

US3032249 (Prod: Meridian Clinical Research (Norfolk-Nebraska))

Generated By: KC Joubran

Generated On: 09 Jun 2021 14:53:49

All time stamps listed in this document are displayed in GMT

US3032249

Form: Participant Creation

Data signed: (b) (4) 28 Sep 2020 17:50:47

Generated On: 09 Jun 2021 14:53:49

[Participant ID](#)

US3032249

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

US3032249

Folder: Screening

Form: Visit Date

Data signed: (b) (4) 28 Sep 2020 17:50:48

Generated On: 09 Jun 2021 14:53:49

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	19 AUG 2020
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	SCRN

US3032249

Folder: Screening

Form: Demographics

Data signed: (b) (4) 28 Sep 2020 17:50:47

Generated On: 09 Jun 2021 14:53:49

Date of Birth (MMM yyyy)	(b) (6) 1948
Age	72
Age Units	YEARS
Age (Derived)	72
Sex	Female <input checked="" type="radio"/> Male <input type="radio"/>
Ethnicity	Hispanic or Latino <input type="radio"/> Not Hispanic or Latino <input checked="" type="radio"/> Not Reported <input type="radio"/> Unknown <input type="radio"/>
Race (Check All That Apply)	
White	True
Black	False
Asian	False
American Indian or Alaska Native	False
Native Hawaiian or other Pacific Islander	False
Other	False
If race is Other, specify _____	
Unknown	False
Not reported	False

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Folder: Screening

Form: Enrollment

Data signed: (b) (4) 28 Sep 2020 17:50:47

Generated On: 09 Jun 2021 14:53:49

Date of Informed Consent (<i>dd MMM yyyy</i>)	19 AUG 2020
Month and Year of Informed Consent (derived)	AUG 2020
Year of Informed Consent (derived)	2020
Protocol Version	Amendment 1 <input type="radio"/> Amendment 2 <input checked="" type="radio"/> Amendment 3 <input type="radio"/> Amendment 4 <input type="radio"/> Amendment 5 <input type="radio"/>
Was participant enrolled in the study?	Yes <input checked="" type="radio"/> No <input type="radio"/>
If No, indicate reason for screen fail	Withdrew Consent <input type="radio"/> Inclusion/Exclusion <input type="radio"/> Cohort Full <input type="radio"/> Other <input type="radio"/>
If reason for screen fail is Other, specify	
Was this participant screened previously?	Yes <input type="radio"/> No <input checked="" type="radio"/>
If Yes, previous participant number	
Enrollment Trigger	1

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Folder: Screening

Form: Inclusion/Exclusion Criteria Summary

Data signed: (b) (4) 28 Sep 2020 17:50:47

Generated On: 09 Jun 2021 14:53:49

Did the participant meet all eligibility criteria?

Yes ☒

No ☐

US3032249

Folder: Screening

Form: Medical History Summary

Data signed: (b) (4) 28 Sep 2020 17:50:48

Generated On: 09 Jun 2021 14:53:49

Were any significant conditions reported?

Yes ☒
No ☐

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Folder: Screening

Form: Medical History (1)

Data signed: (b) (4) 06 Apr 2021 15:41:55

Generated On: 09 Jun 2021 14:53:49

Condition	POLYGLACTIN SUTURE HYPERSENSITIVITY
Start date (dd MMM yyyy)	UN UNK 2014
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 2014
Start Year (derived)	2014
Stop Month and Year (derived)	_____
Stop Year (derived)	_____

US3032249

Folder: Screening

Form: Medical History (2)

Data signed: (b) (4) 06 Apr 2021 15:41:55

Generated On: 09 Jun 2021 14:53:49

Condition	HYSTERECTOMY
Start date (dd MMM yyyy)	UN UNK 1983
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 1983
Stop date completely unknown	False
Start Month and Year (derived)	JAN 1983
Start Year (derived)	1983
Stop Month and Year (derived)	JAN 1983
Stop Year (derived)	1983

US3032249

Folder: Screening

Form: Medical History (3)

Data signed: (b) (4) 06 Apr 2021 15:41:55

Generated On: 09 Jun 2021 14:53:49

Condition	MENORRHAGIA
Start date (dd MMM yyyy)	UN UNK 1981
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 1983
Stop date completely unknown	False
Start Month and Year (derived)	JAN 1981
Start Year (derived)	1981
Stop Month and Year (derived)	JAN 1983
Stop Year (derived)	1983

US3032249

Folder: Screening

Form: Medical History (4)

Data signed: (b) (4) 06 Apr 2021 15:41:55

Generated On: 09 Jun 2021 14:53:49

Condition	ESOPHAGOGASTRODUODENOS COPY
Start date (dd MMM yyyy)	UN JUN 2020
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 JUN 2020
Stop date completely unknown	False
Start Month and Year (derived)	JUN 2020
Start Year (derived)	2020
Stop Month and Year (derived)	JUN 2020
Stop Year (derived)	2020

US3032249

Folder: Screening

Form: Medical History (5)

Data signed: (b) (4) 06 Apr 2021 15:41:55

Generated On: 09 Jun 2021 14:53:49

Condition	GASTRIC EMPTYING SCINTIGRAPHY
Start date (dd MMM yyyy)	UN JUN 2020
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 JUN 2020
Stop date completely unknown	False
Start Month and Year (derived)	JUN 2020
Start Year (derived)	2020
Stop Month and Year (derived)	JUN 2020
Stop Year (derived)	2020

US3032249

Folder: Screening

Form: Medical History (6)

Data signed: (b) (4) 06 Apr 2021 15:41:55

Generated On: 09 Jun 2021 14:53:49

Condition	GASTROPARESIS
Start date (dd MMM yyyy)	UN JUN 2020
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 JUN 2020
Stop date completely unknown	False
Start Month and Year (derived)	JUN 2020
Start Year (derived)	2020
Stop Month and Year (derived)	JUN 2020
Stop Year (derived)	2020

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Folder: Screening

Form: Medical History (7)

Data signed: (b) (4) 06 Apr 2021 15:41:55

Generated On: 09 Jun 2021 14:53:49

Condition	SEASONAL ALLERGIES
Start date (dd MMM yyyy)	UN UNK 2007
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 2007
Start Year (derived)	2007
Stop Month and Year (derived)	_____
Stop Year (derived)	_____

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Folder: Screening

Form: Medical History (8)

Data signed: (b) (4) 06 Apr 2021 15:41:55

Generated On: 09 Jun 2021 14:53:49

Condition	OSTEOARTHRITIS
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)	_____

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Folder: Screening

Form: Medical History (9)

Data signed: (b) (4) 06 Apr 2021 15:41:55

Generated On: 09 Jun 2021 14:53:49

Condition	RIGHT KNEE ARTHROSCOPY
Start date (dd MMM yyyy)	UN UNK 2004
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 2004
Stop date completely unknown	False
Start Month and Year (derived)	JAN 2004
Start Year (derived)	2004
Stop Month and Year (derived)	JAN 2004
Stop Year (derived)	2004

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Folder: Screening

Form: Medical History (10)

Data signed: (b) (4) 06 Apr 2021 15:41:55

Generated On: 09 Jun 2021 14:53:49

Condition	LEFT KNEE ARTHROSCOPY
Start date (dd MMM yyyy)	UN UNK 2005
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 2005
Stop date completely unknown	False
Start Month and Year (derived)	JAN 2005
Start Year (derived)	2005
Stop Month and Year (derived)	JAN 2005
Stop Year (derived)	2005

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Folder: Screening

Form: Medical History (11)

Data signed: (b) (4) 06 Apr 2021 15:41:55

Generated On: 09 Jun 2021 14:53:49

Condition	CHOLECYSTECTOMY
Start date (dd MMM yyyy)	UN UNK 2014
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 2014
Stop date completely unknown	False
Start Month and Year (derived)	JAN 2014
Start Year (derived)	2014
Stop Month and Year (derived)	JAN 2014
Stop Year (derived)	2014

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Folder: Screening

Form: Medical History (12)

Data signed: (b) (4) 06 Apr 2021 15:41:55

Generated On: 09 Jun 2021 14:53:49

Condition	CHOLECYSTITIS
Start date (dd MMM yyyy)	UN UNK 2014
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 2014
Stop date completely unknown	False
Start Month and Year (derived)	JAN 2014
Start Year (derived)	2014
Stop Month and Year (derived)	JAN 2014
Stop Year (derived)	2014

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Folder: Screening

Form: Medical History (13)

Data signed: (b) (4) 06 Apr 2021 15:41:55

Generated On: 09 Jun 2021 14:53:49

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

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Folder: Screening

Form: Medical History (14)

Data signed: (b) (4) 06 Apr 2021 15:41:55

Generated On: 09 Jun 2021 14:53:49

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

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Folder: Screening

Form: Medical History (15)

Data signed: (b) (4) 06 Apr 2021 15:41:55

Generated On: 09 Jun 2021 14:53:49

Condition	CHRONIC OBSTRUCTIVE PULMONARY DISORDER
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)	

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Folder: Screening

Form: Medical History (16)

Data signed: (b) (4) 06 Apr 2021 15:41:55

Generated On: 09 Jun 2021 14:53:49

Condition	ASTHMA
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)	_____

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Folder: Screening

Form: Medical History (17)

Data signed: (b) (4) 06 Apr 2021 15:41:55

Generated On: 09 Jun 2021 14:53:49

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

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Folder: Screening

Form: Medical History (18)

Data signed: (b) (4) 06 Apr 2021 15:41:55

Generated On: 09 Jun 2021 14:53:49

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

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Folder: Screening

Form: Medical History (19)

Data signed: (b) (4) 06 Apr 2021 15:41:55

Generated On: 09 Jun 2021 14:53:49

Condition	DYSLIPIDEMIA
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)	_____

US3032249

Folder: Screening

Form: Medical History (20)

Data signed: (b) (4) 06 Apr 2021 15:41:55

Generated On: 09 Jun 2021 14:53:49

Condition	ESTROGEN DEFICIENCY
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)	_____

US3032249

Folder: Screening

Form: Vital Signs

Data signed: (b) (4) 24 Nov 2020 20:29:25

Generated On: 09 Jun 2021 14:53:49

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (<i>dd MMM yyyy</i>)	19 AUG 2020
Time of assessment (<i>00:00-23:59</i>)	16:57 (24 HR)
Vital Signs Date and Time (derived)	19 AUG 2020 16:57
Height (<i>xxx.x</i>)	160 cm
Weight (<i>xxx.x</i>)	96.6 kg
BMI (<i>xxx.x</i>)	37.73438 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)	

US3032249

Folder: Screening

Form: Physical Examination

Data signed: (b) (4) 28 Sep 2020 17:50:48

Generated On: 09 Jun 2021 14:53:49

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

19 AUG 2020

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

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Folder: Screening

Form: Childbearing Potential

Data signed: (b) (4) 28 Sep 2020 17:50:47

Generated On: 09 Jun 2021 14:53:49

Date of assessment (dd MMM yyyy) 19 AUG 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) UN UNK 1983

Date of surgery unknown False

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

Date of last menstruation unknown False

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Folder: Screening

Form: Risk of Exposure

Data signed: (b) (4) 28 Sep 2020 17:50:48

Generated On: 09 Jun 2021 14:53:49

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

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Folder: Screening

Form: Risk of Exposure

Data signed: (b) (4) 28 Sep 2020 17:50:48

Generated On: 09 Jun 2021 14:53:49

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	

US3032249

Folder: Visit 1 Day 1

Form: Visit Date

Data signed: (b) (4) 28 Sep 2020 17:50:48

Generated On: 09 Jun 2021 14:53:49

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	19 AUG 2020
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	VISIT1

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Folder: Visit 1 Day 1

Form: Randomization

Data signed: (b) (4) 28 Sep 2020 17:50:48

Generated On: 09 Jun 2021 14:53:49

What was the date of randomization? (dd MMM yyyy) 19 AUG 2020

What was the participant's randomization number? 187194

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

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

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

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

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

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

Liver Disease Yes ☐ No ☒

Human Immunodeficiency Virus (HIV) infection Yes ☐ No ☒

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Data signed: (b) (4) 14 Oct 2020 19:37:33

Generated On: 09 Jun 2021 14:53:49

Height	ND - Not Done
Weight	ND - Not Done

US3032249

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 14 Oct 2020 19:37:33

Generated On: 09 Jun 2021 14:53:49

Height	ND - Not Done
Weight	ND - Not Done
Timepoint	Pre-Dose <input checked="" type="radio"/> Post-Dose <input type="radio"/>
Were vital signs assessed?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Date of assessment (dd MMM yyyy)	19 AUG 2020
Time of assessment (00:00-23:59)	16:57 (24 HR)
Vital Signs Date and Time (derived)	19 AUG 2020 16:57
Temperature (xxx.x)	36.6 C
Route of measurement	Oral <input checked="" type="radio"/> Axillary <input type="radio"/> Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	63 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	18 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	135 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	70 mmHg
Diastolic Blood Pressure units	MMHG

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 14 Oct 2020 19:37:33

Generated On: 09 Jun 2021 14:53:49

Height	ND - Not Done
Weight	ND - Not Done
Timepoint	Pre-Dose <input type="radio"/> Post-Dose <input checked="" type="radio"/>
Were vital signs assessed?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Date of assessment (dd MMM yyyy)	19 AUG 2020
Time of assessment (00:00-23:59)	19:11 (24 HR)
Vital Signs Date and Time (derived)	19 AUG 2020 19:11
Temperature (xxx.x)	36.6 C
Route of measurement	Oral <input checked="" type="radio"/> Axillary <input type="radio"/> Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	68 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	128 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	76 mmHg
Diastolic Blood Pressure units	MMHG

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Folder: Visit 1 Day 1

Form: Physical Examination

Data signed: (b) (4) 28 Sep 2020 17:50:48

Generated On: 09 Jun 2021 14:53:49

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

19 AUG 2020

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

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Folder: Visit 1 Day 1

Form: Exposure

Data signed: (b) (4) 28 Sep 2020 17:50:48

Generated On: 09 Jun 2021 14:53:49

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) 19 AUG 2020

What was the treatment time? (00:00-23:59) 18:35 (24 HR)

Treatment Date and Time (derived) 19 AUG 2020 18:35

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

What was the frequency of the study treatment dosing? ONCE

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

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Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Data signed: (b) (4) 28 Sep 2020 17:50:48

Generated On: 09 Jun 2021 14:53:49

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (dd MMM yyyy)	19 AUG 2020
Collection time (00:00-23:59)	17:53 (24 HR)
Collection date and time (derived)	19 AUG 2020 17:53

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Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab

Data signed: (b) (4) 28 Sep 2020 17:50:48

Generated On: 09 Jun 2021 14:53:49

Collection date (dd MMM yyyy)			19 AUG 2020
Lab Test	Was the sample collected?	Collection time (00:00 - 23:59)	Collection date and time (derived)
Nasopharyngeal Swab 1	Yes	17:42	19 AUG 2020 17:42
Nasopharyngeal Swab 2	Yes	17:42	19 AUG 2020 17:42

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Folder: Visit 1 Day 1

Form: Continuing

Data signed: (b) (4) 28 Sep 2020 17:50:48

Generated On: 09 Jun 2021 14:53:49

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3032249

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 14:53:49

TIMEPOINT

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

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.9 °F

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

Yes ☐

No ☒

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

PC Time Stamp

19 AUG 2020 19:14

PC Open Date & Time

19 AUG 2020 18:55

PC Close Date & Time

19 AUG 2020 21:25

US3032249

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 14:53:49

TIMEPOINT

DAY 1, AFTER VACCINATION
(AT HOME)

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

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

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

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

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

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

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

Was **TEMPERATURE** taken? Yes ☒ No ☐

Please record your **TEMPERATURE** in °F 98.0 °F

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

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

PC Time Stamp	19 AUG 2020 22:24
PC Open Date & Time	19 AUG 2020 22:20
PC Close Date & Time	20 AUG 2020 11:59

US3032249

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 14:53:49

TIMEPOINT

DAY 2

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.1 °F

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

Yes ☐

No ☒

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

PC Time Stamp

20 AUG 2020 13:15

PC Open Date & Time

20 AUG 2020 12:00

PC Close Date & Time

21 AUG 2020 11:59

US3032249

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 14:53:49

TIMEPOINT

DAY 3

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.1 °F

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

Yes ☐

No ☒

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

PC Time Stamp

21 AUG 2020 22:28

PC Open Date & Time

21 AUG 2020 12:00

PC Close Date & Time

22 AUG 2020 11:59

US3032249

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 14:53:49

TIMEPOINT

DAY 4

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.8 °F

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

Yes ☐

No ☒

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

PC Time Stamp

22 AUG 2020 19:45

PC Open Date & Time

22 AUG 2020 12:00

PC Close Date & Time

23 AUG 2020 11:59

US3032249

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 14:53:49

TIMEPOINT

DAY 5

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.1 °F

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

Yes ☐

No ☒

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

PC Time Stamp

23 AUG 2020 22:37

PC Open Date & Time

23 AUG 2020 12:00

PC Close Date & Time

24 AUG 2020 11:59

US3032249

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 14:53:49

TIMEPOINT

DAY 6

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.8 °F

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

Yes ☐

No ☒

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

PC Time Stamp

25 AUG 2020 04:49

PC Open Date & Time

24 AUG 2020 12:00

PC Close Date & Time

25 AUG 2020 11:59

US3032249

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 14:53:49

TIMEPOINT

DAY 7

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.4 °F

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

Yes ☐

No ☒

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

PC Time Stamp

25 AUG 2020 23:32

PC Open Date & Time

25 AUG 2020 12:00

PC Close Date & Time

26 AUG 2020 11:59

US3032249

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 14:53:49

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

19 AUG 2020 19:14

PC Open Date & Time

19 AUG 2020 18:55

PC Close Date & Time

19 AUG 2020 21:25

US3032249

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 14:53:49

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

19 AUG 2020 22:25

PC Open Date & Time

19 AUG 2020 22:20

PC Close Date & Time

20 AUG 2020 11:59

US3032249

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 14:53:49

TIMEPOINT

DAY 2

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

20 AUG 2020 13:16

PC Open Date & Time

20 AUG 2020 12:00

PC Close Date & Time

21 AUG 2020 11:59

US3032249

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 14:53:49

TIMEPOINT

DAY 3

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

21 AUG 2020 22:28

PC Open Date & Time

21 AUG 2020 12:00

PC Close Date & Time

22 AUG 2020 11:59

US3032249

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 14:53:49

TIMEPOINT

DAY 4

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

22 AUG 2020 19:46

PC Open Date & Time

22 AUG 2020 12:00

PC Close Date & Time

23 AUG 2020 11:59

US3032249

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 14:53:49

TIMEPOINT

DAY 5

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

23 AUG 2020 22:38

PC Open Date & Time

23 AUG 2020 12:00

PC Close Date & Time

24 AUG 2020 11:59

US3032249

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 14:53:49

TIMEPOINT

DAY 6

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

25 AUG 2020 04:49

PC Open Date & Time

24 AUG 2020 12:00

PC Close Date & Time

25 AUG 2020 11:59

US3032249

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 14:53:49

TIMEPOINT

DAY 7

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

25 AUG 2020 23:32

PC Open Date & Time

25 AUG 2020 12:00

PC Close Date & Time

26 AUG 2020 11:59

US3032249

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 14:53:49

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 ☐

US3032249

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 14:53:49

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

No ☒

Yes ☐

PC Time stamp	19 AUG 2020 19:16
PC Open Date & Time	19 AUG 2020 18:55
PC Close Date & Time	19 AUG 2020 21:25

US3032249

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 14:53:49

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 ☐

US3032249

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 14:53:49

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

No ☒

Yes ☐

PC Time stamp	19 AUG 2020 22:26
PC Open Date & Time	19 AUG 2020 22:20
PC Close Date & Time	20 AUG 2020 11:59

US3032249

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 14:53:49

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 ☒

US3032249

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 14:53:49

Yes <input type="checkbox"/>	
PC Time stamp	20 AUG 2020 13:18
PC Open Date & Time	20 AUG 2020 12:00
PC Close Date & Time	21 AUG 2020 11:59

US3032249

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 14:53:49

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 ☒

US3032249

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 14:53:49

Yes <input type="checkbox"/>	
PC Time stamp	21 AUG 2020 22:29
PC Open Date & Time	21 AUG 2020 12:00
PC Close Date & Time	22 AUG 2020 11:59

US3032249

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 14:53:49

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 ☒

US3032249

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 14:53:49

Yes <input type="checkbox"/>	
PC Time stamp	22 AUG 2020 19:48
PC Open Date & Time	22 AUG 2020 12:00
PC Close Date & Time	23 AUG 2020 11:59

US3032249

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 14:53:49

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 ☒

US3032249

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 14:53:49

Yes <input type="checkbox"/>	
PC Time stamp	23 AUG 2020 22:39
PC Open Date & Time	23 AUG 2020 12:00
PC Close Date & Time	24 AUG 2020 11:59

US3032249

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 14:53:49

TIMEPOINT

DAY 6

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

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

No ☒

PRODUCTION RELEASE (v12.003

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US3032249

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 14:53:49

Yes <input type="checkbox"/>	
PC Time stamp	25 AUG 2020 04:50
PC Open Date & Time	24 AUG 2020 12:00
PC Close Date & Time	25 AUG 2020 11:59

US3032249

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 14:53:49

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 ☒

US3032249

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 14:53:49

Yes <input type="checkbox"/>	
PC Time stamp	25 AUG 2020 23:33
PC Open Date & Time	25 AUG 2020 12:00
PC Close Date & Time	26 AUG 2020 11:59

US3032249

Folder: Safety Call Day 8 (1)

Form: Safety Call

Data signed: (b) (4) 28 Sep 2020 17:50:47

Generated On: 09 Jun 2021 14:53:49

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

26 AUG 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3032249

Folder: Safety Call Day 8 (1)

Form: Continuing

Data signed: (b) (4) 28 Sep 2020 17:50:47

Generated On: 09 Jun 2021 14:53:49

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3032249

Folder: Safety Call Day 15 (1)

Form: Safety Call

Data signed: (b) (4) 28 Sep 2020 17:50:47

Generated On: 09 Jun 2021 14:53:49

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

02 SEP 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3032249

Folder: Safety Call Day 15 (1)

Form: Continuing

Data signed: (b) (4) 28 Sep 2020 17:50:47

Generated On: 09 Jun 2021 14:53:49

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3032249

Folder: Safety Call Day 22 (1)

Form: Safety Call

Data signed: (b) (4) 28 Sep 2020 17:50:47

Generated On: 09 Jun 2021 14:53:49

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

US3032249

Folder: Safety Call Day 22 (1)

Form: Continuing

Data signed: (b) (4) 28 Sep 2020 17:50:47

Generated On: 09 Jun 2021 14:53:49

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3032249

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Data signed: (b) (4) 28 Sep 2020 17:50:48

Generated On: 09 Jun 2021 14:53:49

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	21 SEP 2020
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	VISIT2

US3032249

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 28 Sep 2020 17:50:48

Generated On: 09 Jun 2021 14:53:49

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)	21 SEP 2020
Time of assessment (00:00-23:59)	10:27 (24 HR)
Vital Signs Date and Time (derived)	21 SEP 2020 10:27
Temperature (xxx.x)	36.5 C
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	62 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	123 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	76 mmHg
Diastolic Blood Pressure units	MMHG

US3032249

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 28 Sep 2020 17:50:48

Generated On: 09 Jun 2021 14:53:49

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)	21 SEP 2020
Time of assessment (00:00-23:59)	12:06 (24 HR)
Vital Signs Date and Time (derived)	21 SEP 2020 12:06
Temperature (xxx.x)	36.7 C
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	60 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	14 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	129 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	74 mmHg
Diastolic Blood Pressure units	MMHG

US3032249

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Data signed: (b) (4) 28 Sep 2020 17:50:48

Generated On: 09 Jun 2021 14:53:49

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

21 SEP 2020

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

US3032249

Folder: Visit 2 Day 29 (1)

Form: Exposure

Data signed: (b) (4) 28 Sep 2020 17:50:48

Generated On: 09 Jun 2021 14:53:49

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) 21 SEP 2020

What was the treatment time? (00:00-23:59) 11:35 (24 HR)

