 Aug 2021 21:58:56

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 19:03:31
User entered empty.	Meghan York (b) (4) (b) (4)	01 Oct 2020 15:22:27

US3142034

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 11 Aug 2021 21:58:56

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 19:03:31
User entered 'once daily (QD)'	Meghan York (b) (4) (b) (4)	01 Oct 2020 15:22:27

US3142034

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 11 Aug 2021 21:58:56

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 19:03:31
User entered empty.	Meghan York (b) (4) (b) (4)	01 Oct 2020 15:22:27

US3142034

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 11 Aug 2021 21:58:56

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 19:03:31
User entered 'Oral (ORAL)'	Meghan York (b) (4) (b) (4)	01 Oct 2020 15:22:27

US3142034

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 11 Aug 2021 21:58:56

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 19:03:31
User entered empty.	Meghan York (b) (4) (b) (4)	01 Oct 2020 15:22:27

US3142034

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 11 Aug 2021 21:58:56

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 19:03:31
User entered 'un UNK 2015'	Meghan York (b) (4) (b) (4)	01 Oct 2020 15:22:27

US3142034

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 11 Aug 2021 21:58:56

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 19:03:31
User entered '0'	Meghan York (b) (4) (b) (4)	01 Oct 2020 15:22:27

US3142034

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 11 Aug 2021 21:58:56

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 19:03:31
User entered 'Yes (Y)'	Meghan York (b) (4) (b) (4)	01 Oct 2020 15:22:27

US3142034

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 11 Aug 2021 21:58:56

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 19:03:31
User entered empty.	Meghan York (b) (4) (b) (4)	01 Oct 2020 15:22:27

US3142034

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 11 Aug 2021 21:58:56

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 19:03:31
User entered 'No (N)'	Meghan York (b) (4) (b) (4)	01 Oct 2020 15:22:27

US3142034

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 11 Aug 2021 21:58:56

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	01 Oct 2020 15:22:27

US3142034

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 11 Aug 2021 21:58:56

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	01 Oct 2020 15:22:27

US3142034

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 11 Aug 2021 21:58:56

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	01 Oct 2020 15:22:27

US3142034

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 11 Aug 2021 21:58:56

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:03:31
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: MINERAL SUPPLEMENTS, ATC: CALCIUM, ATC: CALCIUM, PRODUCT: CALCIUM - version WHODrug-Global-B3\202003.	(b) (4) Coder Import (b) (4)	01 Oct 2020 15:25:51
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	01 Oct 2020 15:25:51
Data point term sent to Coder	System	01 Oct 2020 15:24:12
User entered 'calcium'	Meghan York (b) (4) (b) (4)	01 Oct 2020 15:23:15

US3142034

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 11 Aug 2021 21:58:56

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:03:31
User closed query 'Per CDM: Thanks for your response, however, "Prophylaxis = No". Please Update the response appropriately.' (Site from DM).	(b) (4)	17 Nov 2020 04:56:51
Query 'Per CDM: Thanks for your response, however, "Prophylaxis = No". Please Update the response appropriately.' answered with 'now corrected ' (Site from DM).	Meghan York (b) (4)	12 Nov 2020 19:25:43
User entered 'Yes (Y)' reason for change: Data Entry Error	Meghan York (b) (4)	12 Nov 2020 19:25:30
User opened query 'Per CDM: Thanks for your response, however, "Prophylaxis = No". Please Update the response appropriately.' (Site from DM).	(b) (4), (b) (6)	11 Nov 2020 16:48:02
User closed query 'Per DM CLR: Please review the response as this medication appears to be given as prophylaxis. Note that supplements, vitamins, contraceptives/birth control, prophylactically indicated drugs, & heart health medications are examples of it. Update response as appropriate. Otherwise, clarify. ' (Site from DM).	(b) (4), (b) (6)	11 Nov 2020 16:48:02
Query 'Per DM CLR: Please review the response as this medication appears to be given as prophylaxis. Note that supplements, vitamins, contraceptives/birth control, prophylactically indicated drugs, & heart health medications are examples of it. Update response as appropriate. Otherwise, clarify. ' answered with 'now corrected ' (Site from DM).	Meghan York (b) (4)	05 Nov 2020 21:43:34
User opened query 'Per DM CLR: Please review the response as this medication appears to be given as prophylaxis. Note that supplements, vitamins, contraceptives/birth control, prophylactically indicated drugs, & heart health medications are examples of it. Update response as appropriate. Otherwise, clarify. ' (Site from DM).	(b) (4), (b) (6)	05 Nov 2020 18:54:16
User entered 'No (N)'	Meghan York (b) (4)	01 Oct 2020 15:23:15

US3142034

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 11 Aug 2021 21:58:56

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 19:03:31
User entered 'general health'	Meghan York (b) (4) (b) (4)	01 Oct 2020 15:23:15

US3142034

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 11 Aug 2021 21:58:56

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 19:03:31
User entered '200'	Meghan York (b) (4) (b) (4)	01 Oct 2020 15:23:15

US3142034

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 11 Aug 2021 21:58:56

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 19:03:31
User entered 'mg (mg)'	Meghan York (b) (4) (b) (4)	01 Oct 2020 15:23:15

US3142034

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 11 Aug 2021 21:58:56

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 19:03:31
User entered empty.	Meghan York (b) (4) (b) (4)	01 Oct 2020 15:23:15