Treatment Date and Time (derived) 21 SEP 2020 11:35

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

US3032249

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 28 Sep 2020 17:50:48

Generated On: 09 Jun 2021 14:53:49

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>

Collection date (dd MMM yyyy)	21 SEP 2020
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Collection time (00:00-23:59)	11:02 (24 HR)
-------------------------------	---------------

Collection date and time (derived)	21 SEP 2020 11:02
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US3032249

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab

Data signed: (b) (4) 28 Sep 2020 17:50:48

Generated On: 09 Jun 2021 14:53:49

Collection date (dd MMM yyyy)			21 SEP 2020
Lab Test	Was the sample collected?	Collection time (00:00 - 23:59)	Collection date and time (derived)
Nasopharyngeal Swab 1	Yes	10:42	21 SEP 2020 10:42
Nasopharyngeal Swab 2	No		

US3032249

Folder: Visit 2 Day 29 (1)

Form: Continuing

Data signed: (b) (4) 28 Sep 2020 17:50:48

Generated On: 09 Jun 2021 14:53:49

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3032249

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 14:53:49

TIMEPOINT

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

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.1 °F

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

Yes ☐

No ☒

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

PC Time Stamp

21 SEP 2020 12:08

PC Open Date & Time

21 SEP 2020 11:55

PC Close Date & Time

21 SEP 2020 14:25

US3032249

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 14:53:49

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 97.9 °F

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

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

PC Time Stamp	21 SEP 2020 20:15
PC Open Date & Time	21 SEP 2020 15:20
PC Close Date & Time	22 SEP 2020 11:59

US3032249

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 14:53:49

TIMEPOINT

DAY 2

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.7 °F

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

Yes ☐

No ☒

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

PC Time Stamp

22 SEP 2020 22:09

PC Open Date & Time

22 SEP 2020 12:00

PC Close Date & Time

23 SEP 2020 11:59

US3032249

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 14:53:49

TIMEPOINT

DAY 3

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.7 °F

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

Yes ☐

No ☒

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

PC Time Stamp

23 SEP 2020 19:07

PC Open Date & Time

23 SEP 2020 12:00

PC Close Date & Time

24 SEP 2020 11:59

US3032249

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 14:53:49

TIMEPOINT

DAY 4

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.7 °F

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

Yes ☐

No ☒

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

PC Time Stamp

25 SEP 2020 00:03

PC Open Date & Time

24 SEP 2020 12:00

PC Close Date & Time

25 SEP 2020 11:59

US3032249

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 14:53:49

TIMEPOINT

DAY 5

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.1 °F

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

Yes ☐

No ☒

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

PC Time Stamp

25 SEP 2020 12:03

PC Open Date & Time

25 SEP 2020 12:00

PC Close Date & Time

26 SEP 2020 11:59

US3032249

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 14:53:49

TIMEPOINT

DAY 6

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.8 °F

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

Yes ☐

No ☒

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

PC Time Stamp

26 SEP 2020 12:01

PC Open Date & Time

26 SEP 2020 12:00

PC Close Date & Time

27 SEP 2020 11:59

US3032249

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 14:53:49

TIMEPOINT

DAY 7

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.8 °F

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

Yes ☐

No ☒

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

PC Time Stamp

27 SEP 2020 12:32

PC Open Date & Time

27 SEP 2020 12:00

PC Close Date & Time

28 SEP 2020 11:59

US3032249

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 14:53:49

TIMEPOINT

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

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

21 SEP 2020 12:09

PC Open Date & Time

21 SEP 2020 11:55

PC Close Date & Time

21 SEP 2020 14:25

US3032249

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 14:53:49

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

21 SEP 2020 20:16

PC Open Date & Time

21 SEP 2020 15:20

PC Close Date & Time

22 SEP 2020 11:59

US3032249

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 14:53:49

TIMEPOINT

DAY 2

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

22 SEP 2020 22:10

PC Open Date & Time

22 SEP 2020 12:00

PC Close Date & Time

23 SEP 2020 11:59

US3032249

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 14:53:49

TIMEPOINT

DAY 3

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

23 SEP 2020 19:07

PC Open Date & Time

23 SEP 2020 12:00

PC Close Date & Time

24 SEP 2020 11:59

US3032249

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 14:53:49

TIMEPOINT

DAY 4

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

25 SEP 2020 00:03

PC Open Date & Time

24 SEP 2020 12:00

PC Close Date & Time

25 SEP 2020 11:59

US3032249

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 14:53:49

TIMEPOINT

DAY 5

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

25 SEP 2020 12:03

PC Open Date & Time

25 SEP 2020 12:00

PC Close Date & Time

26 SEP 2020 11:59

US3032249

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 14:53:49

TIMEPOINT

DAY 6

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

26 SEP 2020 12:01

PC Open Date & Time

26 SEP 2020 12:00

PC Close Date & Time

27 SEP 2020 11:59

US3032249

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 14:53:49

TIMEPOINT

DAY 7

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

27 SEP 2020 12:33

PC Open Date & Time

27 SEP 2020 12:00

PC Close Date & Time

28 SEP 2020 11:59

US3032249

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 14:53:49

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 ☐

US3032249

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 14:53:49

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

No ☒

Yes ☐

PC Time stamp	21 SEP 2020 12:10
PC Open Date & Time	21 SEP 2020 11:55
PC Close Date & Time	21 SEP 2020 14:25

US3032249

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 14:53:49

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 ☐

US3032249

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 14:53:49

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

No ☒

Yes ☐

PC Time stamp	21 SEP 2020 20:18
PC Open Date & Time	21 SEP 2020 15:20
PC Close Date & Time	22 SEP 2020 11:59

US3032249

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 14:53:49

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 ☒

US3032249

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 14:53:49

Yes <input type="checkbox"/>	
PC Time stamp	22 SEP 2020 22:11
PC Open Date & Time	22 SEP 2020 12:00
PC Close Date & Time	23 SEP 2020 11:59

US3032249

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 14:53:49

TIMEPOINT

DAY 3

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

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

No ☒

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EAB) (1725)

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US3032249

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 14:53:49

Yes <input type="checkbox"/>	
PC Time stamp	23 SEP 2020 19:08
PC Open Date & Time	23 SEP 2020 12:00
PC Close Date & Time	24 SEP 2020 11:59

US3032249

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 14:53:49

TIMEPOINT

DAY 4

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

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

No ☒

PRODUCTION RELEASE (v12.003

EAB) (1725)

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US3032249

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 14:53:49

Yes <input type="checkbox"/>	
PC Time stamp	25 SEP 2020 00:04
PC Open Date & Time	24 SEP 2020 12:00
PC Close Date & Time	25 SEP 2020 11:59

US3032249

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 14:53:49

TIMEPOINT

DAY 5

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

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

No ☒

PRODUCTION RELEASE (v12.003

EAB) (1725)

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US3032249

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 14:53:49

Yes <input type="checkbox"/>	
PC Time stamp	25 SEP 2020 12:04
PC Open Date & Time	25 SEP 2020 12:00
PC Close Date & Time	26 SEP 2020 11:59

US3032249

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 14:53:49

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 ☒

US3032249

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 14:53:49

Yes <input type="checkbox"/>	
PC Time stamp	26 SEP 2020 12:02
PC Open Date & Time	26 SEP 2020 12:00
PC Close Date & Time	27 SEP 2020 11:59

US3032249

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 14:53:49

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 ☒

US3032249

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 14:53:49

Yes <input type="checkbox"/>	
PC Time stamp	27 SEP 2020 12:35
PC Open Date & Time	27 SEP 2020 12:00
PC Close Date & Time	28 SEP 2020 11:59

US3032249

Folder: Safety Call Day 36 (1)

Form: Safety Call

Data signed: (b) (4) 28 Sep 2020 17:50:47

Generated On: 09 Jun 2021 14:53:49

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

28 SEP 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3032249

Folder: Safety Call Day 36 (1)

Form: Continuing

Data signed: (b) (4) 28 Sep 2020 17:50:47

Generated On: 09 Jun 2021 14:53:49

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3032249

Folder: Safety Call Day 43 (1)

Form: Safety Call

Data signed: (b) (4) 08 Oct 2020 15:43:04

Generated On: 09 Jun 2021 14:53:49

Was Contact Attempted? Yes ☒
No ☐

Date of Contact or Contact Attempt (dd MMM yyyy) 5 OCT 2020

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

Comments

If Contact Not Made, please provide Comments

US3032249

Folder: Safety Call Day 43 (1)

Form: Continuing

Data signed: (b) (4) 08 Oct 2020 15:43:04

Generated On: 09 Jun 2021 14:53:49

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3032249

Folder: Safety Call Day 50 (1)

Form: Safety Call

Data signed: (b) (4) 13 Oct 2020 14:01:29

Generated On: 09 Jun 2021 14:53:49

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

12 OCT 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3032249

Folder: Safety Call Day 50 (1)

Form: Continuing

Data signed: (b) (4) 13 Oct 2020 14:01:29

Generated On: 09 Jun 2021 14:53:49

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3032249

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Data signed: (b) (4) 28 Oct 2020 16:40:09

Generated On: 09 Jun 2021 14:53:49

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	23 OCT 2020
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	VISIT3

US3032249

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Data signed: (b) (4) 28 Oct 2020 16:40:09

Generated On: 09 Jun 2021 14:53:49

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (dd MMM yyyy)	23 OCT 2020
Time of assessment (00:00-23:59)	09:00 (24 HR)
Vital Signs Date and Time (derived)	23 OCT 2020 09:00
Temperature (xxx.x)	36.9 C
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	68 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	126 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	65 mmHg
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

US3032249

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Data signed: (b) (4) 28 Oct 2020 16:40:09

Generated On: 09 Jun 2021 14:53:49

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

23 OCT 2020

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

US3032249

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 28 Oct 2020 16:40:09

Generated On: 09 Jun 2021 14:53:49

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (dd MMM yyyy)	23 OCT 2020
Collection time (00:00-23:59)	09:11 (24 HR)
Collection date and time (derived)	23 OCT 2020 09:11

US3032249

Folder: Visit 3 Day 57 (1)

Form: Continuing

Data signed: (b) (4) 28 Oct 2020 16:40:09

Generated On: 09 Jun 2021 14:53:49

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3032249

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:53:49

TIMEPOINT

DAY 64

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

23 OCT 2020 09:24:59

Patient Cloud Open Date & Time

19 OCT 2020 00:01

Patient Cloud Close Date & Time

23 OCT 2020 23:59

US3032249

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:53:49

TIMEPOINT

DAY 71

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

26 OCT 2020 00:03:44

Patient Cloud Open Date & Time

26 OCT 2020 00:01

Patient Cloud Close Date & Time

30 OCT 2020 23:59

US3032249

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:53:49

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

06 NOV 2020 11:37:29

Patient Cloud Open Date & Time

02 NOV 2020 00:01

Patient Cloud Close Date & Time

06 NOV 2020 23:59

US3032249

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:53:49

TIMEPOINT

DAY 92

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

16 NOV 2020 17:18:43

Patient Cloud Open Date & Time

16 NOV 2020 00:01

Patient Cloud Close Date & Time

20 NOV 2020 23:59

US3032249

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:53:49

TIMEPOINT	DAY 96
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	23 NOV 2020 00:42:03
Patient Cloud Open Date & Time	20 NOV 2020 00:01
Patient Cloud Close Date & Time	24 NOV 2020 23:59

US3032249

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:53:49

TIMEPOINT

DAY 103

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

27 NOV 2020 01:09:47

Patient Cloud Open Date & Time

27 NOV 2020 00:01

Patient Cloud Close Date & Time

01 DEC 2020 23:59

US3032249

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:53:49

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 ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

04 DEC 2020 00:02:20

Patient Cloud Open Date & Time

04 DEC 2020 00:01

Patient Cloud Close Date & Time

08 DEC 2020 23:59

US3032249

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:53:49

TIMEPOINT	DAY 117
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	11 DEC 2020 23:37:18
Patient Cloud Open Date & Time	11 DEC 2020 00:01
Patient Cloud Close Date & Time	15 DEC 2020 23:59

US3032249

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:53:49

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

Date and time of submission

19 DEC 2020 08:58:25

Patient Cloud Open Date & Time

18 DEC 2020 00:01

Patient Cloud Close Date & Time

22 DEC 2020 23:59

US3032249

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:53:49

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

US3032249

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:53:49

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	25 DEC 2020 00:01
Patient Cloud Close Date & Time	29 DEC 2020 23:59

US3032249

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:53:49

TIMEPOINT

DAY 138

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

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

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

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

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

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

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

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

US3032249

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:53:49

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

01 JAN 2021 00:01

[Patient Cloud Close Date & Time](#)

05 JAN 2021 23:59

US3032249

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:53:49

TIMEPOINT

DAY 145

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

08 JAN 2021 00:02:53

Patient Cloud Open Date & Time

08 JAN 2021 00:01

Patient Cloud Close Date & Time

12 JAN 2021 23:59

US3032249

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:53:49

TIMEPOINT

DAY 152

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

15 JAN 2021 02:43:14

Patient Cloud Open Date & Time

15 JAN 2021 00:01

Patient Cloud Close Date & Time

19 JAN 2021 23:59

US3032249

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:53:49

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

Date and time of submission

23 JAN 2021 14:23:35

Patient Cloud Open Date & Time

22 JAN 2021 00:01

Patient Cloud Close Date & Time

26 JAN 2021 23:59

US3032249

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:53:49

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

Date and time of submission

29 JAN 2021 00:26:10

Patient Cloud Open Date & Time

29 JAN 2021 00:01

Patient Cloud Close Date & Time

02 FEB 2021 23:59

US3032249

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:53:49

TIMEPOINT	DAY 173
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="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 type="radio"/> Yes <input checked="" 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)	True
Chills	True
Cough	True
Shortness of breath	True
Difficulty breathing	False
Fatigue	True
Muscle aches	False
Body aches	False
Headache	False
New loss of taste	False
New loss of smell	False
Sore throat	True
Congestion	True
Runny nose	False
Nausea	False
Vomiting	False
Diarrhea	False
Please contact your study clinic immediately. Click below to confirm that you have read this message 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 had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input checked="" type="radio"/>

US3032249

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:53:49

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

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



Date and time of submission

05 FEB 2021 22:01:59

Patient Cloud Open Date & Time

05 FEB 2021 00:01

Patient Cloud Close Date & Time

09 FEB 2021 23:59

US3032249

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:53:49

TIMEPOINT	DAY 180
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input 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 type="radio"/> Yes <input checked="" 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)	True
Chills	True
Cough	True
Shortness of breath	True
Difficulty breathing	True
Fatigue	True
Muscle aches	False
Body aches	True
Headache	True
New loss of taste	True
New loss of smell	True
Sore throat	True
Congestion	True
Runny nose	True
Nausea	True
Vomiting	False
Diarrhea	True
Please contact your study clinic immediately. Click below to confirm that you have read this message 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 had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input checked="" type="radio"/>

US3032249

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:53:49

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

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



Date and time of submission

12 FEB 2021 19:26:33

Patient Cloud Open Date & Time

12 FEB 2021 00:01

Patient Cloud Close Date & Time

16 FEB 2021 23:59

US3032249

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:53:49

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

Date and time of submission

19 FEB 2021 12:03:25

Patient Cloud Open Date & Time

19 FEB 2021 00:01

Patient Cloud Close Date & Time

23 FEB 2021 23:59

US3032249

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:53:49

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

Date and time of submission

27 FEB 2021 02:33:53

Patient Cloud Open Date & Time

26 FEB 2021 00:01

Patient Cloud Close Date & Time

02 MAR 2021 23:59

US3032249

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:53:49

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

US3032249

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:53:49

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

[Patient Cloud Open Date & Time](#)

05 MAR 2021 00:01

[Patient Cloud Close Date & Time](#)

09 MAR 2021 23:59

US3032249

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:53:49

TIMEPOINT

DAY 208

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

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

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

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

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

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

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

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

US3032249

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:53:49

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

Date and time of submission	
Patient Cloud Open Date & Time	12 MAR 2021 00:01
Patient Cloud Close Date & Time	16 MAR 2021 23:59

US3032249

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:53:49

TIMEPOINT	DAY 215
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="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 checked="" type="radio"/> Yes <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 checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input checked="" type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input checked="" type="radio"/>
Date and time of submission	21 MAR 2021 16:34:26
Patient Cloud Open Date & Time	19 MAR 2021 00:01
Patient Cloud Close Date & Time	23 MAR 2021 23:59

US3032249

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:53:49

TIMEPOINT

DAY 222

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

29 MAR 2021 15:13:08

Patient Cloud Open Date & Time

26 MAR 2021 00:01

Patient Cloud Close Date & Time

30 MAR 2021 23:59

US3032249

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:53:49

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 ☒

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

02 APR 2021 00:02:08

Patient Cloud Open Date & Time

02 APR 2021 00:01

Patient Cloud Close Date & Time

06 APR 2021 23:59

US3032249

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:53:49

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 ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

09 APR 2021 00:02:06

Patient Cloud Open Date & Time

09 APR 2021 00:01

Patient Cloud Close Date & Time

13 APR 2021 23:59

US3032249

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:53:49

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

20 APR 2021 11:51:26

Patient Cloud Open Date & Time

16 APR 2021 00:01

Patient Cloud Close Date & Time

20 APR 2021 23:59

US3032249

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:53:49

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

23 APR 2021 00:28:35

Patient Cloud Open Date & Time

23 APR 2021 00:01

Patient Cloud Close Date & Time

27 APR 2021 23:59

US3032249

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:53:49

TIMEPOINT

DAY 257

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

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

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

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

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

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

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

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

US3032249

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:53:49

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

[Patient Cloud Open Date & Time](#)

30 APR 2021 00:01

[Patient Cloud Close Date & Time](#)

04 MAY 2021 23:59

US3032249

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:53:49

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°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 ☐

US3032249

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:53:49

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	07 MAY 2021 00:01
Patient Cloud Close Date & Time	11 MAY 2021 23:59

US3032249

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:53:49

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 ☐

US3032249

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:53:49

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

[Patient Cloud Open Date & Time](#)

14 MAY 2021 00:01

[Patient Cloud Close Date & Time](#)

18 MAY 2021 23:59

US3032249

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:53:49

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 ☐

US3032249

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:53:49

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

[Patient Cloud Open Date & Time](#)

21 MAY 2021 00:01

[Patient Cloud Close Date & Time](#)

25 MAY 2021 23:59

US3032249

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:53:49

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

US3032249

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:53:49

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

[Patient Cloud Open Date & Time](#)

28 MAY 2021 00:01

[Patient Cloud Close Date & Time](#)

01 JUN 2021 23:59

US3032249

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:53:49

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

US3032249

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:53:49

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

[Patient Cloud Open Date & Time](#)

04 JUN 2021 00:01

[Patient Cloud Close Date & Time](#)

08 JUN 2021 23:59

US3032249

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:53:49

TIMEPOINT	DAY 299
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

US3032249

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:53:49

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

[Patient Cloud Open Date & Time](#)

11 JUN 2021 00:01

[Patient Cloud Close Date & Time](#)

15 JUN 2021 23:59

US3032249

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:53:49

TIMEPOINT

DAY 306

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3032249

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:53:49

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

US3032249

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:53:49

TIMEPOINT

DAY 313

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

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

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

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

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

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

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

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

US3032249

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:53:49

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

[Patient Cloud Open Date & Time](#)

25 JUN 2021 00:01

[Patient Cloud Close Date & Time](#)

29 JUN 2021 23:59

US3032249

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:53:49

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

US3032249

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:53:49

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

[Patient Cloud Open Date & Time](#)

02 JUL 2021 00:01

[Patient Cloud Close Date & Time](#)

06 JUL 2021 23:59

US3032249

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:53:49

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

US3032249

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:53:49

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	09 JUL 2021 00:01
Patient Cloud Close Date & Time	13 JUL 2021 23:59

US3032249

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:53:49

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 ☐

US3032249

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:53:49

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	16 JUL 2021 00:01
Patient Cloud Close Date & Time	20 JUL 2021 23:59

US3032249

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:53:49

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

US3032249

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:53:49

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

[Patient Cloud Open Date & Time](#)

23 JUL 2021 00:01

[Patient Cloud Close Date & Time](#)

27 JUL 2021 23:59

US3032249

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:53:49

TIMEPOINT	DAY 348
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

US3032249

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:53:49

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

[Patient Cloud Open Date & Time](#)

30 JUL 2021 00:01

[Patient Cloud Close Date & Time](#)

03 AUG 2021 23:59

US3032249

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:53:49

TIMEPOINT

DAY 355

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

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

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

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

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

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

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

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

US3032249

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:53:49

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

[Patient Cloud Open Date & Time](#)

06 AUG 2021 00:01

[Patient Cloud Close Date & Time](#)

10 AUG 2021 23:59

US3032249

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:53:49

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 ☐

US3032249

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:53:49

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

Patient Cloud Open Date & Time	13 AUG 2021 00:01
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Patient Cloud Close Date & Time	17 AUG 2021 23:59
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US3032249

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:53:49

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 ☐

US3032249

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:53:49

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

[Patient Cloud Open Date & Time](#)

20 AUG 2021 00:01

[Patient Cloud Close Date & Time](#)

24 AUG 2021 23:59

US3032249

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:53:49

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 ☐

US3032249

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:53:49

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

[Patient Cloud Open Date & Time](#)

27 AUG 2021 00:01

[Patient Cloud Close Date & Time](#)

31 AUG 2021 23:59

US3032249

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:53:49

TIMEPOINT

DAY 383

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3032249

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:53:49

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

US3032249

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:53:49

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

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 ☐

US3032249

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:53:49

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

US3032249

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:53:49

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 ☐

US3032249

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:53:49

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

Date and time of submission	
Patient Cloud Open Date & Time	17 SEP 2021 00:01
Patient Cloud Close Date & Time	21 SEP 2021 23:59

US3032249

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:53:49

TIMEPOINT	DAY 404
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

US3032249

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:53:49

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

[Patient Cloud Open Date & Time](#)

24 SEP 2021 00:01

[Patient Cloud Close Date & Time](#)

28 SEP 2021 23:59

US3032249

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:53:49

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

US3032249

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:53:49

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	01 OCT 2021 00:01
Patient Cloud Close Date & Time	05 OCT 2021 23:59

US3032249

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:53:49

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 ☐

US3032249

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:53:49

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

[Patient Cloud Open Date & Time](#)

08 OCT 2021 00:01

[Patient Cloud Close Date & Time](#)

12 OCT 2021 23:59

US3032249

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:53:49

TIMEPOINT	DAY 425
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

US3032249

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:53:49

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

Patient Cloud Open Date & Time	15 OCT 2021 00:01
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Patient Cloud Close Date & Time	19 OCT 2021 23:59
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US3032249

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:53:49

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

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 ☐

US3032249

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:53:49

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

Patient Cloud Open Date & Time	22 OCT 2021 00:01
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Patient Cloud Close Date & Time	26 OCT 2021 23:59
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US3032249

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:53:49

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 ☐

US3032249

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:53:49

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	29 OCT 2021 00:01
Patient Cloud Close Date & Time	02 NOV 2021 23:59

US3032249

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:53:49

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

US3032249

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:53:49

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

[Patient Cloud Open Date & Time](#)

05 NOV 2021 00:01

[Patient Cloud Close Date & Time](#)

09 NOV 2021 23:59

US3032249

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:53:49

TIMEPOINT

DAY 453

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3032249

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:53:49

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

[Patient Cloud Open Date & Time](#)

12 NOV 2021 00:01

[Patient Cloud Close Date & Time](#)

16 NOV 2021 23:59

US3032249

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:53:49

TIMEPOINT	DAY 460
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

US3032249

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:53:49

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

[Patient Cloud Open Date & Time](#)

19 NOV 2021 00:01

[Patient Cloud Close Date & Time](#)

23 NOV 2021 23:59

US3032249

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:53:49

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

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 ☐

US3032249

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:53:49

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

US3032249

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:53:49

TIMEPOINT

DAY 474

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3032249

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:53:49

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

[Patient Cloud Open Date & Time](#)

03 DEC 2021 00:01

[Patient Cloud Close Date & Time](#)

07 DEC 2021 23:59

US3032249

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:53:49

TIMEPOINT

DAY 481

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3032249

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:53:49

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

Date and time of submission	
Patient Cloud Open Date & Time	10 DEC 2021 00:01
Patient Cloud Close Date & Time	14 DEC 2021 23:59

US3032249

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:53:49

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

US3032249

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:53:49

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

US3032249

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:53:49

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

US3032249

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:53:49

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

US3032249

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:53:49

TIMEPOINT

DAY 502

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3032249

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:53:49

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

[Patient Cloud Open Date & Time](#)

31 DEC 2021 00:01

[Patient Cloud Close Date & Time](#)

04 JAN 2022 23:59

US3032249

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:53:49

TIMEPOINT

DAY 509

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3032249

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:53:49

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

[Patient Cloud Open Date & Time](#)

07 JAN 2022 00:01

[Patient Cloud Close Date & Time](#)

11 JAN 2022 23:59

US3032249

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:53:49

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

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 ☐

US3032249

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:53:49

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	14 JAN 2022 00:01
Patient Cloud Close Date & Time	18 JAN 2022 23:59

US3032249

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:53:49

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 ☐

US3032249

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:53:49

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

US3032249

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:53:49

TIMEPOINT

DAY 530

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3032249

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:53:49

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

[Patient Cloud Open Date & Time](#)

28 JAN 2022 00:01

[Patient Cloud Close Date & Time](#)

01 FEB 2022 23:59

US3032249

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:53:49

TIMEPOINT

DAY 537

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

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

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

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

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

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

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

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

US3032249

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:53:49

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

[Patient Cloud Open Date & Time](#)

04 FEB 2022 00:01

[Patient Cloud Close Date & Time](#)

08 FEB 2022 23:59

US3032249

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:53:49

TIMEPOINT

DAY 544

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3032249

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:53:49

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

[Patient Cloud Open Date & Time](#)

11 FEB 2022 00:01

[Patient Cloud Close Date & Time](#)

15 FEB 2022 23:59

US3032249

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:53:49

TIMEPOINT

DAY 551

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

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

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

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

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

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

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

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

US3032249

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:53:49

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

[Patient Cloud Open Date & Time](#)

18 FEB 2022 00:01

[Patient Cloud Close Date & Time](#)

22 FEB 2022 23:59

US3032249

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:53:49

TIMEPOINT

DAY 558

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

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

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

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

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

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

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

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

US3032249

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:53:49

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

[Patient Cloud Open Date & Time](#)

25 FEB 2022 00:01

[Patient Cloud Close Date & Time](#)

01 MAR 2022 23:59

US3032249

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:53:49

TIMEPOINT

DAY 565

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

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

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

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

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

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

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

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

US3032249

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:53:49

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

[Patient Cloud Open Date & Time](#)

04 MAR 2022 00:01

[Patient Cloud Close Date & Time](#)

08 MAR 2022 23:59

US3032249

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:53:49

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 ☐

US3032249

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:53:49

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

[Patient Cloud Open Date & Time](#)

11 MAR 2022 00:01

[Patient Cloud Close Date & Time](#)

15 MAR 2022 23:59

US3032249

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:53:49

TIMEPOINT

DAY 579

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3032249

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:53:49

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

[Patient Cloud Open Date & Time](#)

18 MAR 2022 00:01

[Patient Cloud Close Date & Time](#)

22 MAR 2022 23:59

US3032249

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:53:49

TIMEPOINT

DAY 586

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3032249

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:53:49

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

[Patient Cloud Open Date & Time](#)

25 MAR 2022 00:01

[Patient Cloud Close Date & Time](#)

29 MAR 2022 23:59

US3032249

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:53:49

TIMEPOINT

DAY 593

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3032249

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:53:49

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

[Patient Cloud Open Date & Time](#)

01 APR 2022 00:01

[Patient Cloud Close Date & Time](#)

05 APR 2022 23:59

US3032249

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:53:49

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

US3032249

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:53:49

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	08 APR 2022 00:01
Patient Cloud Close Date & Time	12 APR 2022 23:59

US3032249

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:53:49

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 ☐

US3032249

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:53:49

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

15 APR 2022 00:01

[Patient Cloud Close Date & Time](#)

19 APR 2022 23:59

US3032249

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:53:49

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

US3032249

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:53:49

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

[Patient Cloud Open Date & Time](#)

22 APR 2022 00:01

[Patient Cloud Close Date & Time](#)

26 APR 2022 23:59

US3032249

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:53:49

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

US3032249

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:53:49

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

[Patient Cloud Open Date & Time](#)

29 APR 2022 00:01

[Patient Cloud Close Date & Time](#)

03 MAY 2022 23:59

US3032249

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:53:49

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

US3032249

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:53:49

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

[Patient Cloud Open Date & Time](#)

06 MAY 2022 00:01

[Patient Cloud Close Date & Time](#)

10 MAY 2022 23:59

US3032249

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:53:49

TIMEPOINT

DAY 635

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3032249

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:53:49

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

[Patient Cloud Open Date & Time](#)

13 MAY 2022 00:01

[Patient Cloud Close Date & Time](#)

17 MAY 2022 23:59

US3032249

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:53:49

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

US3032249

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:53:49

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

[Patient Cloud Open Date & Time](#)

20 MAY 2022 00:01

[Patient Cloud Close Date & Time](#)

24 MAY 2022 23:59

US3032249

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:53:49

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 ☐

US3032249

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:53:49

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

[Patient Cloud Open Date & Time](#)

27 MAY 2022 00:01

[Patient Cloud Close Date & Time](#)

31 MAY 2022 23:59

US3032249

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:53:49

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 ☐

US3032249

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:53:49

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

03 JUN 2022 00:01

[Patient Cloud Close Date & Time](#)

07 JUN 2022 23:59

US3032249

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:53:49

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 ☐

US3032249

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:53:49

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

[Patient Cloud Open Date & Time](#)

10 JUN 2022 00:01

[Patient Cloud Close Date & Time](#)

14 JUN 2022 23:59

US3032249

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:53:49

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

US3032249

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:53:49

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

[Patient Cloud Open Date & Time](#)

17 JUN 2022 00:01

[Patient Cloud Close Date & Time](#)

21 JUN 2022 23:59

US3032249

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:53:49

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°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 ☐

US3032249

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:53:49

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

[Patient Cloud Close Date & Time](#)

28 JUN 2022 23:59

US3032249

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:53:49

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

US3032249

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:53:49

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

[Patient Cloud Open Date & Time](#)

01 JUL 2022 00:01

[Patient Cloud Close Date & Time](#)

05 JUL 2022 23:59

US3032249

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:53:49

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

US3032249

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:53:49

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

[Patient Cloud Close Date & Time](#)

12 JUL 2022 23:59

US3032249

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:53:49

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

US3032249

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:53:49

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	15 JUL 2022 00:01
Patient Cloud Close Date & Time	19 JUL 2022 23:59

US3032249

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:53:49

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

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 ☐

US3032249

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:53:49

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	22 JUL 2022 00:01
Patient Cloud Close Date & Time	26 JUL 2022 23:59

US3032249

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:53:49

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

US3032249

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:53:49

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

[Patient Cloud Open Date & Time](#)

29 JUL 2022 00:01

[Patient Cloud Close Date & Time](#)

02 AUG 2022 23:59

US3032249

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:53:49

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

US3032249

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:53:49

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

[Patient Cloud Open Date & Time](#)

05 AUG 2022 00:01

[Patient Cloud Close Date & Time](#)

09 AUG 2022 23:59

US3032249

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:53:49

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

US3032249

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:53:49

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

[Patient Cloud Open Date & Time](#)

12 AUG 2022 00:01

[Patient Cloud Close Date & Time](#)

16 AUG 2022 23:59

US3032249

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:53:49

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

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 ☐

US3032249

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:53:49

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

[Patient Cloud Open Date & Time](#)

19 AUG 2022 00:01

[Patient Cloud Close Date & Time](#)

23 AUG 2022 23:59

US3032249

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:53:49

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

US3032249

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:53:49

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

Patient Cloud Open Date & Time	26 AUG 2022 00:01
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Patient Cloud Close Date & Time	30 AUG 2022 23:59
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US3032249

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:53:49

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 ☐

US3032249

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:53:49

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

[Patient Cloud Open Date & Time](#)

02 SEP 2022 00:01

[Patient Cloud Close Date & Time](#)

06 SEP 2022 23:59

US3032249

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:53:49

TIMEPOINT

DAY 754

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

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

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

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

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

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

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

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

US3032249

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:53:49

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	09 SEP 2022 00:01
Patient Cloud Close Date & Time	13 SEP 2022 23:59

US3032249

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:53:49

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

US3032249

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:53:49

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

16 SEP 2022 00:01

[Patient Cloud Close Date & Time](#)

20 SEP 2022 23:59

US3032249

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:53:49

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

US3032249

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:53:49

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

23 SEP 2022 00:01

[Patient Cloud Close Date & Time](#)

27 SEP 2022 23:59

US3032249

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:53:49

TIMEPOINT	DAY 775
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>

US3032249

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:53:49

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

Date and time of submission	
Patient Cloud Open Date & Time	30 SEP 2022 00:01
Patient Cloud Close Date & Time	04 OCT 2022 23:59

US3032249

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:53:49

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 ☐

US3032249

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:53:49

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

Date and time of submission	
Patient Cloud Open Date & Time	07 OCT 2022 00:01
Patient Cloud Close Date & Time	11 OCT 2022 23:59

US3032249

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:53:49

TIMEPOINT

DAY 789

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3032249

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:53:49

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

Date and time of submission	
Patient Cloud Open Date & Time	14 OCT 2022 00:01
Patient Cloud Close Date & Time	18 OCT 2022 23:59

US3032249

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:53:49

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

US3032249

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:53:49

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

Date and time of submission	
Patient Cloud Open Date & Time	21 OCT 2022 00:01
Patient Cloud Close Date & Time	25 OCT 2022 23:59

US3032249

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection_ Dermal Filler eDiary

Generated On: 09 Jun 2021 14:53:49

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		21 MAR 2021 18:27:05

US3032249

Folder: Safety Call Day 85 (1)

Form: Safety Call

Data signed: (b) (4) 08 Dec 2020 19:48:23

Generated On: 09 Jun 2021 14:53:49

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

13 NOV 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3032249

Folder: Safety Call Day 85 (1)

Form: Continuing

Data signed: (b) (4) 08 Dec 2020 19:48:23

Generated On: 09 Jun 2021 14:53:49

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3032249

Folder: Safety Call Day 119 (1)

Form: Safety Call

Data signed: (b) (4) 23 Dec 2020 15:55:06

Generated On: 09 Jun 2021 14:53:49

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

16 DEC 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3032249

Folder: Safety Call Day 119 (1)

Form: Continuing

Data signed: (b) (4) 23 Dec 2020 15:55:06

Generated On: 09 Jun 2021 14:53:49

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3032249

Folder: Safety Call Day 149 (1)

Form: Safety Call

Data signed: (b) (4) 10 Mar 2021 15:38:13

Generated On: 09 Jun 2021 14:53:49

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

18 JAN 2021

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3032249

Folder: Safety Call Day 149 (1)

Form: Continuing

Data signed: (b) (4) 10 Mar 2021 15:38:13

Generated On: 09 Jun 2021 14:53:49

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3032249

Folder: Safety Call Day 179 (1)

Form: Safety Call

Data signed: (b) (4) 10 Mar 2021 15:38:13

Generated On: 09 Jun 2021 14:53:49

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

15 FEB 2021

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3032249

Folder: Safety Call Day 179 (1)

Form: Continuing

Data signed: (b) (4) 10 Mar 2021 15:38:13

Generated On: 09 Jun 2021 14:53:49

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3032249

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Data signed: (b) (4) 06 Apr 2021 15:41:55

Generated On: 09 Jun 2021 14:53:49

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

Visit date (dd MMM yyyy)	22 MAR 2021
--------------------------	-------------

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

Folder OID	VISIT4
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US3032249

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Data signed: (b) (4) 06 Apr 2021 15:41:55

Generated On: 09 Jun 2021 14:53:49

Were vital signs assessed? Yes ☐
No ☒

Date of assessment (dd MMM yyyy) _____

Time of assessment (00:00-23:59) _____

Vital Signs Date and Time (derived) _____

Temperature (xxx.x) _____

Route of measurement Oral ☐
Axillary ☐
Other ☐

If Other, specify _____

Pulse (xxx) _____

Pulse units _____

Respiratory Rate (xxx) _____

Respiratory Rate units _____

Systolic Blood Pressure (xxx) _____

Systolic Blood Pressure units _____

Diastolic Blood Pressure (xxx) _____

Diastolic Blood Pressure units _____

Height (derived) _____

Weight (derived) _____

US3032249

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Data signed: (b) (4) 06 Apr 2021 15:41:55

Generated On: 09 Jun 2021 14:53:49

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.

US3032249

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 06 Apr 2021 15:41:55

Generated On: 09 Jun 2021 14:53:49

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>

Collection date (dd MMM yyyy)	22 MAR 2021
-------------------------------	-------------

Collection time (00:00-23:59)	17:09 (24 HR)
-------------------------------	---------------

Collection date and time (derived)	22 MAR 2021 17:09
------------------------------------	-------------------

US3032249

Folder: Visit 4 Day 209 (1)

Form: Continuing

Data signed: (b) (4) 06 Apr 2021 15:41:55

Generated On: 09 Jun 2021 14:53:49

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3032249

Folder: Safety Call Day 239 (1)

Form: Safety Call

Generated On: 09 Jun 2021 14:53:49

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

US3032249

Folder: Safety Call Day 239 (1)

Form: Continuing

Generated On: 09 Jun 2021 14:53:49

Is the participant continuing to the next visit?

Yes ☐

No ☐

Continuing Flag

US3032249

Folder: Covid-19 Assessment 08 Feb 2021

Form: COVID-19 Contact

Data signed: (b) (4) 04 Mar 2021 16:04:28

Generated On: 09 Jun 2021 14:53:49

Date of Contact	08 FEB 2021
Time of Contact	19:12
Date and Time of Contact (derived)	08 FEB 2021 19:12
Type of Contact	<div>Clinic Visit - Scheduled<input type="checkbox"/></div> <div>Clinical Visit - Unscheduled<input type="checkbox"/></div> <div>Safety Call<input type="checkbox"/></div> <div>Convalescent Tele-visit<input checked="" type="checkbox"/></div>
Has the subject reported symptoms of SARS-COV-2?	<div>Yes<input checked="" type="checkbox"/></div> <div>No<input type="checkbox"/></div>

US3032249

Folder: Covid-19 Assessment 08 Feb 2021

Form: Symptom Log (1)

Data signed: (b) (4) 06 Apr 2021 15:41:51

Generated On: 09 Jun 2021 14:53:49

Symptom Day

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

US3032249

Folder: Covid-19 Assessment 08 Feb 2021

Form: Symptom Log (1)

Data signed: (b) (4) 06 Apr 2021 15:41:51

Generated On: 09 Jun 2021 14:53:49

	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	2 FEB 2021
------	------------

Assessment Not Done	True
---------------------	------

O2 Saturation	<input type="text"/>
---------------	----------------------

O2 Saturation Units	<input type="text"/>
---------------------	----------------------

Temperature	<input type="text"/>
-------------	----------------------

Chills	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input 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"/>

US3032249

Folder: Covid-19 Assessment 08 Feb 2021

Form: Symptom Log (1)

Data signed: (b) (4) 06 Apr 2021 15:41:51

Generated On: 09 Jun 2021 14:53:49

	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"/>

PRODUCTION RELEASE (v12.003

EAB) (1725)

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US3032249

Folder: Covid-19 Assessment 08 Feb 2021

Form: Symptom Log (1)

Data signed: (b) (4) 06 Apr 2021 15:41:51

Generated On: 09 Jun 2021 14:53:49

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

US3032249

Folder: Covid-19 Assessment 08 Feb 2021

Form: Symptom Log (2)

Data signed: (b) (4) 06 Apr 2021 15:41:51

Generated On: 09 Jun 2021 14:53:49

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"/>

US3032249

Folder: Covid-19 Assessment 08 Feb 2021

Form: Symptom Log (2)

Data signed: (b) (4) 06 Apr 2021 15:41:51

Generated On: 09 Jun 2021 14:53:49

	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	3 FEB 2021
------	------------

Assessment Not Done	True
---------------------	------

O2 Saturation	<input type="text"/>
---------------	----------------------

O2 Saturation Units	<input type="text"/>
---------------------	----------------------

Temperature	<input type="text"/>
-------------	----------------------

Chills	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input 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"/>

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Form: Symptom Log (2)

Data signed: (b) (4) 06 Apr 2021 15:41:51

Generated On: 09 Jun 2021 14:53:49

	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"/>

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Folder: Covid-19 Assessment 08 Feb 2021

Form: Symptom Log (2)

Data signed: (b) (4) 06 Apr 2021 15:41:51

Generated On: 09 Jun 2021 14:53:49

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

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Folder: Covid-19 Assessment 08 Feb 2021

Form: Symptom Log (3)

Data signed: (b) (4) 06 Apr 2021 15:41:51

Generated On: 09 Jun 2021 14:53:49

Symptom Day

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

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Folder: Covid-19 Assessment 08 Feb 2021

Form: Symptom Log (3)

Data signed: (b) (4) 06 Apr 2021 15:41:51

Generated On: 09 Jun 2021 14:53:49

	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	4 FEB 2021
------	------------

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"/>

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Form: Symptom Log (3)

Data signed: (b) (4) 06 Apr 2021 15:41:51

Generated On: 09 Jun 2021 14:53:49

	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"/>

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Folder: Covid-19 Assessment 08 Feb 2021

Form: Symptom Log (3)

Data signed: (b) (4) 06 Apr 2021 15:41:51

Generated On: 09 Jun 2021 14:53:49

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

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Folder: Covid-19 Assessment 08 Feb 2021

Form: Symptom Log (4)

Data signed: (b) (4) 06 Apr 2021 15:41:51

Generated On: 09 Jun 2021 14:53:49

Symptom Day

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

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Form: Symptom Log (4)

Data signed: (b) (4) 06 Apr 2021 15:41:51

Generated On: 09 Jun 2021 14:53:49

	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	5 FEB 2021
------	------------

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"/>

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Form: Symptom Log (4)

Data signed: (b) (4) 06 Apr 2021 15:41:51

Generated On: 09 Jun 2021 14:53:49

	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"/>

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Folder: Covid-19 Assessment 08 Feb 2021

Form: Symptom Log (4)

Data signed: (b) (4) 06 Apr 2021 15:41:51

Generated On: 09 Jun 2021 14:53:49

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

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Form: Symptom Log (5)

Data signed: (b) (4) 06 Apr 2021 15:41:51

Generated On: 09 Jun 2021 14:53:49

Symptom Day

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

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Form: Symptom Log (5)

Data signed: (b) (4) 06 Apr 2021 15:41:51

Generated On: 09 Jun 2021 14:53:49

	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	6 FEB 2021
------	------------

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"/>

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Form: Symptom Log (5)

Data signed: (b) (4) 06 Apr 2021 15:41:51

Generated On: 09 Jun 2021 14:53:49

	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"/>

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Folder: Covid-19 Assessment 08 Feb 2021

Form: Symptom Log (5)

Data signed: (b) (4) 06 Apr 2021 15:41:51

Generated On: 09 Jun 2021 14:53:49

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

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Folder: Covid-19 Assessment 08 Feb 2021

Form: Symptom Log (6)

Data signed: (b) (4) 06 Apr 2021 15:41:51

Generated On: 09 Jun 2021 14:53:49

Symptom Day

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

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Form: Symptom Log (6)

Data signed: (b) (4) 06 Apr 2021 15:41:51

Generated On: 09 Jun 2021 14:53:49

	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	7 FEB 2021
------	------------

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"/>

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Folder: Covid-19 Assessment 08 Feb 2021

Form: Symptom Log (6)

Data signed: (b) (4) 06 Apr 2021 15:41:51

Generated On: 09 Jun 2021 14:53:49

	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"/>

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EAB) (1725)

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Folder: Covid-19 Assessment 08 Feb 2021

Form: Symptom Log (6)

Data signed: (b) (4) 06 Apr 2021 15:41:51

Generated On: 09 Jun 2021 14:53:49

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

US3032249

Folder: Covid-19 Assessment 08 Feb 2021

Form: Symptom Log (7)

Data signed: (b) (4) 06 Apr 2021 15:41:51

Generated On: 09 Jun 2021 14:53:49

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"/>

US3032249

Folder: Covid-19 Assessment 08 Feb 2021

Form: Symptom Log (7)

Data signed: (b) (4) 06 Apr 2021 15:41:51

Generated On: 09 Jun 2021 14:53:49

	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	8 FEB 2021	
Assessment Not Done	False	
O2 Saturation	ND - Not Done	
O2 Saturation Units	%	
Temperature	ND - Not Done	
Chills	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input checked="" type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Cough	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input checked="" type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Shortness of Breath	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input checked="" type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Difficulty Breathing	None	<input type="checkbox"/>
	Mild	<input checked="" type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>

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EAB) (1725)

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Folder: Covid-19 Assessment 08 Feb 2021

Form: Symptom Log (7)

Data signed: (b) (4) 06 Apr 2021 15:41:51

Generated On: 09 Jun 2021 14:53:49

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

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Folder: Covid-19 Assessment 08 Feb 2021

Form: Symptom Log (7)

Data signed: (b) (4) 06 Apr 2021 15:41:51

Generated On: 09 Jun 2021 14:53:49

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

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Folder: Covid-19 Assessment 08 Feb 2021

Form: Symptom Log (8)

Data signed: (b) (4) 06 Apr 2021 15:41:51

Generated On: 09 Jun 2021 14:53:49

Symptom Day

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

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Folder: Covid-19 Assessment 08 Feb 2021

Form: Symptom Log (8)

Data signed: (b) (4) 06 Apr 2021 15:41:51

Generated On: 09 Jun 2021 14:53:49

	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	9 FEB 2021
------	------------

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"/>

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EAB) (1725)

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Folder: Covid-19 Assessment 08 Feb 2021

Form: Symptom Log (8)

Data signed: (b) (4) 06 Apr 2021 15:41:51

Generated On: 09 Jun 2021 14:53:49

	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"/>

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Folder: Covid-19 Assessment 08 Feb 2021

Form: Symptom Log (8)

Data signed: (b) (4) 06 Apr 2021 15:41:51

Generated On: 09 Jun 2021 14:53:49

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

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Folder: Covid-19 Assessment 08 Feb 2021

Form: Symptom Log (9)

Data signed: (b) (4) 06 Apr 2021 15:41:51

Generated On: 09 Jun 2021 14:53:49

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"/>

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Folder: Covid-19 Assessment 08 Feb 2021

Form: Symptom Log (9)

Data signed: (b) (4) 06 Apr 2021 15:41:51

Generated On: 09 Jun 2021 14:53:49

	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 FEB 2021
------	-------------

Assessment Not Done	True
---------------------	------

O2 Saturation	<input type="text"/>
---------------	----------------------

O2 Saturation Units	<input type="text"/>
---------------------	----------------------

Temperature	<input type="text"/>
-------------	----------------------

Chills	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input 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"/>

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Folder: Covid-19 Assessment 08 Feb 2021

Form: Symptom Log (9)

Data signed: (b) (4) 06 Apr 2021 15:41:51

Generated On: 09 Jun 2021 14:53:49

	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"/>

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Folder: Covid-19 Assessment 08 Feb 2021

Form: Symptom Log (9)

Data signed: (b) (4) 06 Apr 2021 15:41:51

Generated On: 09 Jun 2021 14:53:49

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

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Folder: Covid-19 Assessment 08 Feb 2021

Form: Symptom Log (10)

Data signed: (b) (4) 06 Apr 2021 15:41:51

Generated On: 09 Jun 2021 14:53:49

Symptom Day

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

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Folder: Covid-19 Assessment 08 Feb 2021

Form: Symptom Log (10)

Data signed: (b) (4) 06 Apr 2021 15:41:51

Generated On: 09 Jun 2021 14:53:49

	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 FEB 2021
------	-------------

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)

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Folder: Covid-19 Assessment 08 Feb 2021

Form: Symptom Log (10)