US3142034

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 11 Aug 2021 21:58:56

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 19:03:31
User entered 'once daily (QD)'	Meghan York (b) (4) (b) (4)	01 Oct 2020 15:23:15

US3142034

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 11 Aug 2021 21:58:56

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 19:03:31
User entered empty.	Meghan York (b) (4) (b) (4)	01 Oct 2020 15:23:15

US3142034

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 11 Aug 2021 21:58:56

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 19:03:31
User entered 'Oral (ORAL)'	Meghan York (b) (4) (b) (4)	01 Oct 2020 15:23:15

US3142034

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 11 Aug 2021 21:58:56

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 19:03:31
User entered empty.	Meghan York (b) (4) (b) (4)	01 Oct 2020 15:23:15

US3142034

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 11 Aug 2021 21:58:56

Start date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 19:03:31
User entered 'un UNK 2010'	Meghan York (b) (4) (b) (4)	01 Oct 2020 15:23:15

US3142034

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 11 Aug 2021 21:58:56

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 19:03:31
User entered '0'	Meghan York (b) (4) (b) (4)	01 Oct 2020 15:23:15

US3142034

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 11 Aug 2021 21:58:56

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 19:03:31
User entered 'Yes (Y)'	Meghan York (b) (4) (b) (4)	01 Oct 2020 15:23:15

US3142034

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 11 Aug 2021 21:58:56

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 19:03:31
User entered empty.	Meghan York (b) (4) (b) (4)	01 Oct 2020 15:23:15

US3142034

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 11 Aug 2021 21:58:56

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 19:03:31
User entered 'No (N)'	Meghan York (b) (4) (b) (4)	01 Oct 2020 15:23:15

US3142034

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 11 Aug 2021 21:58:56

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	01 Oct 2020 15:23:15

US3142034

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 11 Aug 2021 21:58:56

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	01 Oct 2020 15:23:15

US3142034

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 11 Aug 2021 21:58:56

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	01 Oct 2020 15:23:15

US3142034

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 11 Aug 2021 21:58:56

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:03:31
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: MINERAL SUPPLEMENTS, ATC: OTHER MINERAL SUPPLEMENTS, ATC: MAGNESIUM, PRODUCT: MAGNESIUM - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4)	01 Oct 2020 15:25:51
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	01 Oct 2020 15:25:51
Data point term sent to Coder	System	01 Oct 2020 15:24:13
User entered 'magnesium'	Meghan York (b) (4) (b) (4)	01 Oct 2020 15:23:52

US3142034

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 11 Aug 2021 21:58:56

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:03:31
User closed query 'Per DM CLR: Please review the response as this medication appears to be given as prophylaxis. Note that supplements, vitamins, contraceptives/birth control, prophylactically indicated drugs, & heart health medications are examples of it. Update response as appropriate. Otherwise, clarify. '(Site from DM).	(b) (4) (b) (4), (b) (6)	11 Nov 2020 16:48:32
Query 'Per DM CLR: Please review the response as this medication appears to be given as prophylaxis. Note that supplements, vitamins, contraceptives/birth control, prophylactically indicated drugs, & heart health medications are examples of it. Update response as appropriate. Otherwise, clarify. ' answered with 'now corrected ' (Site from DM).	Meghan York (b) (4) (b) (4)	05 Nov 2020 21:43:53
User entered 'Yes (Y)' reason for change: Data Entry Error	Meghan York (b) (4) (b) (4)	05 Nov 2020 21:43:42
User opened query 'Per DM CLR: Please review the response as this medication appears to be given as prophylaxis. Note that supplements, vitamins, contraceptives/birth control, prophylactically indicated drugs, & heart health medications are examples of it. Update response as appropriate. Otherwise, clarify. '(Site from DM).	(b) (4), (b) (6)	05 Nov 2020 18:23:39
User entered 'No (N)'	Meghan York (b) (4) (b) (4)	01 Oct 2020 15:23:52

US3142034

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 11 Aug 2021 21:58:56

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 19:03:31
User entered 'general health'	Meghan York (b) (4) (b) (4)	01 Oct 2020 15:23:52

US3142034

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 11 Aug 2021 21:58:56

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 19:03:31
User entered '250'	Meghan York (b) (4) (b) (4)	01 Oct 2020 15:23:52

US3142034

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 11 Aug 2021 21:58:56

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 19:03:31
User entered 'mg (mg)'	Meghan York (b) (4) (b) (4)	01 Oct 2020 15:23:52

US3142034

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 11 Aug 2021 21:58:56

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 19:03:31
User entered empty.	Meghan York (b) (4) (b) (4)	01 Oct 2020 15:23:52

US3142034

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 11 Aug 2021 21:58:56

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 19:03:31
User entered 'once daily (QD)'	Meghan York (b) (4) (b) (4)	01 Oct 2020 15:23:52

US3142034

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 11 Aug 2021 21:58:56

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 19:03:31
User entered empty.	Meghan York (b) (4) (b) (4)	01 Oct 2020 15:23:52

US3142034

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 11 Aug 2021 21:58:56

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 19:03:31
User entered 'Oral (ORAL)'	Meghan York (b) (4) (b) (4)	01 Oct 2020 15:23:52

US3142034

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 11 Aug 2021 21:58:56

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 19:03:31
User entered empty.	Meghan York (b) (4) (b) (4)	01 Oct 2020 15:23:52

US3142034

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 11 Aug 2021 21:58:56

Start date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 19:03:31
User entered 'un UNK 2010'	Meghan York (b) (4) (b) (4)	01 Oct 2020 15:23:52