Data signed: (b) (4) 06 Apr 2021 15:41:51

Generated On: 09 Jun 2021 14:53:49

	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"/>

PRODUCTION RELEASE (v12.003

EAB) (1725)

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US3032249

Folder: Covid-19 Assessment 08 Feb 2021

Form: Symptom Log (10)

Data signed: (b) (4) 06 Apr 2021 15:41:51

Generated On: 09 Jun 2021 14:53:49

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

US3032249

Folder: Covid-19 Assessment 08 Feb 2021

Form: Symptom Log (11)

Data signed: (b) (4) 06 Apr 2021 15:41:51

Generated On: 09 Jun 2021 14:53:49

Symptom Day

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

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Folder: Covid-19 Assessment 08 Feb 2021

Form: Symptom Log (11)

Data signed: (b) (4) 06 Apr 2021 15:41:51

Generated On: 09 Jun 2021 14:53:49

	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 FEB 2021
------	-------------

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"/>

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Folder: Covid-19 Assessment 08 Feb 2021

Form: Symptom Log (11)

Data signed: (b) (4) 06 Apr 2021 15:41:51

Generated On: 09 Jun 2021 14:53:49

	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"/>

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Folder: Covid-19 Assessment 08 Feb 2021

Form: Symptom Log (11)

Data signed: (b) (4) 06 Apr 2021 15:41:51

Generated On: 09 Jun 2021 14:53:49

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

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Folder: Covid-19 Assessment 08 Feb 2021

Form: Symptom Log (12)

Data signed: (b) (4) 06 Apr 2021 15:41:51

Generated On: 09 Jun 2021 14:53:49

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"/>

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Folder: Covid-19 Assessment 08 Feb 2021

Form: Symptom Log (12)

Data signed: (b) (4) 06 Apr 2021 15:41:51

Generated On: 09 Jun 2021 14:53:49

	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 FEB 2021
------	-------------

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"/>

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EAB) (1725)

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Folder: Covid-19 Assessment 08 Feb 2021

Form: Symptom Log (12)

Data signed: (b) (4) 06 Apr 2021 15:41:51

Generated On: 09 Jun 2021 14:53:49

	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"/>

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Folder: Covid-19 Assessment 08 Feb 2021

Form: Symptom Log (12)

Data signed: (b) (4) 06 Apr 2021 15:41:51

Generated On: 09 Jun 2021 14:53:49

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

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Folder: Covid-19 Assessment 08 Feb 2021

Form: Symptom Log (13)

Data signed: (b) (4) 06 Apr 2021 15:41:51

Generated On: 09 Jun 2021 14:53:49

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"/>

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Folder: Covid-19 Assessment 08 Feb 2021

Form: Symptom Log (13)

Data signed: (b) (4) 06 Apr 2021 15:41:51

Generated On: 09 Jun 2021 14:53:49

	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 FEB 2021
------	-------------

Assessment Not Done	True
---------------------	------

O2 Saturation	<input type="text"/>
---------------	----------------------

O2 Saturation Units	<input type="text"/>
---------------------	----------------------

Temperature	<input type="text"/>
-------------	----------------------

Chills	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input 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"/>

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EAB) (1725)

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Folder: Covid-19 Assessment 08 Feb 2021

Form: Symptom Log (13)

Data signed: (b) (4) 06 Apr 2021 15:41:51

Generated On: 09 Jun 2021 14:53:49

	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"/>

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Folder: Covid-19 Assessment 08 Feb 2021

Form: Symptom Log (13)

Data signed: (b) (4) 06 Apr 2021 15:41:51

Generated On: 09 Jun 2021 14:53:49

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

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Folder: Covid-19 Assessment 08 Feb 2021

Form: Symptom Log (14)

Data signed: (b) (4) 06 Apr 2021 15:41:51

Generated On: 09 Jun 2021 14:53:49

Symptom Day

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

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Folder: Covid-19 Assessment 08 Feb 2021

Form: Symptom Log (14)

Data signed: (b) (4) 06 Apr 2021 15:41:51

Generated On: 09 Jun 2021 14:53:49

	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 FEB 2021	
Assessment Not Done	True	
O2 Saturation	<input type="text"/>	
O2 Saturation Units	<input type="text"/>	
Temperature	<input type="text"/>	
Chills	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input 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"/>

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Folder: Covid-19 Assessment 08 Feb 2021

Form: Symptom Log (14)

Data signed: (b) (4) 06 Apr 2021 15:41:51

Generated On: 09 Jun 2021 14:53:49

	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"/>

PRODUCTION RELEASE (v12.003

EAB) (1725)

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Folder: Covid-19 Assessment 08 Feb 2021

Form: Symptom Log (14)

Data signed: (b) (4) 06 Apr 2021 15:41:51

Generated On: 09 Jun 2021 14:53:49

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

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Folder: Covid-19 Assessment 08 Feb 2021

Form: Symptom Log (15)

Data signed: (b) (4) 06 Apr 2021 15:41:51

Generated On: 09 Jun 2021 14:53:49

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"/>

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Folder: Covid-19 Assessment 08 Feb 2021

Form: Symptom Log (15)

Data signed: (b) (4) 06 Apr 2021 15:41:51

Generated On: 09 Jun 2021 14:53:49

	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 FEB 2021
------	-------------

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)

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Folder: Covid-19 Assessment 08 Feb 2021

Form: Symptom Log (15)

Data signed: (b) (4) 06 Apr 2021 15:41:51

Generated On: 09 Jun 2021 14:53:49

	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"/>

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Folder: Covid-19 Assessment 08 Feb 2021

Form: Symptom Log (15)

Data signed: (b) (4) 06 Apr 2021 15:41:51

Generated On: 09 Jun 2021 14:53:49

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

US3032249

Folder: Covid-19 Assessment 08 Feb 2021

Form: Symptom Log (16)

Data signed: (b) (4) 06 Apr 2021 15:41:51

Generated On: 09 Jun 2021 14:53:49

Symptom Day

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

US3032249

Folder: Covid-19 Assessment 08 Feb 2021

Form: Symptom Log (16)

Data signed: (b) (4) 06 Apr 2021 15:41:51

Generated On: 09 Jun 2021 14:53:49

	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 FEB 2021
------	-------------

Assessment Not Done	True
---------------------	------

O2 Saturation	<input type="text"/>
---------------	----------------------

O2 Saturation Units	<input type="text"/>
---------------------	----------------------

Temperature	<input type="text"/>
-------------	----------------------

Chills	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input 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)

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Folder: Covid-19 Assessment 08 Feb 2021

Form: Symptom Log (16)

Data signed: (b) (4) 06 Apr 2021 15:41:51

Generated On: 09 Jun 2021 14:53:49

	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"/>

PRODUCTION RELEASE (v12.003

EAB) (1725)

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US3032249

Folder: Covid-19 Assessment 08 Feb 2021

Form: Symptom Log (16)

Data signed: (b) (4) 06 Apr 2021 15:41:51

Generated On: 09 Jun 2021 14:53:49

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

US3032249

Folder: Covid-19 Assessment 08 Feb 2021

Form: Symptom Log (17)

Data signed: (b) (4) 06 Apr 2021 15:41:51

Generated On: 09 Jun 2021 14:53:49

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"/>

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Folder: Covid-19 Assessment 08 Feb 2021

Form: Symptom Log (17)

Data signed: (b) (4) 06 Apr 2021 15:41:51

Generated On: 09 Jun 2021 14:53:49

	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 FEB 2021
------	-------------

Assessment Not Done	True
---------------------	------

O2 Saturation	<input type="text"/>
---------------	----------------------

O2 Saturation Units	<input type="text"/>
---------------------	----------------------

Temperature	<input type="text"/>
-------------	----------------------

Chills	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input 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"/>

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EAB) (1725)

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Folder: Covid-19 Assessment 08 Feb 2021

Form: Symptom Log (17)

Data signed: (b) (4) 06 Apr 2021 15:41:51

Generated On: 09 Jun 2021 14:53:49

	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"/>

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Folder: Covid-19 Assessment 08 Feb 2021

Form: Symptom Log (17)

Data signed: (b) (4) 06 Apr 2021 15:41:51

Generated On: 09 Jun 2021 14:53:49

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

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Folder: Covid-19 Assessment 08 Feb 2021

Form: Symptom Log (18)

Data signed: (b) (4) 06 Apr 2021 15:41:51

Generated On: 09 Jun 2021 14:53:49

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"/>

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Folder: Covid-19 Assessment 08 Feb 2021

Form: Symptom Log (18)

Data signed: (b) (4) 06 Apr 2021 15:41:51

Generated On: 09 Jun 2021 14:53:49

	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 FEB 2021	
Assessment Not Done	True	
O2 Saturation	<input type="text"/>	
O2 Saturation Units	<input type="text"/>	
Temperature	<input type="text"/>	
Chills	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input 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"/>

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EAB) (1725)

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Folder: Covid-19 Assessment 08 Feb 2021

Form: Symptom Log (18)

Data signed: (b) (4) 06 Apr 2021 15:41:51

Generated On: 09 Jun 2021 14:53:49

	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"/>

PRODUCTION RELEASE (v12.003

EAB) (1725)

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Folder: Covid-19 Assessment 08 Feb 2021

Form: Symptom Log (18)

Data signed: (b) (4) 06 Apr 2021 15:41:51

Generated On: 09 Jun 2021 14:53:49

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

US3032249

Folder: Covid-19 Assessment 08 Feb 2021

Form: Symptom Log (19)

Data signed: (b) (4) 06 Apr 2021 15:41:51

Generated On: 09 Jun 2021 14:53:49

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"/>

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Folder: Covid-19 Assessment 08 Feb 2021

Form: Symptom Log (19)

Data signed: (b) (4) 06 Apr 2021 15:41:51

Generated On: 09 Jun 2021 14:53:49

	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 FEB 2021	
Assessment Not Done	True	
O2 Saturation	<input type="text"/>	
O2 Saturation Units	<input type="text"/>	
Temperature	<input type="text"/>	
Chills	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input 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)

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Folder: Covid-19 Assessment 08 Feb 2021

Form: Symptom Log (19)

Data signed: (b) (4) 06 Apr 2021 15:41:51

Generated On: 09 Jun 2021 14:53:49

	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"/>

US3032249

Folder: Covid-19 Assessment 08 Feb 2021

Form: Symptom Log (19)

Data signed: (b) (4) 06 Apr 2021 15:41:51

Generated On: 09 Jun 2021 14:53:49

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

US3032249

Folder: Covid-19 Assessment 08 Feb 2021

Form: Symptom Log (20)

Data signed: (b) (4) 06 Apr 2021 15:41:51

Generated On: 09 Jun 2021 14:53:49

Symptom Day

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

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Folder: Covid-19 Assessment 08 Feb 2021

Form: Symptom Log (20)

Data signed: (b) (4) 06 Apr 2021 15:41:51

Generated On: 09 Jun 2021 14:53:49

	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 FEB 2021
------	-------------

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"/>

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Form: Symptom Log (20)

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Generated On: 09 Jun 2021 14:53:49

	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"/>

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Data signed: (b) (4) 06 Apr 2021 15:41:51

Generated On: 09 Jun 2021 14:53:49

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

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Form: Symptom Log (21)

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Symptom Day

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

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Form: Symptom Log (21)

Data signed: (b) (4) 06 Apr 2021 15:41:51

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	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 FEB 2021
------	-------------

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"/>

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Form: Symptom Log (21)

Data signed: (b) (4) 06 Apr 2021 15:41:51

Generated On: 09 Jun 2021 14:53:49

	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"/>

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Folder: Covid-19 Assessment 08 Feb 2021

Form: Symptom Log (21)

Data signed: (b) (4) 06 Apr 2021 15:41:51

Generated On: 09 Jun 2021 14:53:49

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

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Folder: Covid-19 Assessment 08 Feb 2021

Form: Symptom Log (22)

Data signed: (b) (4) 06 Apr 2021 15:41:51

Generated On: 09 Jun 2021 14:53:49

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 checked="" type="checkbox"/>
Day 23	<input type="checkbox"/>
Day 24	<input type="checkbox"/>
Day 25	<input type="checkbox"/>
Day 26	<input type="checkbox"/>
Day 27	<input type="checkbox"/>
Day 28	<input type="checkbox"/>
Day 29	<input type="checkbox"/>
Day 30	<input type="checkbox"/>
Day 31	<input type="checkbox"/>
Day 32	<input type="checkbox"/>

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Form: Symptom Log (22)

Data signed: (b) (4) 06 Apr 2021 15:41:51

Generated On: 09 Jun 2021 14:53:49

	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 FEB 2021
------	-------------

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"/>

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Form: Symptom Log (22)

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Generated On: 09 Jun 2021 14:53:49

	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"/>

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Form: Symptom Log (22)

Data signed: (b) (4) 06 Apr 2021 15:41:51

Generated On: 09 Jun 2021 14:53:49

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

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Form: Symptom Log (23)

Data signed: (b) (4) 06 Apr 2021 15:41:51

Generated On: 09 Jun 2021 14:53:49

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 checked="" type="checkbox"/>
Day 24	<input type="checkbox"/>
Day 25	<input type="checkbox"/>
Day 26	<input type="checkbox"/>
Day 27	<input type="checkbox"/>
Day 28	<input type="checkbox"/>
Day 29	<input type="checkbox"/>
Day 30	<input type="checkbox"/>
Day 31	<input type="checkbox"/>
Day 32	<input type="checkbox"/>

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Form: Symptom Log (23)

Data signed: (b) (4) 06 Apr 2021 15:41:51

Generated On: 09 Jun 2021 14:53:49

	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 FEB 2021	
Assessment Not Done	True	
O2 Saturation	<input type="text"/>	
O2 Saturation Units	<input type="text"/>	
Temperature	<input type="text"/>	
Chills	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input 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"/>

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Form: Symptom Log (23)

Data signed: (b) (4) 06 Apr 2021 15:41:51

Generated On: 09 Jun 2021 14:53:49

	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"/>

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Folder: Covid-19 Assessment 08 Feb 2021

Form: Symptom Log (23)

Data signed: (b) (4) 06 Apr 2021 15:41:51

Generated On: 09 Jun 2021 14:53:49

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

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Form: Symptom Log (24)

Data signed: (b) (4) 06 Apr 2021 15:41:51

Generated On: 09 Jun 2021 14:53:49

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 checked="" type="checkbox"/>
Day 25	<input type="checkbox"/>
Day 26	<input type="checkbox"/>
Day 27	<input type="checkbox"/>
Day 28	<input type="checkbox"/>
Day 29	<input type="checkbox"/>
Day 30	<input type="checkbox"/>
Day 31	<input type="checkbox"/>
Day 32	<input type="checkbox"/>

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Form: Symptom Log (24)

Data signed: (b) (4) 06 Apr 2021 15:41:51

Generated On: 09 Jun 2021 14:53:49

	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 FEB 2021
------	-------------

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"/>

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Form: Symptom Log (24)

Data signed: (b) (4) 06 Apr 2021 15:41:51

Generated On: 09 Jun 2021 14:53:49

	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"/>

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Form: Symptom Log (24)

Data signed: (b) (4) 06 Apr 2021 15:41:51

Generated On: 09 Jun 2021 14:53:49

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

US3032249

Folder: Covid-19 Assessment 08 Feb 2021

Form: Symptom Log (25)

Data signed: (b) (4) 06 Apr 2021 15:41:51

Generated On: 09 Jun 2021 14:53:49

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 checked="" 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"/>

US3032249

Folder: Covid-19 Assessment 08 Feb 2021

Form: Symptom Log (25)

Data signed: (b) (4) 06 Apr 2021 15:41:51

Generated On: 09 Jun 2021 14:53:49

	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 FEB 2021
------	-------------

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)

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Folder: Covid-19 Assessment 08 Feb 2021

Form: Symptom Log (25)

Data signed: (b) (4) 06 Apr 2021 15:41:51

Generated On: 09 Jun 2021 14:53:49

	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"/>

US3032249

Folder: Covid-19 Assessment 08 Feb 2021

Form: Symptom Log (25)

Data signed: (b) (4) 06 Apr 2021 15:41:51

Generated On: 09 Jun 2021 14:53:49

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

US3032249

Folder: Covid-19 Assessment 08 Feb 2021

Form: Symptom Log (26)

Data signed: (b) (4) 06 Apr 2021 15:41:51

Generated On: 09 Jun 2021 14:53:49

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"/>

US3032249

Folder: Covid-19 Assessment 08 Feb 2021

Form: Symptom Log (26)

Data signed: (b) (4) 06 Apr 2021 15:41:51

Generated On: 09 Jun 2021 14:53:49

	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 FEB 2021
------	-------------

Assessment Not Done	True
---------------------	------

O2 Saturation	<input type="text"/>
---------------	----------------------

O2 Saturation Units	<input type="text"/>
---------------------	----------------------

Temperature	<input type="text"/>
-------------	----------------------

Chills	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input 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)

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US3032249

Folder: Covid-19 Assessment 08 Feb 2021

Form: Symptom Log (26)

Data signed: (b) (4) 06 Apr 2021 15:41:51

Generated On: 09 Jun 2021 14:53:49

	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"/>

PRODUCTION RELEASE (v12.003

EAB) (1725)

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US3032249

Folder: Covid-19 Assessment 08 Feb 2021

Form: Symptom Log (26)

Data signed: (b) (4) 06 Apr 2021 15:41:51

Generated On: 09 Jun 2021 14:53:49

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

US3032249

Folder: Covid-19 Assessment 08 Feb 2021

Form: Symptom Log (27)

Data signed: (b) (4) 06 Apr 2021 15:41:51

Generated On: 09 Jun 2021 14:53:49

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 type="checkbox"/>
Day 27	<input checked="" type="checkbox"/>
Day 28	<input type="checkbox"/>
Day 29	<input type="checkbox"/>
Day 30	<input type="checkbox"/>
Day 31	<input type="checkbox"/>
Day 32	<input type="checkbox"/>

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Folder: Covid-19 Assessment 08 Feb 2021

Form: Symptom Log (27)

Data signed: (b) (4) 06 Apr 2021 15:41:51

Generated On: 09 Jun 2021 14:53:49

	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 FEB 2021
------	-------------

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)

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Folder: Covid-19 Assessment 08 Feb 2021

Form: Symptom Log (27)

Data signed: (b) (4) 06 Apr 2021 15:41:51

Generated On: 09 Jun 2021 14:53:49

	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"/>

US3032249

Folder: Covid-19 Assessment 08 Feb 2021

Form: Symptom Log (27)

Data signed: (b) (4) 06 Apr 2021 15:41:51

Generated On: 09 Jun 2021 14:53:49

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

US3032249

Folder: Covid-19 Assessment 08 Feb 2021

Form: Symptom Log (28)

Data signed: (b) (4) 06 Apr 2021 15:41:51

Generated On: 09 Jun 2021 14:53:49

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 type="checkbox"/>
Day 27	<input type="checkbox"/>
Day 28	<input checked="" type="checkbox"/>
Day 29	<input type="checkbox"/>
Day 30	<input type="checkbox"/>
Day 31	<input type="checkbox"/>
Day 32	<input type="checkbox"/>

US3032249

Folder: Covid-19 Assessment 08 Feb 2021

Form: Symptom Log (28)

Data signed: (b) (4) 06 Apr 2021 15:41:51

Generated On: 09 Jun 2021 14:53:49

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

Date	01 MAR 2021
------	-------------

Assessment Not Done	True
---------------------	------

O2 Saturation	<input type="text"/>
---------------	----------------------

O2 Saturation Units	<input type="text"/>
---------------------	----------------------

Temperature	<input type="text"/>
-------------	----------------------

Chills	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input 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)

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Folder: Covid-19 Assessment 08 Feb 2021

Form: Symptom Log (28)

Data signed: (b) (4) 06 Apr 2021 15:41:51

Generated On: 09 Jun 2021 14:53:49

	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"/>

US3032249

Folder: Covid-19 Assessment 08 Feb 2021

Form: Symptom Log (28)

Data signed: (b) (4) 06 Apr 2021 15:41:51

Generated On: 09 Jun 2021 14:53:49

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

US3032249

Folder: Covid-19 Assessment 08 Feb 2021

Form: COVID Diagnostic Test

Data signed: (b) (4) 03 May 2021 16:17:39

Generated On: 09 Jun 2021 14:53:49

Date of Visit 9 FEB 2021

Was the Subject Tested For SARS-CoV-2 by RT-PCR? Yes ☒
No ☐

Did Subject Test Positive For SARS-CoV-2 by RT-PCR? Yes ☒
No ☐

Date of Test 09 FEB 2021

Type of Test Performed Nasopharyngeal Swab ☒
Nasal Swab ☐
Saliva Test ☐
Other ☐

Other, specify

Was this diagnostic test performed at a lab other than the Study Central Lab? Yes ☒
No ☐

If yes, provide lab information below

Lab/ Institution Test Performed FAITH REGIONAL HEALTH SERVICES

CLIA Certified? Yes ☒
No ☐

COVID-19 Positive (CSA Programming Field Only) 1

US3032249

Folder: Covid-19 Assessment 08 Feb 2021

Form: Covid-19 Severity Assessment

Data signed: (b) (4) 14 Apr 2021 19:23:00

Generated On: 09 Jun 2021 14:53:49

Did the subject have Respiratory Rates ≥ 30 per Minute? Yes ☐ No ☒

If Yes, provide:

Start Date _____

End Date _____

Respiratory Rate _____

Did the subject have Heart Rate ≥ 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 02 FEB 2021

End Date 02 FEB 2021

Oxygen Saturation 88 %

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 _____

US3032249

Folder: Covid-19 Assessment 08 Feb 2021

Form: Covid-19 Severity Assessment

Data signed: (b) (4) 14 Apr 2021 19:23:00

Generated On: 09 Jun 2021 14:53:49

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

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Folder: Covid-19 Assessment 08 Feb 2021

Form: Covid-19 Severity Assessment

Data signed: (b) (4) 14 Apr 2021 19:23:00

Generated On: 09 Jun 2021 14:53:49

Hepatic Dysfunction? Yes ☐
No ☒

Start Date

Neurologic Dysfunction? Yes ☐
No ☒

Start Date

Evidence of Pneumonia:

Clinical Evidence Yes ☒
No ☐

Date of Assessment

09 FEB 2021

Radiographical Evidence Yes ☐
No ☒

Date of Assessment

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

Start Date

End Date

US3032249

Folder: Covid-19 Assessment 08 Feb 2021

Form: Generate Next COVID-19 Assessment

Data signed: (b) (4) 04 Mar 2021 16:04:29

Generated On: 09 Jun 2021 14:53:49

[Generate Next COVID-19 Assessment](#)

Yes ☐

No ☒

US3032249

Folder: Illness Visit (1)

Form: Saliva Collection

Data signed: (b) (4) 06 Apr 2021 15:41:54

Generated On: 09 Jun 2021 14:53:49

Visit	Was Saliva Collected?	Date of Collection
Day 3	No	
Day 5	No	
Day 7	No	
Day 9	No	
Day 14	No	
Day 21	No	
Day 28	Yes	22 MAR 2021

US3032249

Folder: Illness Visit Day 1 (1)

Form: Visit Date

Data signed: (b) (4) 06 Apr 2021 15:41:54

Generated On: 09 Jun 2021 14:53:49

Was this visit performed? Yes ☐
No ☒

Visit date (dd MMM yyyy)

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

Folder OID SICKD1

US3032249

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Data signed: (b) (4) 06 Apr 2021 15:41:54

Generated On: 09 Jun 2021 14:53:49

Were vital signs assessed? Yes ☐
No ☒

Date of assessment (dd MMM yyyy) _____

Time of assessment (00:00-23:59) _____

Vital Signs Date and Time (derived) _____

Temperature (xxx.x) _____

Route of measurement Oral ☐
Axillary ☐
Other ☐

If Other, specify _____

Pulse (xxx) _____

Pulse units _____

Respiratory Rate (xxx) _____

Respiratory Rate units _____

Systolic Blood Pressure (xxx) _____

Systolic Blood Pressure units _____

Diastolic Blood Pressure (xxx) _____

Diastolic Blood Pressure units _____

Height (derived) _____

Weight (derived) _____

US3032249

Folder: Illness Visit Day 1 (1)

Form: Physical Examination

Data signed: (b) (4) 06 Apr 2021 15:41:54

Generated On: 09 Jun 2021 14:53:49

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.

US3032249

Folder: Illness Visit Day 1 (1)

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

Data signed: (b) (4) 06 Apr 2021 15:41:54

Generated On: 09 Jun 2021 14:53:49

Was Blood Sample Taken for Immunologic Assessment of
SARS_COV-2 Infection?

Yes ☐

No ☒

NA (COVID-19 Negative) ☐

Date of Collection

US3032249

Folder: Convalescence Visit Day 28 (1)

Form: Visit Date

Data signed: (b) (4) 06 Apr 2021 15:41:15

Generated On: 09 Jun 2021 14:53:49

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	22 MAR 2021
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	SICKD28

US3032249

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Data signed: (b) (4) 06 Apr 2021 15:41:51

Generated On: 09 Jun 2021 14:53:49

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (dd MMM yyyy)	22 MAR 2021
Time of assessment (00:00-23:59)	16:49 (24 HR)
Vital Signs Date and Time (derived)	22 MAR 2021 16:49
Height (xxx.x)	160.67 cm
Weight (xxx.x)	93.44 kg
Temperature (xxx.x)	36.7 C
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	77 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	18 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	121 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	67 mmHg
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

US3032249

Folder: Convalescence Visit Day 28 (1)

Form: Physical Examination

Data signed: (b) (4) 06 Apr 2021 15:41:15

Generated On: 09 Jun 2021 14:53:49

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

22 MAR 2021

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

US3032249

Folder: Convalescence Visit Day 28 (1)

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

Data signed: (b) (4) 06 Apr 2021 15:41:15

Generated On: 09 Jun 2021 14:53:49

Was Blood Sample Taken for Immunologic Assessment of
SARS_COV-2 Infection?

Yes ☒

No ☐

NA (COVID-19 Negative) ☐

Date of Collection

22 MAR 2021

US3032249

Folder: Participant Decision Visit / OL-D1 (1)

Form: Visit Date

Data signed: (b) (4) 30 Jan 2021 16:52:32

Generated On: 09 Jun 2021 14:53:49

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

Visit date (dd MMM yyyy)	28 JAN 2021
--------------------------	-------------

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

Folder OID	UNBLND_DECIDE
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US3032249

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Data signed: (b) (4) 18 Mar 2021 21:21:02

Generated On: 09 Jun 2021 14:53:49

Date of updated informed consent (<i>dd MMM yyyy</i>)	28 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>)	28 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

US3032249

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing

Data signed: (b) (4) 30 Jan 2021 16:52:32

Generated On: 09 Jun 2021 14:53:49

Height	ND - Not Done
Weight	ND - Not Done
BMI (xxx.x)	

US3032249

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 30 Jan 2021 16:52:32

Generated On: 09 Jun 2021 14:53:49

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)	28 JAN 2021
Time of assessment (00:00-23:59)	10:29 (24 HR)
Vital Signs Date and Time (derived)	28 JAN 2021 10:29
Temperature (xxx.x)	36.9 C
Route of measurement	Oral <input checked="" type="radio"/> Axillary <input type="radio"/> Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	72 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	135 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	69 mmHg
Diastolic Blood Pressure units	MMHG

US3032249

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 30 Jan 2021 16:52:32

Generated On: 09 Jun 2021 14:53:49

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)	28 JAN 2021
Time of assessment (00:00-23:59)	11:41 (24 HR)
Vital Signs Date and Time (derived)	28 JAN 2021 11:41
Temperature (xxx.x)	36.5 C
Route of measurement	Oral <input checked="" type="radio"/> Axillary <input type="radio"/> Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	71 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	14 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	118 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	66 mmHg
Diastolic Blood Pressure units	MMHG

US3032249

Folder: Participant Decision Visit / OL-D1 (1)

Form: Physical Examination

Data signed: (b) (4) 30 Jan 2021 16:52:32

Generated On: 09 Jun 2021 14:53:49

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

28 JAN 2021

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

US3032249

Folder: Participant Decision Visit / OL-D1 (1)

Form: Exposure

Data signed: (b) (4) 30 Jan 2021 16:52:32

Generated On: 09 Jun 2021 14:53:49

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) 28 JAN 2021

What was the treatment time? (00:00-23:59) 11:09 (24 HR)

Treatment Date and Time (derived) 28 JAN 2021 11:09

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

US3032249

Folder: Participant Decision Visit / OL-D1 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 30 Jan 2021 16:52:32

Generated On: 09 Jun 2021 14:53:49

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (dd MMM yyyy)	28 JAN 2021
Collection time (00:00-23:59)	10:14 (24 HR)
Collection date and time (derived)	28 JAN 2021 10:14

US3032249

Folder: Participant Decision Visit / OL-D1 (1)

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Data signed: (b) (4) 30 Jan 2021 16:52:32

Generated On: 09 Jun 2021 14:53:49

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (dd MMM yyyy)	28 JAN 2021
Collection time (00:00 - 23:59)	10:19
Collection Date and Time (derived)	28 JAN 2021 10:19

US3032249

Folder: Participant Decision Visit / OL-D1 (1)

Form: Continuing

Data signed: (b) (4) 30 Jan 2021 16:52:32

Generated On: 09 Jun 2021 14:53:49

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

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Folder: Safety Call OL-D8 (1)

Form: Safety Call

Data signed: (b) (4) 06 Apr 2021 15:41:55

Generated On: 09 Jun 2021 14:53:49

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

08 FEB 2021

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

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Folder: Safety Call OL-D8 (1)

Form: Continuing

Data signed: (b) (4) 18 Mar 2021 21:21:02

Generated On: 09 Jun 2021 14:53:49

Is the participant continuing to the next visit?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Continuing Flag	1
OLD29 Placebo Flag	1

US3032249

Folder: OL-D29 (1)

Form: Visit Date

Generated On: 09 Jun 2021 14:53:49

Was this visit performed? Yes ☐
No ☐

Visit date (dd MMM yyyy) _____

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

Folder OID _____

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Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:53:49

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

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Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:53:49

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

US3032249

Folder: OL-D29 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 14:53:49

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.

US3032249

Folder: OL-D29 (1)

Form: Exposure

Generated On: 09 Jun 2021 14:53:49

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

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Folder: OL-D29 (1)

Form: Continuing

Generated On: 09 Jun 2021 14:53:49

Is the participant continuing to the next visit?

Yes ☐

No ☐

Continuing Flag

US3032249

Folder: Adverse Events

Form: Adverse Events Summary

Data signed: (b) (4) 12 Feb 2021 19:56:46

Generated On: 09 Jun 2021 14:53:49

Did the participant experience any adverse events?

Yes ☒

No ☐

If Yes, enter details on the Adverse Events form.

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Folder: Adverse Events

Form: Adverse Events (1)

Data signed: (b) (4) 06 Apr 2021 15:41:14

Generated On: 09 Jun 2021 14:53:49

AEID	USA-US032-2021-MRNA-1273-P30 1000008
Adverse event	COVID-19
Was this a medically-attended AE?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Was this a Solicited Adverse Reaction?	Yes <input type="radio"/> No <input checked="" type="radio"/>
Is this event a confirmed diagnosis of Symptomatic Covid-19?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Start date (dd MMM yyyy)	2 FEB 2021
Start time (00:00-23:59)	
AE start date and time (derived)	
Ongoing?	Yes <input type="radio"/> No <input checked="" type="radio"/>
If not Ongoing, end date (dd MMM yyyy)	1 MAR 2021
End time (00:00-23:59)	
AE End Date and Time (derived)	
Severity	Grade 1/Mild <input type="radio"/> Grade 2/Moderate <input type="radio"/> Grade 3/Severe <input checked="" type="radio"/> Grade 4 <input type="radio"/>
Is the adverse event serious?	Yes <input checked="" type="radio"/> No <input type="radio"/>
AE is serious due To (check all that apply)	
Death	False
Life threatening	False
Requires inpatient or prolongation of existing Hospitalization	True
Hospital Admission Date (dd MMM yyyy)	9 FEB 2021
Hospital Discharge Date (dd MMM yyyy)	12 FEB 2021
Admitted to ICU?	Yes <input type="radio"/> No <input checked="" type="radio"/> Unknown <input type="radio"/>

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Folder: Adverse Events

Form: Adverse Events (1)

Data signed: (b) (4) 06 Apr 2021 15:41:14

Generated On: 09 Jun 2021 14:53:49

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 checked="" type="radio"/> Related <input type="radio"/> Not Applicable <input type="radio"/>
Action taken with investigational product	None <input type="radio"/> Dose Delayed <input checked="" type="radio"/> Investigational Product Withdrawn <input type="radio"/> Not Applicable <input type="radio"/>
Other action taken (check all that apply)	
None	False
Concomitant Medication	True
Concomitant Procedure	False
Outcome	Fatal <input type="radio"/> Not Recovered/Not Resolved <input type="radio"/> Recovered/Resolved <input type="radio"/> Recovered/Resolved with Sequelae <input checked="" type="radio"/> Recovering/Resolving <input type="radio"/> Unknown <input type="radio"/>
If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:	DEVELOPED BILATERAL PNEUMONIA AND RE-HOSPITALIZED
Narrative	

US3032249

Folder: Adverse Events

Form: Adverse Events (1)

Data signed: (b) (4) 06 Apr 2021 15:41:14

Generated On: 09 Jun 2021 14:53:49

09FEB2021 SUBJECT CALLED
SITE TO REPORT SHE IS
GETTING A BAM INFUSION
CURRENTLY. SUBJECT DID
CALL THE ER ON 08FEB2021
AND THEY TOLD HER TO
FOLLOW UP WITH HER PCP OM
09FEB2021. SHE CALLED HER
PCP 09FEB2021 AND GOT A
RAPID COVID TEST THAT
CONFIRMED SHE WAS COVID
POSITIVE AND GOT THE BAM
INFUSION ON 09FEB2021.
10FEB2021 ATTEMPTED TO
CALL THE SUBJECT TO SEE
HOW SHE WAS DOING AND NO
ANSWER. 11FEB2021- SITE WAS
ABLE TO GET CONTACT WITH
THE SUBJECT. SUBJECT
STATED SHE HAS BEEN
ADMITTED TO THE HOSPITAL
ON 09FEB2021 FOR COVID 19
SYMPTOMS. SUBJECT IS STILL
CURRENTLY ADMITTED AT
THIS TIME. MEDICAL RECORDS
RELEASE WILL BE SENT TO
PATIENT. WILL UPDATE SAE
WHEN MEDICAL RECORDS
COME BACK TO THE SITE.
SUBJECT DID GET HER FIRST
DOSE ON 28JAN2021 UNDER
THE EUA UNBLINDING.
UPDATE 25MAR2021:
MEDICAL RECORDS RECEIVED
AND REVIEWED.

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Folder: Adverse Events

Form: Adverse Events (1)

Data signed: (b) (4) 06 Apr 2021 15:41:14

Generated On: 09 Jun 2021 14:53:49

THE FOLLOWING IS A SUMMARY SINCE HER INITIAL HOSPITALIZATION: THE SUBJECT INITIALLY SAW HER PCP 09FEB2021 FOR COUGH, FEVER, CHILLS, AND INCREASED SHORTNESS OF BREATH. BP WAS 142/76, HR 92, TEMP 99.9, AND O2 95% ROOM AIR. SHE WAS SENT TO HOSPITAL FOR A BAM INFUSION. WHILE THERE, HER O2 CONSISTENTLY DROPPED TO LOW 80S. SHE HAD TESTED POSITIVE FOR COVID AT PCP VISIT. SHE WAS ADMITTED FOR OBSERVATION. CHEST X-RAY SHOWED INFILTRATES. SHE WAS PLACED ON 2L O2 AND GIVEN PRESCRIBED MEDICATIONS TO EASE BREATHING. DUE TO CONTINUED HYPOXIA SHE WAS TRANSFERRED TO INPATIENT ACUTE CARE STATUS ON 10FEB2021. SHE WAS PRESCRIBED AZITHROMYCIN, ROCEPHIN, PREDNISONE, AND IV FLUIDS. SHE IMPROVED AND WAS DISCHARGED 12FEB2021. SHE RETURNED HOME. ON 19FEB2021 THE SUBJECT SAW HER PCP FOR HOSPITAL FOLLOW-UP. SHE CONTINUED

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Folder: Adverse Events

Form: Adverse Events (1)

Data signed: (b) (4) 06 Apr 2021 15:41:14

Generated On: 09 Jun 2021 14:53:49

TO EXPERIENCE SHORTNESS
OF BREATH, FATIGUE,
PRODUCTIVE COUGH. NO
CHANGES WERE MADE THAT
DAY.

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

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Folder: Adverse Events

Form: Adverse Events (2)

Data signed: (b) (4) 06 Apr 2021 15:41:14

Generated On: 09 Jun 2021 14:53:49

AEID	USA-US032-2021-MRNA-1273-P30 1000008
Adverse event	BILATERAL PNEUMONIA
Was this a medically-attended AE?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Was this a Solicited Adverse Reaction?	Yes <input type="radio"/> No <input checked="" type="radio"/>
Is this event a confirmed diagnosis of Symptomatic Covid-19?	Yes <input type="radio"/> No <input checked="" type="radio"/>
Start date (dd MMM yyyy)	01 MAR 2021
Start time (00:00-23:59)	
AE start date and time (derived)	
Ongoing?	Yes <input type="radio"/> No <input checked="" type="radio"/>
If not Ongoing, end date (dd MMM yyyy)	5 MAR 2021
End time (00:00-23:59)	
AE End Date and Time (derived)	
Severity	Grade 1/Mild <input type="radio"/> Grade 2/Moderate <input type="radio"/> Grade 3/Severe <input checked="" type="radio"/> Grade 4 <input type="radio"/>
Is the adverse event serious?	Yes <input checked="" type="radio"/> No <input type="radio"/>
AE is serious due To (check all that apply)	
Death	False
Life threatening	False
Requires inpatient or prolongation of existing Hospitalization	True
Hospital Admission Date (dd MMM yyyy)	01 MAR 2021
Hospital Discharge Date (dd MMM yyyy)	05 MAR 2021
Admitted to ICU?	Yes <input type="radio"/> No <input checked="" type="radio"/> Unknown <input type="radio"/>

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Folder: Adverse Events

Form: Adverse Events (2)

Data signed: (b) (4) 06 Apr 2021 15:41:14

Generated On: 09 Jun 2021 14:53:49

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 checked="" type="radio"/> Related <input type="radio"/> Not Applicable <input type="radio"/>
Action taken with investigational product	None <input type="radio"/> Dose Delayed <input checked="" type="radio"/> Investigational Product Withdrawn <input type="radio"/> Not Applicable <input type="radio"/>
Other action taken (check all that apply)	
None	False
Concomitant Medication	True
Concomitant Procedure	False
Outcome	Fatal <input type="radio"/> Not Recovered/Not Resolved <input type="radio"/> Recovered/Resolved <input checked="" type="radio"/> Recovered/Resolved with Sequelae <input type="radio"/> Recovering/Resolving <input type="radio"/> Unknown <input type="radio"/>
If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:	
Narrative	

US3032249

Folder: Adverse Events

Form: Adverse Events (2)

Data signed: (b) (4) 06 Apr 2021 15:41:14

Generated On: 09 Jun 2021 14:53:49

SUBJECT CALLS TO REPORT
SHE HAS BEEN
RE-HOSPITALIZED FOR
BILATERAL PNEUMONIA. SHE
STATES SHE HAS CONTINUED
TO FEEL UNWELL SINCE HER
INITIAL COVID DIAGNOSIS. SHE
NOTED INCREASING
SHORTNESS OF BREATH,
WEAKNESS, UNCONTROLLED
COUGHING, AND O2
SATURATION <90% ON ROOM
AIR AT REST. SHE SOUGHT
CARE AT THE ER AND WAS
ADMITTED. SHE IS ON
ANTIBIOTICS AND BREATHING
TREATMENTS CURRENTLY.
MEDICAL RECORDS HAVE
BEEN REQUESTED. SHE
REPORTS SHE IS STILL IN THE
HOSPITAL BUT "THIS IS THE
BEST" SHE HAS FELT SINCE
HER ORIGINAL COVID
DIAGNOSIS. SHE DID HAVE HER
28 DAY FOLLOW UP
SCHEDULED, SO THIS WILL BE
RESCHEDULED. WILL
CONTINUE TO FOLLOW
PATIENTS CONDITION.
UPDATE 09MAR2021: SUBJECT
REPORTS SHE WAS
DISCHARGED 05MAR2021.
CONTINUES TO EXPERIENCE
WEAKNESS, SHORTNESS OF
BREATH, AND PRODUCTIVE

US3032249

Folder: Adverse Events

Form: Adverse Events (2)

Data signed: (b) (4) 06 Apr 2021 15:41:14

Generated On: 09 Jun 2021 14:53:49

COUGH. AWAITING MEDICAL RECORDS. UPDATE 25 MAR 2021: ON 01 MAR 2021 THE SUBJECT RETURNED TO THE ER. SHE WAS EXPERIENCING ABRUPT INCREASE IN SHORTNESS OF BREATH, PRODUCTIVE COUGH, POSTTUSSIVE EMESIS, FEVERS/SWEATS, DYSPNEA WITH EXERTION, OXYGEN 91-93%, LYMPHADENITIS TO RIGHT AXILLARY LYMPH NODE, CHEST PAIN, AND HEAVINESS. HER PRO-CALCITONIN WAS 1.91, D-DIMER ELEVATED AT 10,000. A CHEST X-RAY WAS PERFORMED BUT SUBJECT DID NOT TOLERATE WELL DUE TO DYSPNEA. A CT ANGIOGRAM OF CHEST WAS PERFORMED. IT RULED OUT A PULMONARY EMBOLISM BUT DID SHOW UPPER LUNG LOBE INFILTRATES BILATERAL. IT ALSO SHOWED THE RIGHT AXILLARY LYMPH NODE WAS SWOLLEN. THE SUBJECTS HOSPITALIZATION INCLUDED O2 USAGE, LEVAQUIN, ZOSYN, ENOXAPARIN, AND BREATHING TREATMENTS FOR A DIAGNOSIS OF BILATERAL PNEUMONIA. THE SUBJECT

US3032249

Folder: Adverse Events

Form: Adverse Events (2)

Data signed: (b) (4) 06 Apr 2021 15:41:14

Generated On: 09 Jun 2021 14:53:49

WAS DISCHARGED 05MAR2021
AFTER PROVING SHE COULD
WALK 300 FT AND KEEP O2
>90% ON ROOM AIR. THE
SUBJECT SAW HER PCP ON
11MAR2021 FOR HOSPITAL
FOLLOW UP. SHE REPORTS
IMPROVEMENT IN MOST
SYMPTOMS BUT STILL HAS
FATIGUE AND NIGHT SWEATS.

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

US3032249

Folder: Adverse Events

Form: Adverse Events (3)

Data signed: (b) (4) 06 Apr 2021 15:41:14

Generated On: 09 Jun 2021 14:53:49

AEID

Adverse event

WORSENING OF ASTHMA

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)

23 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 JAN 2021

End time (00:00-23:59)

AE End Date and Time (derived)

Severity

Grade 1/Mild ☐

Grade 2/Moderate ☒

Grade 3/Severe ☐

Grade 4 ☐

Is the adverse event serious?

Yes ☐

No ☒

AE is serious due To (check all that apply)

Death

False

Life threatening

False

Requires inpatient or prolongation of existing Hospitalization

False

Hospital Admission Date (dd MMM yyyy)

Hospital Discharge Date (dd MMM yyyy)

Admitted to ICU?

Yes ☐

No ☐

Unknown ☐

Number of Days in ICU

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EAB) (1725)

US3032249

Folder: Adverse Events

Form: Adverse Events (3)

Data signed: (b) (4) 06 Apr 2021 15:41:14

Generated On: 09 Jun 2021 14:53:49

Persistent or significant disability or incapacity	False
Congenital anomaly or birth defect	False
Other medically important event	False
Relationship to investigational product	Not Related <input checked="" type="radio"/> Related <input type="radio"/> Not Applicable <input type="radio"/>
Relationship to Study Procedure	Not Related <input checked="" type="radio"/> Related <input type="radio"/> Not Applicable <input type="radio"/>
Action taken with investigational product	None <input type="radio"/> Dose Delayed <input type="radio"/> Investigational Product <input type="radio"/> Withdrawn <input type="radio"/> Not Applicable <input checked="" type="radio"/>
Other action taken (check all that apply)	
None	False
Concomitant Medication	True
Concomitant Procedure	False
Outcome	Fatal <input type="radio"/> Not Recovered/Not Resolved <input type="radio"/> Recovered/Resolved <input checked="" type="radio"/> Recovered/Resolved with Sequelae <input type="radio"/> Recovering/Resolving <input type="radio"/> Unknown <input type="radio"/>
If outcome is Recovered/Resolved with Sequelae, please specify the sequelae: _____	
Narrative _____	
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)	_____

US3032249

Folder: Adverse Events

Form: Adverse Events (4)

Data signed: (b) (4) 06 Apr 2021 15:41:14

Generated On: 09 Jun 2021 14:53:49

AEID

Adverse event

HEMATOCHEZIA

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)

17 MAR 2021

Start time (00:00-23:59)

AE start date and time (derived)

Ongoing?

Yes ☐

No ☒

If not Ongoing, end date (dd MMM yyyy)

19 MAR 2021

End time (00:00-23:59)

AE End Date and Time (derived)

Severity

Grade 1/Mild ☐

Grade 2/Moderate ☒

Grade 3/Severe ☐

Grade 4 ☐

Is the adverse event serious?

Yes ☐

No ☒

AE is serious due To (check all that apply)

Death

False

Life threatening

False

Requires inpatient or prolongation of existing Hospitalization

False

Hospital Admission Date (dd MMM yyyy)

Hospital Discharge Date (dd MMM yyyy)

Admitted to ICU?

Yes ☐

No ☐

Unknown ☐

Number of Days in ICU

PRODUCTION RELEASE (v12.003

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EAB) (1725)

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Folder: Adverse Events

Form: Adverse Events (4)

Data signed: (b) (4) 06 Apr 2021 15:41:14

Generated On: 09 Jun 2021 14:53:49

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

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Folder: Adverse Events

Form: Adverse Events (5)

Data signed: (b) (4) 06 Apr 2021 15:41:14

Generated On: 09 Jun 2021 14:53:49

AEID	
Adverse event	HEMORRHOIDS
Was this a medically-attended AE?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Was this a Solicited Adverse Reaction?	Yes <input type="radio"/> No <input checked="" type="radio"/>
Is this event a confirmed diagnosis of Symptomatic Covid-19?	Yes <input type="radio"/> No <input checked="" type="radio"/>
Start date (dd MMM yyyy)	19 MAR 2021
Start time (00:00-23:59)	
AE start date and time (derived)	
Ongoing?	Yes <input checked="" type="radio"/> No <input type="radio"/>
If not Ongoing, end date (dd MMM yyyy)	
End time (00:00-23:59)	
AE End Date and Time (derived)	
Severity	Grade 1/Mild <input checked="" type="radio"/> Grade 2/Moderate <input type="radio"/> Grade 3/Severe <input type="radio"/> Grade 4 <input type="radio"/>
Is the adverse event serious?	Yes <input type="radio"/> No <input checked="" type="radio"/>
AE is serious due To (check all that apply)	
Death	False
Life threatening	False
Requires inpatient or prolongation of existing Hospitalization	False
Hospital Admission Date (dd MMM yyyy)	
Hospital Discharge Date (dd MMM yyyy)	
Admitted to ICU?	Yes <input type="radio"/> No <input type="radio"/> Unknown <input type="radio"/>
Number of Days in ICU	

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Folder: Adverse Events

Form: Adverse Events (5)

Data signed: (b) (4) 06 Apr 2021 15:41:14

Generated On: 09 Jun 2021 14:53:49

Persistent or significant disability or incapacity	False
Congenital anomaly or birth defect	False
Other medically important event	False
Relationship to investigational product	Not Related <input checked="" type="radio"/> Related <input type="radio"/> Not Applicable <input type="radio"/>
Relationship to Study Procedure	Not Related <input checked="" type="radio"/> Related <input type="radio"/> Not Applicable <input type="radio"/>
Action taken with investigational product	None <input type="radio"/> Dose Delayed <input type="radio"/> Investigational Product <input type="radio"/> Withdrawn <input type="radio"/> Not Applicable <input checked="" type="radio"/>
Other action taken (check all that apply)	
None	True
Concomitant Medication	False
Concomitant Procedure	False
Outcome	Fatal <input type="radio"/> Not Recovered/Not Resolved <input type="radio"/> Recovered/Resolved <input type="radio"/> Recovered/Resolved with Sequelae <input type="radio"/> Recovering/Resolving <input checked="" type="radio"/> Unknown <input type="radio"/>
If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:	
Narrative	
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)	

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Folder: Adverse Events

Form: Adverse Events (6)

Data signed: (b) (4) 06 Apr 2021 15:41:14

Generated On: 09 Jun 2021 14:53:49

AEID

Adverse event

DYSPNEA DUE TO COVID-19

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)

1 MAR 2021

Start time (00:00-23:59)

AE start date and time (derived)

Ongoing?