US3142034

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 11 Aug 2021 21:58:56

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 19:03:31
User entered '0'	Meghan York (b) (4) (b) (4)	01 Oct 2020 15:23:52

US3142034

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 11 Aug 2021 21:58:56

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 19:03:31
User entered 'Yes (Y)'	Meghan York (b) (4) (b) (4)	01 Oct 2020 15:23:52

US3142034

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 11 Aug 2021 21:58:56

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 19:03:31
User entered empty.	Meghan York (b) (4) (b) (4)	01 Oct 2020 15:23:52

US3142034

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 11 Aug 2021 21:58:56

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 19:03:31
User entered 'No (N)'	Meghan York (b) (4) (b) (4)	01 Oct 2020 15:23:52

US3142034

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 11 Aug 2021 21:58:56

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	01 Oct 2020 15:23:52

US3142034

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 11 Aug 2021 21:58:56

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	01 Oct 2020 15:23:52

US3142034

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 11 Aug 2021 21:58:56

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	01 Oct 2020 15:23:52

US3142034

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 11 Aug 2021 21:58:56

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:03:31
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: MINERAL SUPPLEMENTS, ATC: OTHER MINERAL SUPPLEMENTS, ATC: ZINC, PRODUCT: ZINC - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4)	01 Oct 2020 15:25:52
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	01 Oct 2020 15:25:52
Data point term sent to Coder	System	01 Oct 2020 15:25:14
User entered 'zinc'	Meghan York (b) (4) (b) (4)	01 Oct 2020 15:24:27

US3142034

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 11 Aug 2021 21:58:56

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:03:31
User closed query 'Per DM CLR: Please review the response as this medication appears to be given as prophylaxis. Note that supplements, vitamins, contraceptives/birth control, prophylactically indicated drugs, & heart health medications are examples of it. Update response as appropriate. Otherwise, clarify. '(Site from DM).	(b) (4) (b) (4), (b) (6)	11 Nov 2020 16:48:39
Query 'Per DM CLR: Please review the response as this medication appears to be given as prophylaxis. Note that supplements, vitamins, contraceptives/birth control, prophylactically indicated drugs, & heart health medications are examples of it. Update response as appropriate. Otherwise, clarify. ' answered with 'now corrected ' (Site from DM).	Meghan York (b) (4) (b) (4)	05 Nov 2020 21:44:13
User entered 'Yes (Y)' reason for change: Data Entry Error	Meghan York (b) (4) (b) (4)	05 Nov 2020 21:44:04
User opened query 'Per DM CLR: Please review the response as this medication appears to be given as prophylaxis. Note that supplements, vitamins, contraceptives/birth control, prophylactically indicated drugs, & heart health medications are examples of it. Update response as appropriate. Otherwise, clarify. '(Site from DM).	(b) (4), (b) (6)	05 Nov 2020 18:42:56
User entered 'No (N)'	Meghan York (b) (4) (b) (4)	01 Oct 2020 15:24:27

US3142034

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 11 Aug 2021 21:58:56

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 19:03:31
User entered 'general health'	Meghan York (b) (4) (b) (4)	01 Oct 2020 15:24:27

US3142034

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 11 Aug 2021 21:58:56

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 19:03:31
User entered '250'	Meghan York (b) (4) (b) (4)	01 Oct 2020 15:24:27

US3142034

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 11 Aug 2021 21:58:56

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 19:03:31
User entered 'mg (mg)'	Meghan York (b) (4) (b) (4)	01 Oct 2020 15:24:27

US3142034

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 11 Aug 2021 21:58:56

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 19:03:31
User entered empty.	Meghan York (b) (4) (b) (4)	01 Oct 2020 15:24:27

US3142034

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 11 Aug 2021 21:58:56

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 19:03:31
User entered 'once daily (QD)'	Meghan York (b) (4) (b) (4)	01 Oct 2020 15:24:27

US3142034

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 11 Aug 2021 21:58:56

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 19:03:31
User entered empty.	Meghan York (b) (4) (b) (4)	01 Oct 2020 15:24:27

US3142034

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 11 Aug 2021 21:58:56

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 19:03:31
User entered 'Oral (ORAL)'	Meghan York (b) (4) (b) (4)	01 Oct 2020 15:24:27

US3142034

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 11 Aug 2021 21:58:56

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 19:03:31
User entered empty.	Meghan York (b) (4) (b) (4)	01 Oct 2020 15:24:27

US3142034

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 11 Aug 2021 21:58:56

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:03:31
	(b) (4)	
User entered 'un Mar 2020'	Meghan York (b) (4)	01 Oct 2020 15:24:27
	(b) (4)	

US3142034

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 11 Aug 2021 21:58:56

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 19:03:31
User entered '0'	Meghan York (b) (4) (b) (4)	01 Oct 2020 15:24:27

US3142034

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 11 Aug 2021 21:58:56

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 19:03:31
User entered 'Yes (Y)'	Meghan York (b) (4) (b) (4)	01 Oct 2020 15:24:27

US3142034

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 11 Aug 2021 21:58:56

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 19:03:31
User entered empty.	Meghan York (b) (4) (b) (4)	01 Oct 2020 15:24:27

US3142034

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 11 Aug 2021 21:58:56

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 19:03:31
User entered 'No (N)'	Meghan York (b) (4) (b) (4)	01 Oct 2020 15:24:27