Yes ☐

No ☒

If not Ongoing, end date (dd MMM yyyy)

5 MAR 2021

End time (00:00-23:59)

AE End Date and Time (derived)

Severity

Grade 1/Mild ☐

Grade 2/Moderate ☐

Grade 3/Severe ☒

Grade 4 ☐

Is the adverse event serious?

Yes ☐

No ☒

AE is serious due To (check all that apply)

Death

False

Life threatening

False

Requires inpatient or prolongation of existing Hospitalization

False

Hospital Admission Date (dd MMM yyyy)

Hospital Discharge Date (dd MMM yyyy)

Admitted to ICU?

Yes ☐

No ☐

Unknown ☐

Number of Days in ICU

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Folder: Adverse Events

Form: Adverse Events (6)

Data signed: (b) (4) 06 Apr 2021 15:41:14

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

US3032249

Folder: Adverse Events

Form: Adverse Events (7)

Data signed: (b) (4) 06 Apr 2021 15:41:14

Generated On: 09 Jun 2021 14:53:49

AEID

Adverse event

PERINEAL IRRITATION IN
FEMALE

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)

19 MAR 2021

Start time (00:00-23:59)

AE start date and time (derived)

Ongoing?

Yes ☐

No ☒

If not Ongoing, end date (dd MMM yyyy)

22 MAR 2021

End time (00:00-23:59)

AE End Date and Time (derived)

Severity

Grade 1/Mild ☒

Grade 2/Moderate ☐

Grade 3/Severe ☐

Grade 4 ☐

Is the adverse event serious?

Yes ☐

No ☒

AE is serious due To (check all that apply)

Death

False

Life threatening

False

Requires inpatient or prolongation of existing Hospitalization

False

Hospital Admission Date (dd MMM yyyy)

Hospital Discharge Date (dd MMM yyyy)

Admitted to ICU?

Yes ☐

No ☐

Unknown ☐

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Folder: Adverse Events

Form: Adverse Events (7)

Data signed: (b) (4) 06 Apr 2021 15:41:14

Generated On: 09 Jun 2021 14:53:49

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

US3032249

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Data signed: (b) (4) 28 Sep 2020 17:50:47

Generated On: 09 Jun 2021 14:53:49

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

Yes ☒

No ☐

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

US3032249

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Data signed: (b) (4) 06 Apr 2021 15:41:14

Generated On: 09 Jun 2021 14:53:49

Name of Medication OMEPRAZOLE

Prophylaxis Yes ☐
No ☒

Indication MEDICAL HISTORY: ACID
REFLUX

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 ☐

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EAB) (1725)

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Data signed: (b) (4) 06 Apr 2021 15:41:14

Generated On: 09 Jun 2021 14:53:49

	Intraocular	<input type="checkbox"/>
	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify		
Start date (dd MMM yyyy)	UN UNK 2017	
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy)		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>

US3032249

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Data signed: (b) (4) 06 Apr 2021 15:41:14

Generated On: 09 Jun 2021 14:53:49

Name of Medication OLMESARTAN HCTZ

Prophylaxis Yes ☐
No ☒

Indication MEDICAL HISTORY:
HYPERTENSION

Dose per administration 40/12.5

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 ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Data signed: (b) (4) 06 Apr 2021 15:41:14

Generated On: 09 Jun 2021 14:53:49

	Intraocular	<input type="checkbox"/>
	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify		
Start date (dd MMM yyyy)	UN UNK 2017	
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy)		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Data signed: (b) (4) 06 Apr 2021 15:41:14

Generated On: 09 Jun 2021 14:53:49

Name of Medication FUROSEMIDE

Prophylaxis Yes ☐
No ☒

Indication MEDICAL HISTORY:
BILATERAL LOWER LEG
EDEMA

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 ☐

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EAB) (1725)

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Data signed: (b) (4) 06 Apr 2021 15:41:14

Generated On: 09 Jun 2021 14:53:49

	Intraocular	<input type="checkbox"/>
	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify		
Start date (dd MMM yyyy)	UN	UNK 2018
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy)		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>

US3032249

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Data signed: (b) (4) 06 Apr 2021 15:41:14

Generated On: 09 Jun 2021 14:53:49

Name of Medication OXBUTYNIN ER

Prophylaxis Yes ☐
No ☒

Indication MEDICAL HISTORY:
OVERACTIVE BLADDER

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

Route of administration Oral ☒
Topical ☐
Subcutaneous ☐
Transdermal ☐

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EAB) (1725)

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Data signed: (b) (4) 06 Apr 2021 15:41:14

Generated On: 09 Jun 2021 14:53:49

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Data signed: (b) (4) 06 Apr 2021 15:41:14

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Name of Medication FLUTICASONE SPRAY

Prophylaxis Yes ☐
No ☒

Indication MEDICAL HISTORY: SEASONAL ALLERGIES

Dose per administration 50

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 ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Data signed: (b) (4) 06 Apr 2021 15:41:14

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	Intraocular	<input type="radio"/>
	Intramuscular	<input type="radio"/>
	Respiratory (Inhalation)	<input checked="" type="radio"/>
	Intralesional	<input type="radio"/>
	Intraperitoneal	<input type="radio"/>
	Nasal	<input type="radio"/>
	Vaginal	<input type="radio"/>
	Rectal	<input type="radio"/>
	Intravenous	<input type="radio"/>
	Intravenous Bolus	<input type="radio"/>
	Intravenous Drip	<input type="radio"/>
	Other	<input type="radio"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	UN	UNK 2008
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Data signed: (b) (4) 06 Apr 2021 15:41:14

Generated On: 09 Jun 2021 14:53:49

Name of Medication FEXOFENADINE

Prophylaxis Yes ☐
No ☒

Indication MEDICAL HISTORY: SEASONAL ALLERGIES

Dose per administration 180

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 ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Data signed: (b) (4) 06 Apr 2021 15:41:14

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	Intraocular	<input type="checkbox"/>
	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify		
Start date (dd MMM yyyy)	UN UNK 2009	
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy)		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Data signed: (b) (4) 06 Apr 2021 15:41:14

Generated On: 09 Jun 2021 14:53:49

Name of Medication GLUCOSAMINE CHONDROITIN

Prophylaxis Yes ☐
No ☒

Indication MEDICAL HISTORY:
OSTEOARTHRITIS

Dose per administration 1500/1200

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 ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Data signed: (b) (4) 06 Apr 2021 15:41:14

Generated On: 09 Jun 2021 14:53:49

	Intraocular	<input type="checkbox"/>
	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify		
Start date (dd MMM yyyy)	UN UNK 2015	
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy)		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Data signed: (b) (4) 06 Apr 2021 15:41:14

Generated On: 09 Jun 2021 14:53:49

Name of Medication METOCLOPRAMIDE

Prophylaxis Yes ☐
No ☒

Indication MEDICAL HISTORY:
GASTROPARESIS

Dose per administration 5

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

BEFORE MEALS

Route of administration Oral ☒
Topical ☐
Subcutaneous ☐
Transdermal ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Data signed: (b) (4) 06 Apr 2021 15:41:14

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Data signed: (b) (4) 06 Apr 2021 15:41:14

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Name of Medication MONTELUKAST

Prophylaxis Yes ☐
No ☒

Indication MEDICAL HISTORY: SEASONAL ALLERGIES

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

Route of administration Oral ☒
Topical ☐
Subcutaneous ☐
Transdermal ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Data signed: (b) (4) 06 Apr 2021 15:41:14

Generated On: 09 Jun 2021 14:53:49

	Intraocular	<input type="checkbox"/>
	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	UN	UNK 2015
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Data signed: (b) (4) 06 Apr 2021 15:41:14

Generated On: 09 Jun 2021 14:53:49

Name of Medication TRELEGY INHALER
(FLUTICASONE
FUROATE/UMECLIPINIUM
BROMIDE/VILANTEROL
TRIFENATE)

Prophylaxis Yes ☐
No ☒

Indication MEDICAL HISTORY: COPD &
ASTHMA

Dose per administration 100/62.5/25

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 ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

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	Topical	<input type="checkbox"/>
	Subcutaneous	<input type="checkbox"/>
	Transdermal	<input type="checkbox"/>
	Intraocular	<input type="checkbox"/>
	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input checked="" type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify		
Start date (dd MMM yyyy)	UN UNK 2017	
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="checkbox"/>
	No	<input type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)		
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input checked="" type="checkbox"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Data signed: (b) (4) 06 Apr 2021 15:41:14

Generated On: 09 Jun 2021 14:53:49

Name of Medication DUPILUMAB

Prophylaxis Yes ☐
No ☒

Indication ASTHMA

Dose per administration 300

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 2 WEEKS

Route of administration Oral ☐
Topical ☐
Subcutaneous ☒
Transdermal ☐
Intraocular ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Data signed: (b) (4) 06 Apr 2021 15:41:14

Generated On: 09 Jun 2021 14:53:49

	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 JAN 2021	
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived) _____		
Interval Dosage Unit Number (derived) _____		
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input type="radio"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Data signed: (b) (4) 06 Apr 2021 15:41:14

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Name of Medication BAMLANIVIMAB

Prophylaxis Yes ☐
No ☒

Indication COVID-19

Dose per administration 700

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

If dose unit is Other, specify

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

If frequency is Other, specify

Route of administration Oral ☐
Topical ☐
Subcutaneous ☐
Transdermal ☐
Intraocular ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Data signed: (b) (4) 06 Apr 2021 15:41:14

Generated On: 09 Jun 2021 14:53:49

	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 checked="" type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)		9 FEB 2021
Start date completely unknown		False
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy) 9 FEB 2021		
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived) _____		
Interval Dosage Unit Number (derived) _____		
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input type="checkbox"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Data signed: (b) (4) 06 Apr 2021 15:41:14

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Name of Medication ALBUTEROL

Prophylaxis Yes ☐
No ☒

Indication BILATERAL PNEUMONIA

Dose per administration 9

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

If dose unit is Other, specify

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

If frequency is Other, specify

Route of administration Oral ☐
Topical ☐
Subcutaneous ☐
Transdermal ☐
Intraocular ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Data signed: (b) (4) 06 Apr 2021 15:41:14

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	Intramuscular	<input type="radio"/>
	Respiratory (Inhalation)	<input checked="" type="radio"/>
	Intralesional	<input type="radio"/>
	Intraperitoneal	<input type="radio"/>
	Nasal	<input type="radio"/>
	Vaginal	<input type="radio"/>
	Rectal	<input type="radio"/>
	Intravenous	<input type="radio"/>
	Intravenous Bolus	<input type="radio"/>
	Intravenous Drip	<input type="radio"/>
	Other	<input type="radio"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	5 MAR 2021	
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)	3	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Data signed: (b) (4) 06 Apr 2021 15:41:14

Generated On: 09 Jun 2021 14:53:49

Name of Medication ACETAMINOPHEN

Prophylaxis Yes ☐
No ☒

Indication COVID-19

Dose per administration 650

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

If dose unit is Other, specify

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

If frequency is Other, specify

Route of administration Oral ☒
Topical ☐
Subcutaneous ☐
Transdermal ☐
Intraocular ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Data signed: (b) (4) 06 Apr 2021 15:41:14

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	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)	9 FEB 2021	
Start date completely unknown	False	
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy) 12 FEB 2021		
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived) _____		
Interval Dosage Unit Number (derived) _____		
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input type="checkbox"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Data signed: (b) (4) 06 Apr 2021 15:41:14

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Name of Medication ALBUTEROL

Prophylaxis Yes ☐
No ☒

Indication COVID-19

Dose per administration 2.5

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

If dose unit is Other, specify

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

If frequency is Other, specify

Route of administration Oral ☐
Topical ☐
Subcutaneous ☐
Transdermal ☐
Intraocular ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Data signed: (b) (4) 06 Apr 2021 15:41:14

Generated On: 09 Jun 2021 14:53:49

	Intramuscular	<input type="radio"/>
	Respiratory (Inhalation)	<input checked="" type="radio"/>
	Intralesional	<input type="radio"/>
	Intraperitoneal	<input type="radio"/>
	Nasal	<input type="radio"/>
	Vaginal	<input type="radio"/>
	Rectal	<input type="radio"/>
	Intravenous	<input type="radio"/>
	Intravenous Bolus	<input type="radio"/>
	Intravenous Drip	<input type="radio"/>
	Other	<input type="radio"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	9 FEB 2021	
Start date completely unknown	False	
Ongoing?	Yes <input type="radio"/>	
	No <input checked="" type="radio"/>	
If not Ongoing, End date (dd MMM yyyy) 12 FEB 2021		
Was this medication taken for solicited event?	Yes <input type="radio"/>	
	No <input checked="" type="radio"/>	
Separate Dosage Number (derived) _____		
Interval Dosage Unit Number (derived) _____		
Interval Dosage Definition (derived)	802 <input type="radio"/>	
	803 <input type="radio"/>	
	804 <input type="radio"/>	

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Data signed: (b) (4) 06 Apr 2021 15:41:14

Generated On: 09 Jun 2021 14:53:49

Name of Medication PANTOPRAZOLE

Prophylaxis Yes ☐
No ☒

Indication COVID-19

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 ☐

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EAB) (1725)

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Data signed: (b) (4) 06 Apr 2021 15:41:14

Generated On: 09 Jun 2021 14:53:49

	Intramuscular	<input type="radio"/>
	Respiratory (Inhalation)	<input type="radio"/>
	Intralesional	<input type="radio"/>
	Intraperitoneal	<input type="radio"/>
	Nasal	<input type="radio"/>
	Vaginal	<input type="radio"/>
	Rectal	<input type="radio"/>
	Intravenous	<input type="radio"/>
	Intravenous Bolus	<input type="radio"/>
	Intravenous Drip	<input type="radio"/>
	Other	<input type="radio"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	9 FEB 2021	
Start date completely unknown	False	
Ongoing?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
If not Ongoing, End date (dd MMM yyyy)	12 FEB 2021	
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Data signed: (b) (4) 06 Apr 2021 15:41:14

Generated On: 09 Jun 2021 14:53:49

Name of Medication PREDNISONE

Prophylaxis Yes ☐
No ☒

Indication COVID-19

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

Route of administration Oral ☒
Topical ☐
Subcutaneous ☐
Transdermal ☐
Intraocular ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Data signed: (b) (4) 06 Apr 2021 15:41:14

Generated On: 09 Jun 2021 14:53:49

	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)	9 FEB 2021	
Start date completely unknown	False	
Ongoing?	Yes <input type="checkbox"/>	
	No <input checked="" type="radio"/>	
If not Ongoing, End date (dd MMM yyyy)	12 FEB 2021	
Was this medication taken for solicited event?	Yes <input type="checkbox"/>	
	No <input checked="" type="radio"/>	
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802 <input type="checkbox"/>	
	803 <input type="checkbox"/>	
	804 <input checked="" type="radio"/>	

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Data signed: (b) (4) 06 Apr 2021 15:41:14

Generated On: 09 Jun 2021 14:53:49

Name of Medication	PROMETHAZINE WITH CODEINE
Prophylaxis	Yes <input type="radio"/> No <input checked="" type="radio"/>
Indication	COVID-19
Dose per administration	6.25/10
Dose unit	mg <input checked="" type="radio"/> ug <input type="radio"/> mL <input type="radio"/> g <input type="radio"/> IU <input type="radio"/> tablet <input type="radio"/> capsule <input type="radio"/> puff <input type="radio"/> Other <input type="radio"/>
If dose unit is Other, specify _____	
Frequency	once daily <input type="radio"/> twice daily <input type="radio"/> three times daily <input type="radio"/> four times daily <input type="radio"/> every other day <input type="radio"/> every week <input type="radio"/> every month <input type="radio"/> as needed <input checked="" type="radio"/> once <input type="radio"/> unknown <input type="radio"/> other <input type="radio"/>
If frequency is Other, specify _____	
Route of administration	Oral <input checked="" type="radio"/> Topical <input type="radio"/> Subcutaneous <input type="radio"/> Transdermal <input type="radio"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Data signed: (b) (4) 06 Apr 2021 15:41:14

Generated On: 09 Jun 2021 14:53:49

	Intraocular	<input type="checkbox"/>
	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify		
Start date (dd MMM yyyy)	9 FEB 2021	
Start date completely unknown	False	
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)		24 MAR 2021
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived)		
Interval Dosage Unit Number (derived)		
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input type="checkbox"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Data signed: (b) (4) 06 Apr 2021 15:41:14

Generated On: 09 Jun 2021 14:53:49

Name of Medication CEFTRIAXONE

Prophylaxis Yes ☐
No ☒

Indication COVID-19

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 ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Data signed: (b) (4) 06 Apr 2021 15:41:14

Generated On: 09 Jun 2021 14:53:49

	Intramuscular	<input type="radio"/>
	Respiratory (Inhalation)	<input type="radio"/>
	Intralesional	<input type="radio"/>
	Intraperitoneal	<input type="radio"/>
	Nasal	<input type="radio"/>
	Vaginal	<input type="radio"/>
	Rectal	<input type="radio"/>
	Intravenous	<input checked="" type="radio"/>
	Intravenous Bolus	<input type="radio"/>
	Intravenous Drip	<input type="radio"/>
	Other	<input type="radio"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	9 FEB 2021	
Start date completely unknown	False	
Ongoing?	Yes <input type="radio"/>	
	No <input checked="" type="radio"/>	
If not Ongoing, End date (dd MMM yyyy)	12 FEB 2021	
Was this medication taken for solicited event?	Yes <input type="radio"/>	
	No <input checked="" type="radio"/>	
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802 <input type="radio"/>	
	803 <input type="radio"/>	
	804 <input checked="" type="radio"/>	

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Data signed: (b) (4) 06 Apr 2021 15:41:14

Generated On: 09 Jun 2021 14:53:49

Name of Medication SODIUM CHLORIDE 0.9%

Prophylaxis Yes ☐
No ☒

Indication COVID-19

Dose per administration 100

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

CONTINUOUS

Route of administration Oral ☐
Topical ☐
Subcutaneous ☐
Transdermal ☐
Intraocular ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Data signed: (b) (4) 06 Apr 2021 15:41:14

Generated On: 09 Jun 2021 14:53:49

	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 checked="" type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	9 FEB 2021	
Start date completely unknown	False	
Ongoing?	Yes <input type="checkbox"/>	
	No <input checked="" type="checkbox"/>	
If not Ongoing, End date (dd MMM yyyy)	12 FEB 2021	
Was this medication taken for solicited event?	Yes <input type="checkbox"/>	
	No <input checked="" type="checkbox"/>	
Separate Dosage Number (derived)	_____	
Interval Dosage Unit Number (derived)	_____	
Interval Dosage Definition (derived)	802 <input type="checkbox"/>	
	803 <input type="checkbox"/>	
	804 <input type="checkbox"/>	

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Data signed: (b) (4) 06 Apr 2021 15:41:14

Generated On: 09 Jun 2021 14:53:49

Name of Medication AZITHROMYCIN

Prophylaxis Yes ☐
No ☒

Indication COVID-19

Dose per administration 500

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

If dose unit is Other, specify

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

If frequency is Other, specify

Route of administration Oral ☒
Topical ☐
Subcutaneous ☐
Transdermal ☐
Intraocular ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Data signed: (b) (4) 06 Apr 2021 15:41:14

Generated On: 09 Jun 2021 14:53:49

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)		10 FEB 2021
Start date completely unknown		False
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy) 12 FEB 2021		
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived)		1
Interval Dosage Unit Number (derived)		1
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input checked="" type="checkbox"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Data signed: (b) (4) 06 Apr 2021 15:41:14

Generated On: 09 Jun 2021 14:53:49

Name of Medication BUDESONIDE

Prophylaxis Yes ☐
No ☒

Indication COVID-19

Dose per administration 0.5

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

If dose unit is Other, specify

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

If frequency is Other, specify

Route of administration Oral ☐
Topical ☐
Subcutaneous ☐
Transdermal ☐
Intraocular ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Data signed: (b) (4) 06 Apr 2021 15:41:14

Generated On: 09 Jun 2021 14:53:49

	Intramuscular	<input type="radio"/>
	Respiratory (Inhalation)	<input checked="" type="radio"/>
	Intralesional	<input type="radio"/>
	Intraperitoneal	<input type="radio"/>
	Nasal	<input type="radio"/>
	Vaginal	<input type="radio"/>
	Rectal	<input type="radio"/>
	Intravenous	<input type="radio"/>
	Intravenous Bolus	<input type="radio"/>
	Intravenous Drip	<input type="radio"/>
	Other	<input type="radio"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	09 FEB 2021	
Start date completely unknown	False	
Ongoing?	Yes <input type="radio"/>	
	No <input checked="" type="radio"/>	
If not Ongoing, End date (dd MMM yyyy)	12 FEB 2021	
Was this medication taken for solicited event?	Yes <input type="radio"/>	
	No <input checked="" type="radio"/>	
Separate Dosage Number (derived)	2	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802 <input type="radio"/>	
	803 <input type="radio"/>	
	804 <input checked="" type="radio"/>	

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Data signed: (b) (4) 06 Apr 2021 15:41:14

Generated On: 09 Jun 2021 14:53:49

Name of Medication FORMOTEROL

Prophylaxis Yes ☐
No ☒

Indication COVID-19

Dose per administration 20

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

If dose unit is Other, specify

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

If frequency is Other, specify

Route of administration Oral ☐
Topical ☐
Subcutaneous ☐
Transdermal ☐
Intraocular ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Data signed: (b) (4) 06 Apr 2021 15:41:14

Generated On: 09 Jun 2021 14:53:49

	Intramuscular	<input type="radio"/>
	Respiratory (Inhalation)	<input checked="" type="radio"/>
	Intralesional	<input type="radio"/>
	Intraperitoneal	<input type="radio"/>
	Nasal	<input type="radio"/>
	Vaginal	<input type="radio"/>
	Rectal	<input type="radio"/>
	Intravenous	<input type="radio"/>
	Intravenous Bolus	<input type="radio"/>
	Intravenous Drip	<input type="radio"/>
	Other	<input type="radio"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	9 FEB 2021	
Start date completely unknown	False	
Ongoing?	Yes <input type="radio"/>	
	No <input checked="" type="radio"/>	
If not Ongoing, End date (dd MMM yyyy)	12 FEB 2021	
Was this medication taken for solicited event?	Yes <input type="radio"/>	
	No <input checked="" type="radio"/>	
Separate Dosage Number (derived)	2	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802 <input type="radio"/>	
	803 <input type="radio"/>	
	804 <input checked="" type="radio"/>	

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Data signed: (b) (4) 06 Apr 2021 15:41:14

Generated On: 09 Jun 2021 14:53:49

Name of Medication ENOXAPARIN

Prophylaxis Yes ☐
No ☒

Indication COVID-19

Dose per administration 30

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

If dose unit is Other, specify

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

If frequency is Other, specify

Route of administration Oral ☐
Topical ☐
Subcutaneous ☒
Transdermal ☐
Intraocular ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Data signed: (b) (4) 06 Apr 2021 15:41:14

Generated On: 09 Jun 2021 14:53:49

	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)	9 FEB 2021	
Start date completely unknown	False	
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy) 12 FEB 2021		
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived)	2	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input checked="" type="checkbox"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Data signed: (b) (4) 06 Apr 2021 15:41:14