US3142034

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 11 Aug 2021 21:58:56

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	01 Oct 2020 15:24:27

US3142034

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 11 Aug 2021 21:58:56

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	01 Oct 2020 15:24:27

US3142034

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 11 Aug 2021 21:58:56

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	01 Oct 2020 15:24:27

US3142034

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 11 Aug 2021 21:58:56

Name of Medication

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:03:31
User coded data point as ATC: BLOOD AND BLOOD FORMING ORGANS, ATC: ANTIANEMIC PREPARATIONS, ATC: VITAMIN B12 AND FOLIC ACID, ATC: FOLIC ACID AND DERIVATIVES, PRODUCT: FOLIC ACID - version WHODrug-Global-B3\202003.	Coder Import (b) (4)	01 Oct 2020 15:25:52
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\202003.	Coder Import (b) (4)	01 Oct 2020 15:25:52
Data point term sent to Coder	System	01 Oct 2020 15:25:14
User entered 'folic acid'	Meghan York (b) (4)	01 Oct 2020 15:24:59

US3142034

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 11 Aug 2021 21:58:56

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:03:31
User closed query 'Per DM CLR: Please review the response as this medication appears to be given as prophylaxis. Note that supplements, vitamins, contraceptives/birth control, prophylactically indicated drugs, & heart health medications are examples of it. Update response as appropriate. Otherwise, clarify. '(Site from DM).	(b) (4) (b) (4), (b) (6)	11 Nov 2020 16:48:44
Query 'Per DM CLR: Please review the response as this medication appears to be given as prophylaxis. Note that supplements, vitamins, contraceptives/birth control, prophylactically indicated drugs, & heart health medications are examples of it. Update response as appropriate. Otherwise, clarify. ' answered with 'now corrected ' (Site from DM).	Meghan York (b) (4) (b) (4)	05 Nov 2020 21:44:28
User entered 'Yes (Y)' reason for change: Data Entry Error	Meghan York (b) (4) (b) (4)	05 Nov 2020 21:44:22
User opened query 'Per DM CLR: Please review the response as this medication appears to be given as prophylaxis. Note that supplements, vitamins, contraceptives/birth control, prophylactically indicated drugs, & heart health medications are examples of it. Update response as appropriate. Otherwise, clarify. '(Site from DM).	(b) (4), (b) (6)	05 Nov 2020 18:43:47
User entered 'No (N)'	Meghan York (b) (4) (b) (4)	01 Oct 2020 15:24:59

US3142034

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 11 Aug 2021 21:58:56

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 19:03:31
User entered 'general health'	Meghan York (b) (4) (b) (4)	01 Oct 2020 15:24:59

US3142034

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 11 Aug 2021 21:58:56

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 19:03:31
User entered '800'	Meghan York (b) (4) (b) (4)	01 Oct 2020 15:24:59

US3142034

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 11 Aug 2021 21:58:56

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 19:03:31
User entered 'mg (mg)'	Meghan York (b) (4) (b) (4)	01 Oct 2020 15:24:59

US3142034

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 11 Aug 2021 21:58:56

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 19:03:31
User entered empty.	Meghan York (b) (4) (b) (4)	01 Oct 2020 15:24:59

US3142034

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 11 Aug 2021 21:58:56

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 19:03:31
User entered 'once daily (QD)'	Meghan York (b) (4) (b) (4)	01 Oct 2020 15:24:59

US3142034

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 11 Aug 2021 21:58:56

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 19:03:31
User entered empty.	Meghan York (b) (4) (b) (4)	01 Oct 2020 15:24:59

US3142034

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 11 Aug 2021 21:58:56

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 19:03:31
User entered 'Oral (ORAL)'	Meghan York (b) (4) (b) (4)	01 Oct 2020 15:24:59

US3142034

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 11 Aug 2021 21:58:56

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 19:03:31
User entered empty.	Meghan York (b) (4) (b) (4)	01 Oct 2020 15:24:59

US3142034

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 11 Aug 2021 21:58:56

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 19:03:31
User entered 'un UNK 2000'	Meghan York (b) (4) (b) (4)	01 Oct 2020 15:24:59

US3142034

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 11 Aug 2021 21:58:56

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 19:03:31
User entered '0'	Meghan York (b) (4) (b) (4)	01 Oct 2020 15:24:59

US3142034

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 11 Aug 2021 21:58:56

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 19:03:31
User entered 'Yes (Y)'	Meghan York (b) (4) (b) (4)	01 Oct 2020 15:24:59

US3142034

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 11 Aug 2021 21:58:56

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 19:03:31
User entered empty.	Meghan York (b) (4) (b) (4)	01 Oct 2020 15:24:59

US3142034

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 11 Aug 2021 21:58:56

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 19:03:31
User entered 'No (N)'	Meghan York (b) (4) (b) (4)	01 Oct 2020 15:24:59

US3142034

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 11 Aug 2021 21:58:56

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	01 Oct 2020 15:24:59

US3142034

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 11 Aug 2021 21:58:56

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	01 Oct 2020 15:24:59

US3142034

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 11 Aug 2021 21:58:56

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	01 Oct 2020 15:24:59

US3142034

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 11 Aug 2021 21:58:56

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:03:31
User coded data point as ATC: BLOOD AND BLOOD FORMING ORGANS, ATC: ANTIANEMIC PREPARATIONS, ATC: VITAMIN B12 AND FOLIC ACID, ATC: VITAMIN B12 (CYANOCOBALAMIN AND ANALOGUES), PRODUCT: VITAMIN B12 NOS, PRODUCTSYNONYM: VITAMIN B12 [VITAMIN B12 NOS] - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4)	01 Oct 2020 15:26:51
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	01 Oct 2020 15:26:51
Data point term sent to Coder	System	01 Oct 2020 15:26:15
User entered 'vitamin b12'	Meghan York (b) (4) (b) (4)	01 Oct 2020 15:25:30