Generated On: 09 Jun 2021 14:53:49

Name of Medication OXYGEN

Prophylaxis Yes ☐
No ☒

Indication COVID-19

Dose per administration 2

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

If dose unit is Other, specify L

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 CONTINUOUS

Route of administration Oral ☐
Topical ☐
Subcutaneous ☐
Transdermal ☐
Intraocular ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Data signed: (b) (4) 06 Apr 2021 15:41:14

Generated On: 09 Jun 2021 14:53:49

	Intramuscular	<input type="radio"/>
	Respiratory (Inhalation)	<input checked="" type="radio"/>
	Intralesional	<input type="radio"/>
	Intraperitoneal	<input type="radio"/>
	Nasal	<input type="radio"/>
	Vaginal	<input type="radio"/>
	Rectal	<input type="radio"/>
	Intravenous	<input type="radio"/>
	Intravenous Bolus	<input type="radio"/>
	Intravenous Drip	<input type="radio"/>
	Other	<input type="radio"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	9 FEB 2021	
Start date completely unknown	False	
Ongoing?	Yes <input type="radio"/>	
	No <input checked="" type="radio"/>	
If not Ongoing, End date (dd MMM yyyy)	12 FEB 2021	
Was this medication taken for solicited event?	Yes <input type="radio"/>	
	No <input checked="" type="radio"/>	
Separate Dosage Number (derived)	_____	
Interval Dosage Unit Number (derived)	_____	
Interval Dosage Definition (derived)	802 <input type="radio"/>	
	803 <input type="radio"/>	
	804 <input type="radio"/>	

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Data signed: (b) (4) 06 Apr 2021 15:41:14

Generated On: 09 Jun 2021 14:53:49

Name of Medication ACETAMINOPHEN

Prophylaxis Yes ☐
No ☒

Indication BILATERAL PNEUMONIA

Dose per administration 650

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

If dose unit is Other, specify

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

If frequency is Other, specify

Route of administration Oral ☒
Topical ☐
Subcutaneous ☐
Transdermal ☐
Intraocular ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Data signed: (b) (4) 06 Apr 2021 15:41:14

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	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)		1 MAR 2021
Start date completely unknown		False
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)		5 MAR 2021
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived) _____		
Interval Dosage Unit Number (derived) _____		
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input type="checkbox"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Data signed: (b) (4) 06 Apr 2021 15:41:14

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Name of Medication ALBUTEROL

Prophylaxis Yes ☐
No ☒

Indication BILATERAL PNEUMONIA

Dose per administration 2.5

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

If dose unit is Other, specify

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

If frequency is Other, specify

Route of administration Oral ☐
Topical ☐
Subcutaneous ☐
Transdermal ☐
Intraocular ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

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	Intramuscular	<input type="radio"/>
	Respiratory (Inhalation)	<input checked="" type="radio"/>
	Intralesional	<input type="radio"/>
	Intraperitoneal	<input type="radio"/>
	Nasal	<input type="radio"/>
	Vaginal	<input type="radio"/>
	Rectal	<input type="radio"/>
	Intravenous	<input type="radio"/>
	Intravenous Bolus	<input type="radio"/>
	Intravenous Drip	<input type="radio"/>
	Other	<input type="radio"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	1 MAR 2021	
Start date completely unknown	False	
Ongoing?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
If not Ongoing, End date (dd MMM yyyy)		5 MAR 2021
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived) _____		
Interval Dosage Unit Number (derived) _____		
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input type="radio"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Data signed: (b) (4) 06 Apr 2021 15:41:14

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Name of Medication DUONEB

Prophylaxis Yes ☐
No ☒

Indication BILATERAL PNEUMONIA

Dose per administration 2.5/3

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

If dose unit is Other, specify

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

If frequency is Other, specify

Route of administration Oral ☐
Topical ☐
Subcutaneous ☒
Transdermal ☐
Intraocular ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Data signed: (b) (4) 06 Apr 2021 15:41:14

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	Intramuscular	<input type="radio"/>
	Respiratory (Inhalation)	<input type="radio"/>
	Intralesional	<input type="radio"/>
	Intraperitoneal	<input type="radio"/>
	Nasal	<input type="radio"/>
	Vaginal	<input type="radio"/>
	Rectal	<input type="radio"/>
	Intravenous	<input type="radio"/>
	Intravenous Bolus	<input type="radio"/>
	Intravenous Drip	<input type="radio"/>
	Other	<input type="radio"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	1 MAR 2021	
Start date completely unknown	False	
Ongoing?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
If not Ongoing, End date (dd MMM yyyy)	5 MAR 2021	
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)	2	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (29)

Data signed: (b) (4) 06 Apr 2021 15:41:14

Generated On: 09 Jun 2021 14:53:49

Name of Medication ENOXAPARIN

Prophylaxis Yes ☐
No ☒

Indication BILATERAL PNEUMONIA

Dose per administration 100

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

If dose unit is Other, specify

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

If frequency is Other, specify

Route of administration Oral ☐
Topical ☐
Subcutaneous ☒
Transdermal ☐
Intraocular ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (29)

Data signed: (b) (4) 06 Apr 2021 15:41:14

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	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)	1 MAR 2021	
Start date completely unknown	False	
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)	5 MAR 2021	
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived)	2	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input checked="" type="checkbox"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (30)

Data signed: (b) (4) 06 Apr 2021 15:41:14

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Name of Medication LEVOFLOXACIN

Prophylaxis Yes ☐
No ☒

Indication BILATERAL PNEUMONIA

Dose per administration 750

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

Q48H

Route of administration Oral ☐
Topical ☐
Subcutaneous ☐
Transdermal ☐
Intraocular ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (30)

Data signed: (b) (4) 06 Apr 2021 15:41:14

Generated On: 09 Jun 2021 14:53:49

	Intramuscular	<input type="radio"/>
	Respiratory (Inhalation)	<input type="radio"/>
	Intralesional	<input type="radio"/>
	Intraperitoneal	<input type="radio"/>
	Nasal	<input type="radio"/>
	Vaginal	<input type="radio"/>
	Rectal	<input type="radio"/>
	Intravenous	<input checked="" type="radio"/>
	Intravenous Bolus	<input type="radio"/>
	Intravenous Drip	<input type="radio"/>
	Other	<input type="radio"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	1 MAR 2021	
Start date completely unknown	False	
Ongoing?	Yes <input type="radio"/>	
	No <input checked="" type="radio"/>	
If not Ongoing, End date (dd MMM yyyy)	5 MAR 2021	
Was this medication taken for solicited event?	Yes <input type="radio"/>	
	No <input checked="" type="radio"/>	
Separate Dosage Number (derived)	_____	
Interval Dosage Unit Number (derived)	_____	
Interval Dosage Definition (derived)	802 <input type="radio"/>	
	803 <input type="radio"/>	
	804 <input type="radio"/>	

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (31)

Data signed: (b) (4) 06 Apr 2021 15:41:14

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Name of Medication PANTOPRAZOLE

Prophylaxis Yes ☐
No ☒

Indication BILATERAL PNEUMONIA

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 ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (31)

Data signed: (b) (4) 06 Apr 2021 15:41:14

Generated On: 09 Jun 2021 14:53:49

	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)	1 MAR 2021	
Start date completely unknown	False	
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)		5 MAR 2021
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input checked="" type="checkbox"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (32)

Data signed: (b) (4) 06 Apr 2021 15:41:14

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Name of Medication TESSALON PERLES

Prophylaxis Yes ☐
No ☒

Indication BILATERAL PNEUMONIA

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 ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (32)

Data signed: (b) (4) 06 Apr 2021 15:41:14

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	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)		1 MAR 2021
Start date completely unknown		False
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)		5 MAR 2021
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived) _____		
Interval Dosage Unit Number (derived) _____		
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input type="checkbox"/>

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Folder: Concomitant Medication and Vaccination (1)

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Data signed: (b) (4) 06 Apr 2021 15:41:14

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Name of Medication ZOSYN

Prophylaxis Yes ☐
No ☒

Indication BILATERAL PNEUMONIA

Dose per administration 3.375

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

Q6H

Route of administration Oral ☐
Topical ☐
Subcutaneous ☐
Transdermal ☐
Intraocular ☐

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Form: Prior/Concomitant Medication and Vaccination (33)

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	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 checked="" type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)		1 MAR 2021
Start date completely unknown		False
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)		5 MAR 2021
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived) _____		
Interval Dosage Unit Number (derived) _____		
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input type="checkbox"/>

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Folder: Concomitant Medication and Vaccination (1)

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Data signed: (b) (4) 06 Apr 2021 15:41:14

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Name of Medication ESTRADIOL

Prophylaxis Yes ☐
No ☒

Indication ESTROGEN DEFICIENCY

Dose per administration 0.5

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 TWO WEEKS

Route of administration Oral ☐
Topical ☐
Subcutaneous ☐
Transdermal ☐
Intraocular ☐

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Form: Prior/Concomitant Medication and Vaccination (34)

Data signed: (b) (4) 06 Apr 2021 15:41:14

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	Intramuscular	<input type="radio"/>
	Respiratory (Inhalation)	<input type="radio"/>
	Intralesional	<input type="radio"/>
	Intraperitoneal	<input type="radio"/>
	Nasal	<input type="radio"/>
	Vaginal	<input type="radio"/>
	Rectal	<input type="radio"/>
	Intravenous	<input type="radio"/>
	Intravenous Bolus	<input type="radio"/>
	Intravenous Drip	<input type="radio"/>
	Other	<input checked="" type="radio"/>
If route of administration is Other, specify	INTRAVAGINAL	
Start date (dd MMM yyyy)	UN UNK 2018	
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy)		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)		
Interval Dosage Unit Number (derived)		
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input type="radio"/>

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Form: Prior/Concomitant Medication and Vaccination (35)

Data signed: (b) (4) 06 Apr 2021 15:41:14

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Name of Medication FLUCONAZOLE

Prophylaxis Yes ☐
No ☒

Indication PERINEAL IRRITATION IN
FEMALE

Dose per administration 150

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 ☐

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	Intraocular	<input type="checkbox"/>
	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)		19 MAR 2021
Start date completely unknown		False
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)		19 MAR 2021
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived) _____		
Interval Dosage Unit Number (derived) _____		
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input type="checkbox"/>

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Form: Prior/Concomitant Medication and Vaccination (36)

Data signed: (b) (4) 06 Apr 2021 15:41:14

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Name of Medication NYSTATIN CREAM

Prophylaxis Yes ☐
No ☒

Indication PERINEAL IRRITATION IN
FEMALE

Dose per administration 100000

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

If dose unit is Other, specify UNITS

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 ☐

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Data signed: (b) (4) 06 Apr 2021 15:41:14

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	Intraocular	<input type="checkbox"/>
	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify		
Start date (dd MMM yyyy)	19 MAR 2021	
Start date completely unknown	False	
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)	22 MAR 2021	
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived)	2	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input checked="" type="checkbox"/>

US3032249

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (37)

Data signed: (b) (4) 06 Apr 2021 15:41:14

Generated On: 09 Jun 2021 14:53:49

Name of Medication COLESEVELAM

Prophylaxis Yes ☐
No ☒

Indication DYSLIPIDEMIA

Dose per administration 2500

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

If dose unit is Other, specify

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

If frequency is Other, specify

Route of administration Oral ☐
Topical ☐
Subcutaneous ☐
Transdermal ☐
Intraocular ☐

PRODUCTION RELEASE (v12.003
EAB) (1725)

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US3032249

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (37)

Data signed: (b) (4) 06 Apr 2021 15:41:14

Generated On: 09 Jun 2021 14:53:49

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input checked="" 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 2018	
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="checkbox"/>
	No	<input type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived)	2	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input checked="" type="checkbox"/>

US3032249

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures Summary

Data signed: (b) (4) 06 Apr 2021 15:41:15

Generated On: 09 Jun 2021 14:53:49

Were any concomitant procedures performed?

Yes ☒

No ☐

If yes, please complete Concomitant Procedures form.

US3032249

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures

Data signed: (b) (4) 06 Apr 2021 15:41:15

Generated On: 09 Jun 2021 14:53:49

Procedure/Surgery date (dd MMM yyyy)	Procedure/Surgery	Indication	If indication is Other, specify
9 FEB 2021	RAPID COVID-19 TEST	Adverse Event	
1 MAR 2021	CHEST X-RAY	Adverse Event	
1 MAR 2021	ELEVATED D-DIMER	Adverse Event	
1 MAR 2021	CT ANGIOGRAM CHEST WITH CONTRAST	Adverse Event	
1 MAR 2021	PRO-CALCITONIN	Adverse Event	
1 MAR 2021	COMPLETE BLOOD COUNT	Adverse Event	
1 MAR 2021	BLOOD CULTURES	Adverse Event	
1 MAR 2021	FLUTTER/PCP THERAPY	Adverse Event	
3 MAR 2021	CHEST X-RAY	Adverse Event	
1 MAR 2021	BASAL METABOLIC PANEL	Adverse Event	
9 FEB 2021	CHEST X-RAY	Adverse Event	
9 FEB 2021	COMPLETE BLOOD COUNT	Adverse Event	
9 FEB 2021	BASAL METABOLIC PANEL	Adverse Event	

US3032249

Folder: End of Study (1)

Form: Dosing Discontinuation

Generated On: 09 Jun 2021 14:53:49

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

US3032249

Folder: End of Study (1)

Form: End of Study / Study Discontinuation

Generated On: 09 Jun 2021 14:53:49

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 ☐

US3032249

Folder: SAE USA-US032-2021-MRNA-1273-P301000008

Form: Safety Report Form

Data signed: (b) (4) 06 Apr 2021 15:41:55

Generated On: 09 Jun 2021 14:53:49

SAEID	USA-US032-2021-MRNA-1273-P301000008
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input type="radio"/> No <input checked="" type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input checked="" type="radio"/> No <input type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input type="radio"/> No <input checked="" type="radio"/>
Investigator's First Name	KEITH
Investigator's Last Name	VRBICKY
Site Address: Street	
Site Address: City	
Site Address: State	
Site Address: Postal Code	
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	6

US3032249

Folder: SAE USA-US032-2021-MRNA-1273-P301000008

Form: Safety Report Form (1)

Data signed: (b) (4) 06 Apr 2021 15:41:55

Generated On: 09 Jun 2021 14:53:49

SAEID	USA-US032-2021-MRNA-1273-P301000008
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input type="radio"/> No <input checked="" type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input checked="" type="radio"/> No <input type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input type="radio"/> No <input checked="" type="radio"/>
Investigator's First Name	KEITH
Investigator's Last Name	VRBICKY
Site Address: Street	
Site Address: City	
Site Address: State	
Site Address: Postal Code	
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	6
Date of submission (Pre-filled from custom function)	12/FEB/2021 08:30
Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.	True

US3032249

Folder: SAE USA-US032-2021-MRNA-1273-P301000008

Form: Safety Report Form (2)

Data signed: (b) (4) 06 Apr 2021 15:41:55

Generated On: 09 Jun 2021 14:53:49

SAEID	USA-US032-2021-MRNA-1273-P301000008
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input type="radio"/> No <input checked="" type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input checked="" type="radio"/> No <input type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input type="radio"/> No <input checked="" type="radio"/>
Investigator's First Name	KEITH
Investigator's Last Name	VRBICKY
Site Address: Street	
Site Address: City	
Site Address: State	
Site Address: Postal Code	
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	6
Date of submission (Pre-filled from custom function)	04/MAR/2021 09:40
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

US3032249

Folder: SAE USA-US032-2021-MRNA-1273-P301000008

Form: Safety Report Form (3)

Data signed: (b) (4) 06 Apr 2021 15:41:55

Generated On: 09 Jun 2021 14:53:49

SAEID	USA-US032-2021-MRNA-1273-P301000008
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input type="radio"/> No <input checked="" type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input checked="" type="radio"/> No <input type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input type="radio"/> No <input checked="" type="radio"/>
Investigator's First Name	KEITH
Investigator's Last Name	VRBICKY
Site Address: Street	
Site Address: City	
Site Address: State	
Site Address: Postal Code	
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	6
Date of submission (Pre-filled from custom function)	04/MAR/2021 09:45
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

US3032249

Folder: SAE USA-US032-2021-MRNA-1273-P301000008

Form: Safety Report Form (4)

Data signed: (b) (4) 06 Apr 2021 15:41:55

Generated On: 09 Jun 2021 14:53:49

SAEID	USA-US032-2021-MRNA-1273-P301000008
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input type="radio"/> No <input checked="" type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input checked="" type="radio"/> No <input type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input type="radio"/> No <input checked="" type="radio"/>
Investigator's First Name	KEITH
Investigator's Last Name	VRBICKY
Site Address: Street	
Site Address: City	
Site Address: State	
Site Address: Postal Code	
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	6
Date of submission (Pre-filled from custom function)	10/MAR/2021 11:02
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

US3032249

Folder: SAE USA-US032-2021-MRNA-1273-P301000008

Form: Safety Report Form (5)

Data signed: (b) (4) 06 Apr 2021 15:41:55

Generated On: 09 Jun 2021 14:53:49

SAEID	USA-US032-2021-MRNA-1273-P301000008
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input type="radio"/> No <input checked="" type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input checked="" type="radio"/> No <input type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input type="radio"/> No <input checked="" type="radio"/>
Investigator's First Name	KEITH
Investigator's Last Name	VRBICKY
Site Address: Street	
Site Address: City	
Site Address: State	
Site Address: Postal Code	
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	6
Date of submission (Pre-filled from custom function)	24/MAR/2021 12:05
Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.	True

US3032249

Folder: SAE USA-US032-2021-MRNA-1273-P301000008

Form: Safety Report Form (6)

Data signed: (b) (4) 06 Apr 2021 15:41:55

Generated On: 09 Jun 2021 14:53:49

SAEID	USA-US032-2021-MRNA-1273-P301000008
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input type="radio"/> No <input checked="" type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input checked="" type="radio"/> No <input type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input type="radio"/> No <input checked="" type="radio"/>
Investigator's First Name	KEITH
Investigator's Last Name	VRBICKY
Site Address: Street	
Site Address: City	
Site Address: State	
Site Address: Postal Code	
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	6
Date of submission (Pre-filled from custom function)	26/MAR/2021 10:26
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

US3032249 (Prod: Meridian Clinical Research (Norfolk-Nebraska))

US3032249

Form: Participant Creation

Generated On: 09 Jun 2021 14:53:49

[Participant ID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 15:12:36
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:50:49
User entered 'US3032249'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	19 Aug 2020 22:29:19

US3032249

Folder: Screening

Form: Visit Date

Generated On: 09 Jun 2021 14:53:49

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:40:23
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:50:49
User entered 'Yes (Y)'	Samantha Wieseler (b) (4)	20 Aug 2020 02:56:27

US3032249

Folder: Screening

Form: Visit Date

Generated On: 09 Jun 2021 14:53:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:40:23
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:50:49
User entered '19 AUG 2020'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	19 Aug 2020 22:29:20

US3032249

Folder: Screening

Form: Visit Date

Generated On: 09 Jun 2021 14:53:49

[Was visit performed at the participant's home or at the clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:40:23
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:50:49
User entered 'Clinic (Clinic)'	Samantha Wieseler (b) (4)	20 Aug 2020 02:56:27

US3032249

Folder: Screening

Form: Visit Date

Generated On: 09 Jun 2021 14:53:49

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:40:23
User entered 'SCRN'	System	20 Aug 2020 02:56:27

US3032249

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 14:53:49

[Date of Birth \(MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:40:23
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:50:49
User entered '(b) (6)1948'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	19 Aug 2020 22:29:21

US3032249

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 14:53:49

[Age](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:40:23
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:50:49
User entered '72'	Samantha Wieseler (b) (4)	20 Aug 2020 02:56:43

US3032249

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 14:53:49

[Age Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:40:23
User entered 'YEARS'	System	20 Aug 2020 02:56:43

US3032249

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 14:53:49

[Age \(Derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:40:23
User entered '72'	System	19 Aug 2020 23:40:28

US3032249

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 14:53:49

[Sex](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:40:23
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:50:49
User entered 'Female (F)'	Samantha Wieseler (b) (4)	20 Aug 2020 02:56:43

US3032249

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 14:53:49

[Ethnicity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:40:23
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:50:49
User entered 'Not Hispanic or Latino (NOT HISPANIC OR LATINO)'	Samantha Wieseler (b) (4)	20 Aug 2020 02:56:43

US3032249

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 14:53:49

[White](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:40:23
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:50:49
User entered 'I'	Samantha Wieseler (b) (4)	20 Aug 2020 02:56:43

US3032249

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 14:53:49

[Black](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:40:23
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:50:49
User entered '0'	Samantha Wieseler (b) (4)	20 Aug 2020 02:56:43

US3032249

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 14:53:49

[Asian](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:40:23
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:50:49
User entered '0'	Samantha Wieseler (b) (4)	20 Aug 2020 02:56:43

US3032249

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 14:53:49

[American Indian or Alaska Native](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:40:23
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:50:49
User entered '0'	Samantha Wieseler (b) (4)	20 Aug 2020 02:56:43

US3032249

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 14:53:49

[Native Hawaiian or other Pacific Islander](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:40:23
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:50:49
User entered '0'	Samantha Wieseler (b) (4)	20 Aug 2020 02:56:43

US3032249

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 14:53:49

[Other](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:40:23
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:50:49
User entered '0'	Samantha Wieseler (b) (4)	20 Aug 2020 02:56:43

US3032249

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 14:53:49

[If race is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:40:23
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:50:49
User entered empty.	Samantha Wieseler (b) (4)	20 Aug 2020 02:56:43

US3032249

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 14:53:49

[Unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:40:23
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:50:49
User entered '0'	Samantha Wieseler (b) (4)	20 Aug 2020 02:56:43

US3032249

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 14:53:49

[Not reported](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:40:23
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:50:49
User entered '0'	Samantha Wieseler (b) (4)	20 Aug 2020 02:56:43

US3032249

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 14:53:49

[Date of Informed Consent \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:40:23
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:50:49
User entered '19 Aug 2020'	Kelsey Kelley (b) (4)	19 Aug 2020 23:40:28

US3032249

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 14:53:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:40:23
User entered 'Aug 2020'	System	19 Aug 2020 23:40:28

US3032249

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 14:53:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:40:23
User entered '2020'	System	19 Aug 2020 23:40:28

US3032249

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 14:53:49

[Protocol Version](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:40:23
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:50:49
User entered 'Amendment 2 (2)'	Kelsey Kelley (b) (4)	19 Aug 2020 23:40:28

US3032249

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 14:53:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:40:23
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:50:49
User entered 'Yes (Y)'	Kelsey Kelley (b) (4)	19 Aug 2020 23:40:28

US3032249

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 14:53:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:40:23
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:50:49
User entered empty.	(b) (4) Kelsey Kelley (b) (4)	19 Aug 2020 23:40:28
	(b) (4)	

US3032249

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 14:53:49

If reason for screen fail is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:40:23
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:50:49
User entered empty.	(b) (4) Kelsey Kelley (b) (4)	19 Aug 2020 23:40:28
	(b) (4)	

US3032249

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 14:53:49

[Was this participant screened previously?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:40:23
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:50:49
User entered 'No (N)'	(b) (4) Kelsey Kelley (b) (4)	19 Aug 2020 23:40:28

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Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 14:53:49

[If Yes, previous participant number](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:40:23
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:50:49
User entered empty.	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	19 Aug 2020 22:29:20

US3032249

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 14:53:49

[Enrollment Trigger](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:40:23
User entered 'I'	System	19 Aug 2020 23:40:28

US3032249

Folder: Screening

Form: Inclusion/Exclusion Criteria Summary

Generated On: 09 Jun 2021 14:53:49

[Did the participant meet all eligibility criteria?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:40:23
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:50:49
User entered 'Yes (Y)'	(b) (4) Kelsey Kelley (b) (4)	19 Aug 2020 23:40:02

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Folder: Screening

Form: Medical History Summary

Generated On: 09 Jun 2021 14:53:49

[Were any significant conditions reported?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:40:23
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:50:49
User entered 'Yes (Y)'	Samantha Wieseler (b) (4)	20 Aug 2020 02:57:17