US3142034

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 11 Aug 2021 21:58:56

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:03:31
User closed query 'Per DM CLR: Please review the response as this medication appears to be given as prophylaxis. Note that supplements, vitamins, contraceptives/birth control, prophylactically indicated drugs, & heart health medications are examples of it. Update response as appropriate. Otherwise, clarify. '(Site from DM).	(b) (4) (b) (4), (b) (6)	11 Nov 2020 16:48:48
Query 'Per DM CLR: Please review the response as this medication appears to be given as prophylaxis. Note that supplements, vitamins, contraceptives/birth control, prophylactically indicated drugs, & heart health medications are examples of it. Update response as appropriate. Otherwise, clarify. ' answered with 'now corrected ' (Site from DM).	Meghan York (b) (4) (b) (4)	05 Nov 2020 21:44:45
User entered 'Yes (Y)' reason for change: Data Entry Error	Meghan York (b) (4) (b) (4)	05 Nov 2020 21:44:37
User opened query 'Per DM CLR: Please review the response as this medication appears to be given as prophylaxis. Note that supplements, vitamins, contraceptives/birth control, prophylactically indicated drugs, & heart health medications are examples of it. Update response as appropriate. Otherwise, clarify. '(Site from DM).	(b) (4), (b) (6)	05 Nov 2020 18:44:15
User entered 'No (N)'	Meghan York (b) (4) (b) (4)	01 Oct 2020 15:25:30

US3142034

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 11 Aug 2021 21:58:56

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 19:03:31
User entered 'general health'	Meghan York (b) (4) (b) (4)	01 Oct 2020 15:25:30

US3142034

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 11 Aug 2021 21:58:56

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 19:03:31
User entered '1000'	Meghan York (b) (4) (b) (4)	01 Oct 2020 15:25:30

US3142034

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 11 Aug 2021 21:58:56

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 19:03:31
User entered 'mg (mg)'	Meghan York (b) (4) (b) (4)	01 Oct 2020 15:25:30

US3142034

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 11 Aug 2021 21:58:56

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 19:03:31
User entered empty.	Meghan York (b) (4) (b) (4)	01 Oct 2020 15:25:30

US3142034

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 11 Aug 2021 21:58:56

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 19:03:31
User entered 'once daily (QD)'	Meghan York (b) (4) (b) (4)	01 Oct 2020 15:25:30

US3142034

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 11 Aug 2021 21:58:56

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 19:03:31
User entered empty.	Meghan York (b) (4) (b) (4)	01 Oct 2020 15:25:30

US3142034

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 11 Aug 2021 21:58:56

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 19:03:31
User entered 'Oral (ORAL)'	Meghan York (b) (4) (b) (4)	01 Oct 2020 15:25:30

US3142034

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 11 Aug 2021 21:58:56

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 19:03:31
User entered empty.	Meghan York (b) (4) (b) (4)	01 Oct 2020 15:25:30

US3142034

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 11 Aug 2021 21:58:56

Start date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 19:03:31
User entered 'un UNK 2000'	Meghan York (b) (4) (b) (4)	01 Oct 2020 15:25:30

US3142034

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 11 Aug 2021 21:58:56

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 19:03:31
User entered '0'	Meghan York (b) (4) (b) (4)	01 Oct 2020 15:25:30

US3142034

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 11 Aug 2021 21:58:56

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 19:03:31
User entered 'Yes (Y)'	Meghan York (b) (4) (b) (4)	01 Oct 2020 15:25:30

US3142034

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 11 Aug 2021 21:58:56

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 19:03:31
User entered empty.	Meghan York (b) (4) (b) (4)	01 Oct 2020 15:25:30

US3142034

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 11 Aug 2021 21:58:56

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 19:03:31
User entered 'No (N)'	Meghan York (b) (4) (b) (4)	01 Oct 2020 15:25:30

US3142034

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 11 Aug 2021 21:58:56

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	01 Oct 2020 15:25:30

US3142034

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 11 Aug 2021 21:58:56

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	01 Oct 2020 15:25:30

US3142034

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 11 Aug 2021 21:58:56

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	01 Oct 2020 15:25:30

US3142034

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 11 Aug 2021 21:58:56

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:03:31
User coded data point as ATC: VARIOUS, ATC: GENERAL NUTRIENTS, ATC: OTHER NUTRIENTS, ATC: OTHER COMBINATIONS OF NUTRIENTS, PRODUCT: FISH OIL - version WHODrug-Global-B3\202003.	(b) (4) Coder Import (b) (4)	01 Oct 2020 15:26:50
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	01 Oct 2020 15:26:50
Data point term sent to Coder	System	01 Oct 2020 15:26:19
User entered 'fish oil'	Meghan York (b) (4) (b) (4)	01 Oct 2020 15:26:01

US3142034

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 11 Aug 2021 21:58:56

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:03:31
User closed query 'Per DM CLR: Please review the response as this medication appears to be given as prophylaxis. Note that supplements, vitamins, contraceptives/birth control, prophylactically indicated drugs, & heart health medications are examples of it. Update response as appropriate. Otherwise, clarify. '(Site from DM).	(b) (4) (b) (4), (b) (6)	11 Nov 2020 16:48:54
Query 'Per DM CLR: Please review the response as this medication appears to be given as prophylaxis. Note that supplements, vitamins, contraceptives/birth control, prophylactically indicated drugs, & heart health medications are examples of it. Update response as appropriate. Otherwise, clarify. ' answered with 'now corrected ' (Site from DM).	Meghan York (b) (4) (b) (4)	05 Nov 2020 21:45:04
User entered 'Yes (Y)' reason for change: Data Entry Error	Meghan York (b) (4) (b) (4)	05 Nov 2020 21:44:52
User opened query 'Per DM CLR: Please review the response as this medication appears to be given as prophylaxis. Note that supplements, vitamins, contraceptives/birth control, prophylactically indicated drugs, & heart health medications are examples of it. Update response as appropriate. Otherwise, clarify. '(Site from DM).	(b) (4), (b) (6)	05 Nov 2020 18:44:49
User entered 'No (N)'	Meghan York (b) (4) (b) (4)	01 Oct 2020 15:26:01

US3142034

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 11 Aug 2021 21:58:56

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 19:03:31
User entered 'general health'	Meghan York (b) (4) (b) (4)	01 Oct 2020 15:26:01

US3142034

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 11 Aug 2021 21:58:56

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 19:03:31
User entered '250'	Meghan York (b) (4) (b) (4)	01 Oct 2020 15:26:01

US3142034

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 11 Aug 2021 21:58:56

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 19:03:31
User entered 'mg (mg)'	Meghan York (b) (4) (b) (4)	01 Oct 2020 15:26:01

US3142034

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 11 Aug 2021 21:58:56

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 19:03:31
User entered empty.	Meghan York (b) (4) (b) (4)	01 Oct 2020 15:26:01

US3142034

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 11 Aug 2021 21:58:56

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 19:03:31
User entered 'once daily (QD)'	Meghan York (b) (4) (b) (4)	01 Oct 2020 15:26:01

US3142034

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 11 Aug 2021 21:58:56

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 19:03:31
User entered empty.	Meghan York (b) (4) (b) (4)	01 Oct 2020 15:26:01

US3142034

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 11 Aug 2021 21:58:56

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 19:03:31
User entered 'Oral (ORAL)'	Meghan York (b) (4) (b) (4)	01 Oct 2020 15:26:01

US3142034

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 11 Aug 2021 21:58:56

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 19:03:31
User entered empty.	Meghan York (b) (4) (b) (4)	01 Oct 2020 15:26:01

US3142034

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 11 Aug 2021 21:58:56

Start date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 19:03:31
User entered 'un UNK 2000'	Meghan York (b) (4) (b) (4)	01 Oct 2020 15:26:01

US3142034

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 11 Aug 2021 21:58:56

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 19:03:31
User entered '0'	Meghan York (b) (4) (b) (4)	01 Oct 2020 15:26:01

US3142034

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 11 Aug 2021 21:58:56

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 19:03:31
User entered 'Yes (Y)'	Meghan York (b) (4) (b) (4)	01 Oct 2020 15:26:01

US3142034

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 11 Aug 2021 21:58:56

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 19:03:31
User entered empty.	Meghan York (b) (4) (b) (4)	01 Oct 2020 15:26:01

US3142034

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 11 Aug 2021 21:58:56

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 19:03:31
User entered 'No (N)'	Meghan York (b) (4) (b) (4)	01 Oct 2020 15:26:01

US3142034

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 11 Aug 2021 21:58:56

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	01 Oct 2020 15:26:01

US3142034

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 11 Aug 2021 21:58:56

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	01 Oct 2020 15:26:01

US3142034

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 11 Aug 2021 21:58:56

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	01 Oct 2020 15:26:01

US3142034

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 11 Aug 2021 21:58:56

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:03:31
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: ANTIDIARRHEALS, INTESTINAL ANTIINFLAMMATORY/ANTIINFECTIVE AGENTS, ATC: ANTIDIARRHEAL MICROORGANISMS, ATC: ANTIDIARRHEAL MICROORGANISMS, PRODUCT: LACTOBACILLUS ACIDOPHILUS, PRODUCTSYNONYM: ACIDOPHILUS [LACTOBACILLUS ACIDOPHILUS] - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4)	01 Oct 2020 16:00:57
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	01 Oct 2020 16:00:57
Data point term sent to Coder	System	01 Oct 2020 15:27:20
User entered 'acidophilus'	Meghan York (b) (4) (b) (4)	01 Oct 2020 15:26:32

US3142034

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 11 Aug 2021 21:58:56

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:03:31
User closed query 'Per DM CLR: Please review the response as this medication appears to be given as prophylaxis. Note that supplements, vitamins, contraceptives/birth control, prophylactically indicated drugs, & heart health medications are examples of it. Update response as appropriate. Otherwise, clarify. '(Site from DM).	(b) (4) (b) (4), (b) (6)	11 Nov 2020 16:48:58
Query 'Per DM CLR: Please review the response as this medication appears to be given as prophylaxis. Note that supplements, vitamins, contraceptives/birth control, prophylactically indicated drugs, & heart health medications are examples of it. Update response as appropriate. Otherwise, clarify. ' answered with 'now corrected ' (Site from DM).	Meghan York (b) (4) (b) (4)	05 Nov 2020 21:45:18
User entered 'Yes (Y)' reason for change: Data Entry Error	Meghan York (b) (4) (b) (4)	05 Nov 2020 21:45:10
User opened query 'Per DM CLR: Please review the response as this medication appears to be given as prophylaxis. Note that supplements, vitamins, contraceptives/birth control, prophylactically indicated drugs, & heart health medications are examples of it. Update response as appropriate. Otherwise, clarify. '(Site from DM).	(b) (4), (b) (6)	05 Nov 2020 18:45:59
User entered 'No (N)'	Meghan York (b) (4) (b) (4)	01 Oct 2020 15:26:32

US3142034

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 11 Aug 2021 21:58:56

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 19:03:31
User entered 'general health'	Meghan York (b) (4) (b) (4)	01 Oct 2020 15:26:32

US3142034

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 11 Aug 2021 21:58:56

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 19:03:31
User entered '1'	Meghan York (b) (4) (b) (4)	01 Oct 2020 15:26:32

US3142034

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 11 Aug 2021 21:58:56

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 19:03:31
User entered 'tablet (TABLET)'	Meghan York (b) (4) (b) (4)	01 Oct 2020 15:26:32

US3142034

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 11 Aug 2021 21:58:56

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 19:03:31
User entered empty.	Meghan York (b) (4) (b) (4)	01 Oct 2020 15:26:32

US3142034

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 11 Aug 2021 21:58:56

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 19:03:31
User entered 'once daily (QD)'	Meghan York (b) (4) (b) (4)	01 Oct 2020 15:26:32

US3142034

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 11 Aug 2021 21:58:56

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 19:03:31
User entered empty.	Meghan York (b) (4) (b) (4)	01 Oct 2020 15:26:32

US3142034

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 11 Aug 2021 21:58:56

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 19:03:31
User entered 'Oral (ORAL)'	Meghan York (b) (4) (b) (4)	01 Oct 2020 15:26:32

US3142034

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 11 Aug 2021 21:58:56

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 19:03:31
User entered empty.	Meghan York (b) (4) (b) (4)	01 Oct 2020 15:26:32

US3142034

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 11 Aug 2021 21:58:56

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 19:03:31
User entered 'un UNK 2000'	Meghan York (b) (4) (b) (4)	01 Oct 2020 15:26:32

US3142034

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 11 Aug 2021 21:58:56

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 19:03:31
User entered '0'	Meghan York (b) (4) (b) (4)	01 Oct 2020 15:26:32

US3142034

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 11 Aug 2021 21:58:56

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 19:03:31
User entered 'Yes (Y)'	Meghan York (b) (4) (b) (4)	01 Oct 2020 15:26:32

US3142034

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 11 Aug 2021 21:58:56

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 19:03:31
User entered empty.	Meghan York (b) (4) (b) (4)	01 Oct 2020 15:26:32

US3142034

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 11 Aug 2021 21:58:56

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 19:03:31
User entered 'No (N)'	Meghan York (b) (4) (b) (4)	01 Oct 2020 15:26:32

US3142034

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 11 Aug 2021 21:58:56

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	01 Oct 2020 15:26:32

US3142034

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 11 Aug 2021 21:58:56

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	01 Oct 2020 15:26:32

US3142034

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 11 Aug 2021 21:58:56

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	01 Oct 2020 15:26:32

US3142034

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures Summary

Generated On: 11 Aug 2021 21:58:56

[Were any concomitant procedures performed?](#)

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 19:03:31
User entered 'No (N)'	Jami Wagner (b) (4) (b) (4)	18 Mar 2021 17:41:46

US3142034

Folder: SAE USA-US064-2021-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 11 Aug 2021 21:58:56

[SAEID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 16:21:24
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:03:50
User entered 'USA-US064-2021-MRNA-1273-P301000007'	(b) (4) System	26 Mar 2021 18:56:31

US3142034

Folder: SAE USA-US064-2021-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 11 Aug 2021 21:58:56

Serious

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 16:21:24
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:03:50
User entered 'No (N)'	(b) (4) System	26 Mar 2021 18:56:31

US3142034

Folder: SAE USA-US064-2021-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 11 Aug 2021 21:58:56

Death

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 16:21:24
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:03:50
User entered 'No (N)'	(b) (4) System	26 Mar 2021 18:56:31

US3142034

Folder: SAE USA-US064-2021-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 11 Aug 2021 21:58:56

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 16:21:24
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:03:50
User entered 'No (N)'	(b) (4) System	26 Mar 2021 18:56:31

US3142034

Folder: SAE USA-US064-2021-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 11 Aug 2021 21:58:56

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 16:21:24
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:03:50
User entered 'No (N)'	(b) (4) System	26 Mar 2021 18:56:31

US3142034

Folder: SAE USA-US064-2021-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 11 Aug 2021 21:58:56

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 16:21:24
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:03:50
User entered 'No (N)'	(b) (4) System	26 Mar 2021 18:56:31

US3142034

Folder: SAE USA-US064-2021-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 11 Aug 2021 21:58:56

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 16:21:24
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:03:50
User entered 'No (N)'	(b) (4) System	26 Mar 2021 18:56:31

US3142034

Folder: SAE USA-US064-2021-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 11 Aug 2021 21:58:56

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 16:21:24
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:03:50
User entered 'No (N)'	(b) (4) System	26 Mar 2021 18:56:31

US3142034

Folder: SAE USA-US064-2021-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 11 Aug 2021 21:58:56

[Investigator's First Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 16:21:24
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:03:50
User entered 'Ripley'	(b) (4) System	26 Mar 2021 18:56:31

US3142034

Folder: SAE USA-US064-2021-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 11 Aug 2021 21:58:56

[Investigator's Last Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 16:21:24
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:03:50
User entered 'Hollister'	(b) (4) System	26 Mar 2021 18:56:31

US3142034

Folder: SAE USA-US064-2021-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 11 Aug 2021 21:58:56

Site Address: Street

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 16:21:24
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:03:50
User entered '4190 East Woodmen Road Suite 210'	(b) (4) System	26 Mar 2021 18:56:31

US3142034

Folder: SAE USA-US064-2021-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 11 Aug 2021 21:58:56

Site Address: [City](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 16:21:24
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:03:50
User entered 'Colorado Springs'	(b) (4) System	26 Mar 2021 18:56:31

US3142034

Folder: SAE USA-US064-2021-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 11 Aug 2021 21:58:56

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 16:21:24
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:03:50
User entered '80920'	(b) (4) System	26 Mar 2021 18:56:31

US3142034

Folder: SAE USA-US064-2021-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 11 Aug 2021 21:58:56

[Investigator Country](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 16:21:24
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:03:50
User entered 'US'	(b) (4) System	26 Mar 2021 18:56:47

US3142034

Folder: SAE USA-US064-2021-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 11 Aug 2021 21:58:56

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '1'	System	26 Mar 2021 18:56:47

US3142034

Folder: SAE USA-US064-2021-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 11 Aug 2021 21:58:56

[SAEID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 16:21:24
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:03:50
User entered 'USA-US064-2021-MRNA-1273-P301000007'	(b) (4) System	26 Mar 2021 18:56:31

US3142034

Folder: SAE USA-US064-2021-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 11 Aug 2021 21:58:56

Serious

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 16:21:24
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:03:50
User entered 'No (N)'	(b) (4) System	26 Mar 2021 18:56:31

US3142034

Folder: SAE USA-US064-2021-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 11 Aug 2021 21:58:56

[Death](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 16:21:24
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:03:50
User entered 'No (N)'	(b) (4) System	26 Mar 2021 18:56:31

US3142034

Folder: SAE USA-US064-2021-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 11 Aug 2021 21:58:56

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 16:21:24
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:03:50
User entered 'No (N)'	(b) (4) System	26 Mar 2021 18:56:31

US3142034

Folder: SAE USA-US064-2021-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 11 Aug 2021 21:58:56

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 16:21:24
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:03:50
User entered 'No (N)'	(b) (4) System	26 Mar 2021 18:56:31

US3142034

Folder: SAE USA-US064-2021-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 11 Aug 2021 21:58:56

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 16:21:24
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:03:50
User entered 'No (N)'	(b) (4) System	26 Mar 2021 18:56:31

US3142034

Folder: SAE USA-US064-2021-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 11 Aug 2021 21:58:56

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 16:21:24
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:03:50
User entered 'No (N)'	(b) (4) System	26 Mar 2021 18:56:31

US3142034

Folder: SAE USA-US064-2021-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 11 Aug 2021 21:58:56

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 16:21:24
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:03:50
User entered 'No (N)'	(b) (4) System	26 Mar 2021 18:56:31

US3142034

Folder: SAE USA-US064-2021-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 11 Aug 2021 21:58:56

[Investigator's First Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 16:21:24
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:03:50
User entered 'Ripley'	(b) (4) System	26 Mar 2021 18:56:31

US3142034

Folder: SAE USA-US064-2021-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 11 Aug 2021 21:58:56

[Investigator's Last Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 16:21:24
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:03:50
User entered 'Hollister'	(b) (4) System	26 Mar 2021 18:56:31

US3142034

Folder: SAE USA-US064-2021-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 11 Aug 2021 21:58:56

Site Address: Street

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 16:21:24
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:03:50
User entered '4190 East Woodmen Road Suite 210'	(b) (4) System	26 Mar 2021 18:56:31

US3142034

Folder: SAE USA-US064-2021-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 11 Aug 2021 21:58:56

Site Address: City

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 16:21:24
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:03:50
User entered 'Colorado Springs'	(b) (4) System	26 Mar 2021 18:56:31

US3142034

Folder: SAE USA-US064-2021-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 11 Aug 2021 21:58:56

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 16:21:24
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:03:50
User entered '80920'	(b) (4) System	26 Mar 2021 18:56:31

US3142034

Folder: SAE USA-US064-2021-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 11 Aug 2021 21:58:56

[Investigator Country](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 16:21:24
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:03:50
User entered 'US'	(b) (4) System	26 Mar 2021 18:56:47

US3142034

Folder: SAE USA-US064-2021-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 11 Aug 2021 21:58:56

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '1'	System	26 Mar 2021 18:56:47

US3142034

Folder: SAE USA-US064-2021-MRNA-1273-P301000007

Form: Safety Report Form (1)

Generated On: 11 Aug 2021 21:58:56

Date of submission (Pre-filled from custom function)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 16:21:24
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:03:50
User entered '26/Mar/2021 14:56'	(b) (4) System	26 Mar 2021 18:56:47

US3142034

Folder: SAE USA-US064-2021-MRNA-1273-P301000007

Form: Safety Report Form (1)

Generated On: 11 Aug 2021 21:58:56

Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 16:21:24
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:03:50
User entered '1'	(b) (4) (b) (4), (b) (6)	26 Mar 2021 18:56:47