US3032249

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 14:53:49

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:40:23
User coded data point as SOC: Immune system disorders, HLGT: Allergic conditions, HLT: Allergic conditions NEC, PT: Allergy to surgical sutures, LLT: Allergy to surgical sutures - version MedDRA\\23.0.	Coder Import (b) (4)	24 Nov 2020 13:46:11
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4)	24 Nov 2020 13:46:11
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:50:49
Data point term sent to Coder	(b) (4) System	20 Aug 2020 02:59:54
User entered 'Polyglactin Suture Hypersensitivity'	Samantha Wieseler (b) (4)	20 Aug 2020 02:59:15
	(b) (4)	

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Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 14:53:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:40:23
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:50:49
User entered 'UN UNK 2014'	Samantha Wieseler (b) (4)	20 Aug 2020 02:59:15

US3032249

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 14:53:49

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:40:23
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:50:49
User entered '0'	Samantha Wieseler (b) (4)	20 Aug 2020 02:59:15

US3032249

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 14:53:49

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:40:23
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:50:49
User entered 'Yes (Y)'	Samantha Wieseler (b) (4)	20 Aug 2020 02:59:15

US3032249

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 14:53:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:40:23
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:50:49
User entered empty.	Samantha Wieseler (b) (4)	20 Aug 2020 02:59:15

US3032249

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 14:53:49

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:40:23
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:50:49
User entered '0'	Samantha Wieseler (b) (4)	20 Aug 2020 02:59:15

US3032249

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 14:53:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:40:23
User entered 'Jan 2014'	System	20 Aug 2020 02:59:15

US3032249

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 14:53:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:40:23
User entered '2014'	System	20 Aug 2020 02:59:15

US3032249

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 14:53:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:40:23
User entered empty.	System	20 Aug 2020 02:59:15

US3032249

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 14:53:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:40:23
User entered empty.	System	20 Aug 2020 02:59:15

US3032249

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 14:53:49

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:40:23
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:50:49
User coded data point as SOC: Surgical and medical procedures, HLGT: Obstetric and gynaecological therapeutic procedures, HLT: Uterine therapeutic procedures, PT: Hysterectomy, LLT: Hysterectomy - version MedDRA\\23.0.	(b) (4) Coder Import (b) (4)	(b) (4) 20 Aug 2020 03:04:21
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	(b) (4) 20 Aug 2020 03:04:21
User coded data point as SOC: Surgical and medical procedures, HLGT: Obstetric and gynaecological therapeutic procedures, HLT: Uterine therapeutic procedures, PT: Hysterectomy, LLT: Hysterectomy - version MedDRA\\23.0.	Coder Import (b) (4)	(b) (4) 20 Aug 2020 03:00:22
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	(b) (4) 20 Aug 2020 03:00:22
Data point term sent to Coder	System	20 Aug 2020 02:59:54
User entered 'Hysterectomy'	Samantha Wieseler (b) (4)	20 Aug 2020 02:59:37
	(b) (4)	

US3032249

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 14:53:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:40:23
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:50:49
User entered 'UN UNK 1983'	Samantha Wieseler (b) (4)	20 Aug 2020 02:59:37

US3032249

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 14:53:49

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:40:23
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:50:49
User entered '0'	Samantha Wieseler (b) (4)	20 Aug 2020 02:59:37

US3032249

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 14:53:49

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:40:23
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:50:49
User entered 'No (N)'	Samantha Wieseler (b) (4)	20 Aug 2020 02:59:37

US3032249

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 14:53:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:40:23
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:50:49
User entered 'UN UNK 1983'	Samantha Wieseler (b) (4)	20 Aug 2020 02:59:37

US3032249

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 14:53:49

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:40:23
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:50:49
User entered '0'	Samantha Wieseler (b) (4)	20 Aug 2020 02:59:37

US3032249

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 14:53:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:40:23
User entered 'Jan 1983'	System	20 Aug 2020 02:59:37

US3032249

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 14:53:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:40:23
User entered '1983'	System	20 Aug 2020 02:59:37

US3032249

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 14:53:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:40:23
User entered 'Jan 1983'	System	20 Aug 2020 02:59:37

US3032249

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 14:53:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:40:23
User entered '1983'	System	20 Aug 2020 02:59:37

US3032249

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 14:53:49

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:40:23
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:50:49
User coded data point as SOC: Reproductive system and breast disorders, HLGT: Menstrual cycle and uterine bleeding disorders, HLT: Menstruation with increased bleeding, PT: Menorrhagia, LLT: Menorrhagia - version MedDRA\\23.0.	Coder Import (b) (4)	20 Aug 2020 03:04:12
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	20 Aug 2020 03:04:12
Data point term sent to Coder	System	20 Aug 2020 03:04:01
User entered 'Menorrhagia'	Samantha Wieseler (b) (4)	20 Aug 2020 03:04:00

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Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 14:53:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:40:23
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:50:49
User entered 'UN UNK 1981'	Samantha Wieseler (b) (4)	20 Aug 2020 03:04:00

US3032249

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 14:53:49

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:40:23
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:50:49
User entered '0'	Samantha Wieseler (b) (4)	20 Aug 2020 03:04:00

US3032249

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 14:53:49

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:40:23
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:50:49
User entered 'No (N)'	Samantha Wieseler (b) (4)	20 Aug 2020 03:04:00

US3032249

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 14:53:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:40:23
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:50:49
User entered 'UN UNK 1983'	Samantha Wieseler (b) (4)	20 Aug 2020 03:04:00

US3032249

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 14:53:49

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:40:23
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:50:49
User entered '0'	Samantha Wieseler (b) (4)	20 Aug 2020 03:04:00

US3032249

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 14:53:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:40:23
User entered 'Jan 1981'	System	20 Aug 2020 03:04:00

US3032249

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 14:53:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:40:23
User entered '1981'	System	20 Aug 2020 03:04:00

US3032249

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 14:53:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:40:23
User entered 'Jan 1983'	System	20 Aug 2020 03:04:00

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Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 14:53:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:40:23
User entered '1983'	System	20 Aug 2020 03:04:00

US3032249

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 14:53:49

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:40:23
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:50:49
User coded data point as SOC: Investigations, HLT: Gastrointestinal investigations, HLT: Gastrointestinal and abdominal imaging procedures, PT: Oesophagogastrroduodenoscopy, LLT: Esophagogastrroduodenoscopy - version MedDRA\\23.0.	Coder Import (b) (4)	20 Aug 2020 14:09:21
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	20 Aug 2020 14:09:21
Data point term sent to Coder	System	20 Aug 2020 14:08:11
User entered 'Esophagogastrroduodenoscopy'	Samantha Wieseler (b) (4)	20 Aug 2020 14:07:23

US3032249

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 14:53:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:40:23
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:50:49
User entered 'UN Jun 2020'	Samantha Wieseler (b) (4)	20 Aug 2020 14:07:23

US3032249

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 14:53:49

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:40:23
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:50:49
User entered '0'	Samantha Wieseler (b) (4)	20 Aug 2020 14:07:23

US3032249

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 14:53:49

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:40:23
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:50:49
User entered 'No (N)'	Samantha Wieseler (b) (4)	20 Aug 2020 14:07:23

US3032249

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 14:53:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:40:23
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:50:49
User entered 'UN Jun 2020'	Samantha Wieseler (b) (4)	20 Aug 2020 14:07:23

US3032249

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 14:53:49

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:40:23
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:50:49
User entered '0'	Samantha Wieseler (b) (4)	20 Aug 2020 14:07:23

US3032249

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 14:53:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:40:23
User entered 'Jun 2020'	System	20 Aug 2020 14:07:23

US3032249

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 14:53:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:40:23
User entered '2020'	System	20 Aug 2020 14:07:23

US3032249

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 14:53:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:40:23
User entered 'Jun 2020'	System	20 Aug 2020 14:07:23

US3032249

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 14:53:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:40:23
User entered '2020'	System	20 Aug 2020 14:07:23

US3032249

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 14:53:49

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:40:23
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:50:49
User coded data point as SOC: Investigations, HLT: Investigations, imaging and histopathology procedures NEC, HLT: Imaging procedures NEC, PT: Radioisotope scan, LLT: Scintigraphy - version MedDRA\\23.0.	Coder Import (b) (4)	20 Aug 2020 14:44:16
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4)	20 Aug 2020 14:44:16
Data point term sent to Coder	System	20 Aug 2020 14:08:13
User entered 'Gastric Emptying Scintigraphy'	Samantha Wieseler (b) (4)	20 Aug 2020 14:07:59

US3032249

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 14:53:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:40:23
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:50:49
User entered 'UN Jun 2020'	Samantha Wieseler (b) (4)	20 Aug 2020 14:07:59

US3032249

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 14:53:49

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:40:23
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:50:49
User entered '0'	Samantha Wieseler (b) (4)	20 Aug 2020 14:07:59

US3032249

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 14:53:49

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:40:23
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:50:49
User entered 'No (N)'	Samantha Wieseler (b) (4)	20 Aug 2020 14:07:59

US3032249

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 14:53:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:40:23
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:50:49
User entered 'UN Jun 2020'	Samantha Wieseler (b) (4)	20 Aug 2020 14:07:59

US3032249

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 14:53:49

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:40:23
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:50:49
User entered '0'	Samantha Wieseler (b) (4)	20 Aug 2020 14:07:59

US3032249

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 14:53:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:40:23
User entered 'Jun 2020'	System	20 Aug 2020 14:07:59

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Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 14:53:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:40:23
User entered '2020'	System	20 Aug 2020 14:07:59

US3032249

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 14:53:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:40:23
User entered 'Jun 2020'	System	20 Aug 2020 14:07:59

US3032249

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 14:53:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:40:23
User entered '2020'	System	20 Aug 2020 14:07:59

US3032249

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 14:53:49

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:40:23
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:50:49
User coded data point as SOC: Gastrointestinal disorders, HLGT: Gastrointestinal motility and defaecation conditions, HLT: Gastrointestinal atonic and hypomotility disorders NEC, PT: Impaired gastric emptying, LLT: Gastroparesis - version MedDRA\\23.0.	(b) (4) Coder Import (b) (4)	20 Aug 2020 14:10:21
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	20 Aug 2020 14:10:21
Data point term sent to Coder	System	20 Aug 2020 14:09:15
User entered 'Gastroparesis'	Samantha Wieseler (b) (4)	20 Aug 2020 14:08:23
	(b) (4)	

US3032249

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 14:53:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:40:23
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:50:49
User entered 'UN Jun 2020'	Samantha Wieseler (b) (4)	20 Aug 2020 14:08:23

US3032249

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 14:53:49

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:40:23
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:50:49
User entered '0'	Samantha Wieseler (b) (4)	20 Aug 2020 14:08:23

US3032249

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 14:53:49

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:40:23
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:50:49
User entered 'No (N)'	Samantha Wieseler (b) (4)	20 Aug 2020 14:08:23

US3032249

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 14:53:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:40:23
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:50:49
User entered 'UN Jun 2020'	Samantha Wieseler (b) (4)	20 Aug 2020 14:08:23

US3032249

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 14:53:49

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:40:23
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:50:49
User entered '0'	Samantha Wieseler (b) (4)	20 Aug 2020 14:08:23

US3032249

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 14:53:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:40:23
User entered 'Jun 2020'	System	20 Aug 2020 14:08:23

US3032249

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 14:53:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:40:23
User entered '2020'	System	20 Aug 2020 14:08:23

US3032249

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 14:53:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:40:23
User entered 'Jun 2020'	System	20 Aug 2020 14:08:23

US3032249

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 14:53:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:40:23
User entered '2020'	System	20 Aug 2020 14:08:23

US3032249

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 14:53:49

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:40:23
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:50:49
User coded data point as SOC: Immune system disorders, HLGT: Allergic conditions, HLT: Atopic disorders, PT: Seasonal allergy, LLT: Seasonal allergy - version MedDRA\\23.0.	(b) (4) (b) (4) Coder Import	20 Aug 2020 14:10:21
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	(b) (4)	20 Aug 2020 14:10:21
Data point term sent to Coder	System	20 Aug 2020 14:09:15
User entered 'Seasonal Allergies'	Samantha Wieseler (b) (4)	20 Aug 2020 14:08:39
	(b) (4)	

US3032249

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 14:53:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:40:23
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:50:49
User entered 'UN UNK 2007'	Samantha Wieseler (b) (4)	20 Aug 2020 14:08:39

US3032249

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 14:53:49

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:40:23
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:50:49
User entered '0'	Samantha Wieseler (b) (4)	20 Aug 2020 14:08:39

US3032249

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 14:53:49

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:40:23
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:50:49
User entered 'Yes (Y)'	Samantha Wieseler (b) (4)	20 Aug 2020 14:08:39

US3032249

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 14:53:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:40:23
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:50:49
User entered empty.	Samantha Wieseler (b) (4)	20 Aug 2020 14:08:39

US3032249

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 14:53:49

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:40:23
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:50:49
User entered '0'	Samantha Wieseler (b) (4)	20 Aug 2020 14:08:39

US3032249

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 14:53:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:40:23
User entered 'Jan 2007'	System	20 Aug 2020 14:08:39

US3032249

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 14:53:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:40:23
User entered '2007'	System	20 Aug 2020 14:08:39

US3032249

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 14:53:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:40:23
User entered empty.	System	20 Aug 2020 14:08:39

US3032249

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 14:53:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:40:23
User entered empty.	System	20 Aug 2020 14:08:39

US3032249

Folder: Screening

Form: Medical History (8)

Generated On: 09 Jun 2021 14:53:49

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:40:23
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:50:49
User coded data point as SOC: Musculoskeletal and connective tissue disorders, HLGT: Joint disorders, HLT: Osteoarthropathies, PT: Osteoarthritis, LLT: Osteoarthritis - version MedDRA\\23.0.	Coder Import (b) (4)	20 Aug 2020 14:10:21
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	20 Aug 2020 14:10:21
Data point term sent to Coder	System	20 Aug 2020 14:09:15
User entered 'Osteoarthritis'	Samantha Wieseler (b) (4)	20 Aug 2020 14:08:53

US3032249

Folder: Screening

Form: Medical History (8)

Generated On: 09 Jun 2021 14:53:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:40:23
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:50:49
User entered 'UN UNK 2006'	Samantha Wieseler (b) (4)	20 Aug 2020 14:08:53

US3032249

Folder: Screening

Form: Medical History (8)

Generated On: 09 Jun 2021 14:53:49

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:40:23
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:50:49
User entered '0'	Samantha Wieseler (b) (4)	20 Aug 2020 14:08:53

US3032249

Folder: Screening

Form: Medical History (8)

Generated On: 09 Jun 2021 14:53:49

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:40:23
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:50:49
User entered 'Yes (Y)'	Samantha Wieseler (b) (4)	20 Aug 2020 14:08:53

US3032249

Folder: Screening

Form: Medical History (8)

Generated On: 09 Jun 2021 14:53:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:40:23
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:50:49
User entered empty.	Samantha Wieseler (b) (4)	20 Aug 2020 14:08:53

US3032249

Folder: Screening

Form: Medical History (8)

Generated On: 09 Jun 2021 14:53:49

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:40:23
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:50:49
User entered '0'	Samantha Wieseler (b) (4)	20 Aug 2020 14:08:53

US3032249

Folder: Screening

Form: Medical History (8)

Generated On: 09 Jun 2021 14:53:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:40:23
User entered 'Jan 2006'	System	20 Aug 2020 14:08:53

US3032249

Folder: Screening

Form: Medical History (8)

Generated On: 09 Jun 2021 14:53:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:40:23
User entered '2006'	System	20 Aug 2020 14:08:53

US3032249

Folder: Screening

Form: Medical History (8)

Generated On: 09 Jun 2021 14:53:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:40:23
User entered empty.	System	20 Aug 2020 14:08:53

US3032249

Folder: Screening

Form: Medical History (8)

Generated On: 09 Jun 2021 14:53:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:40:23
User entered empty.	System	20 Aug 2020 14:08:53

US3032249

Folder: Screening

Form: Medical History (9)

Generated On: 09 Jun 2021 14:53:49

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:40:23
User signature succeeded.	Keith Vrbicky (b) (4)	24 Nov 2020 20:29:25
User coded data point as SOC: Investigations, HLGT: Musculoskeletal and soft tissue investigations (excl enzyme tests), HLT: Musculoskeletal and soft tissue imaging procedures, PT: Arthroscopy, LLT: Arthroscopy R knee - version MedDRA\\23.0.	Coder Import (b) (4)	23 Nov 2020 20:37:08
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	23 Nov 2020 20:37:08
Data point term sent to Coder	System	23 Nov 2020 20:36:29
Coding entries removed.	(b) (4), (b) (6)	23 Nov 2020 20:36:22
Signature has been broken.		23 Nov 2020 20:36:22
User entered 'Right KNEE ARTHROSCOPY' reason for change: Data Entry Error		23 Nov 2020 20:36:22
User signature succeeded.		28 Sep 2020 17:50:49
User coded data point as SOC: Investigations, HLGT: Musculoskeletal and soft tissue investigations (excl enzyme tests), HLT: Musculoskeletal and soft tissue imaging procedures, PT: Arthroscopy, LLT: Knee arthroscopy - version MedDRA\\23.0.	Coder Import (b) (4)	20 Aug 2020 14:10:20
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	20 Aug 2020 14:10:20
Data point term sent to Coder	System	20 Aug 2020 14:09:16
User entered 'Knee Arthroscopy'	Samantha Wieseler (b) (4)	20 Aug 2020 14:09:12

US3032249

Folder: Screening

Form: Medical History (9)

Generated On: 09 Jun 2021 14:53:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:40:23
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:50:49
User entered 'UN UNK 2004'	Samantha Wieseler (b) (4)	20 Aug 2020 14:09:12

US3032249

Folder: Screening

Form: Medical History (9)

Generated On: 09 Jun 2021 14:53:49

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:40:23
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:50:49
User entered '0'	Samantha Wieseler (b) (4)	20 Aug 2020 14:09:12

US3032249

Folder: Screening

Form: Medical History (9)

Generated On: 09 Jun 2021 14:53:49

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:40:23
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:50:49
User entered 'No (N)'	Samantha Wieseler (b) (4)	20 Aug 2020 14:09:12

US3032249

Folder: Screening

Form: Medical History (9)

Generated On: 09 Jun 2021 14:53:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:40:23
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:50:49
User entered 'UN UNK 2004'	Samantha Wieseler (b) (4)	20 Aug 2020 14:09:12

US3032249

Folder: Screening

Form: Medical History (9)

Generated On: 09 Jun 2021 14:53:49

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:40:23
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:50:49
User entered '0'	Samantha Wieseler (b) (4)	20 Aug 2020 14:09:12

US3032249

Folder: Screening

Form: Medical History (9)

Generated On: 09 Jun 2021 14:53:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:40:23
User entered 'Jan 2004'	System	20 Aug 2020 14:09:12

US3032249

Folder: Screening

Form: Medical History (9)

Generated On: 09 Jun 2021 14:53:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:40:23
User entered '2004'	System	20 Aug 2020 14:09:12

US3032249

Folder: Screening

Form: Medical History (9)

Generated On: 09 Jun 2021 14:53:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:40:23
User entered 'Jan 2004'	System	20 Aug 2020 14:09:12

US3032249

Folder: Screening

Form: Medical History (9)

Generated On: 09 Jun 2021 14:53:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:40:23
User entered '2004'	System	20 Aug 2020 14:09:12

US3032249

Folder: Screening

Form: Medical History (10)

Generated On: 09 Jun 2021 14:53:49

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:40:23
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:50:49
User coded data point as SOC: Investigations, HLT: Musculoskeletal and soft tissue investigations (excl enzyme tests), HLT: Musculoskeletal and soft tissue imaging procedures, PT: Arthroscopy, LLT: Arthroscopy L knee - version MedDRA\\23.0.	Coder Import (b) (4)	20 Aug 2020 14:11:22
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	20 Aug 2020 14:11:22
Data point term sent to Coder	System	20 Aug 2020 14:10:17
User entered 'Left Knee Arthroscopy'	Samantha Wieseler (b) (4)	20 Aug 2020 14:09:37
	(b) (4)	

US3032249

Folder: Screening

Form: Medical History (10)

Generated On: 09 Jun 2021 14:53:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:40:23
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:50:49
User entered 'UN UNK 2005'	Samantha Wieseler (b) (4)	20 Aug 2020 14:09:37

US3032249

Folder: Screening

Form: Medical History (10)

Generated On: 09 Jun 2021 14:53:49

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:40:23
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:50:49
User entered '0'	Samantha Wieseler (b) (4)	20 Aug 2020 14:09:37

US3032249

Folder: Screening

Form: Medical History (10)

Generated On: 09 Jun 2021 14:53:49

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:40:23
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:50:49
User entered 'No (N)'	Samantha Wieseler (b) (4)	20 Aug 2020 14:09:37

US3032249

Folder: Screening

Form: Medical History (10)

Generated On: 09 Jun 2021 14:53:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:40:23
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:50:49
User entered 'UN UNK 2005'	Samantha Wieseler (b) (4)	20 Aug 2020 14:09:37

US3032249

Folder: Screening

Form: Medical History (10)

Generated On: 09 Jun 2021 14:53:49

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:40:23
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:50:49
User entered '0'	Samantha Wieseler (b) (4)	20 Aug 2020 14:09:37

US3032249

Folder: Screening

Form: Medical History (10)

Generated On: 09 Jun 2021 14:53:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:40:23
User entered 'Jan 2005'	System	20 Aug 2020 14:09:37

US3032249

Folder: Screening

Form: Medical History (10)

Generated On: 09 Jun 2021 14:53:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:40:23
User entered '2005'	System	20 Aug 2020 14:09:37

US3032249

Folder: Screening

Form: Medical History (10)

Generated On: 09 Jun 2021 14:53:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:40:23
User entered 'Jan 2005'	System	20 Aug 2020 14:09:37

US3032249

Folder: Screening

Form: Medical History (10)

Generated On: 09 Jun 2021 14:53:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:40:23
User entered '2005'	System	20 Aug 2020 14:09:37

US3032249

Folder: Screening

Form: Medical History (11)

Generated On: 09 Jun 2021 14:53:49

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:40:23
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:50:49
User coded data point as SOC: Surgical and medical procedures, HLGT: Hepatobiliary therapeutic procedures, HLT: Biliary tract and gallbladder therapeutic procedures, PT: Cholecystectomy, LLT: Cholecystectomy - version MedDRA\\23.0.	Coder Import (b) (4)	20 Aug 2020 14:11:23
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	20 Aug 2020 14:11:23
Data point term sent to Coder	System	20 Aug 2020 14:10:18
User entered 'Cholecystectomy'	Samantha Wieseler (b) (4)	20 Aug 2020 14:09:58

US3032249

Folder: Screening

Form: Medical History (11)

Generated On: 09 Jun 2021 14:53:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:40:23
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:50:49
User entered 'UN UNK 2014'	Samantha Wieseler (b) (4)	20 Aug 2020 14:09:58

US3032249

Folder: Screening

Form: Medical History (11)

Generated On: 09 Jun 2021 14:53:49

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:40:23
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:50:49
User entered '0'	Samantha Wieseler (b) (4)	20 Aug 2020 14:09:58

US3032249

Folder: Screening

Form: Medical History (11)

Generated On: 09 Jun 2021 14:53:49

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:40:23
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:50:49
User entered 'No (N)'	Samantha Wieseler (b) (4)	20 Aug 2020 14:09:58

US3032249

Folder: Screening

Form: Medical History (11)

Generated On: 09 Jun 2021 14:53:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:40:23
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:50:49
User entered 'UN UNK 2014'	Samantha Wieseler (b) (4)	20 Aug 2020 14:09:58

US3032249

Folder: Screening

Form: Medical History (11)

Generated On: 09 Jun 2021 14:53:49

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:40:23
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:50:49
User entered '0'	Samantha Wieseler (b) (4)	20 Aug 2020 14:09:58

US3032249

Folder: Screening

Form: Medical History (11)

Generated On: 09 Jun 2021 14:53:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:40:23
User entered 'Jan 2014'	System	20 Aug 2020 14:09:58

US3032249

Folder: Screening

Form: Medical History (11)

Generated On: 09 Jun 2021 14:53:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:40:23
User entered '2014'	System	20 Aug 2020 14:09:58

US3032249

Folder: Screening

Form: Medical History (11)

Generated On: 09 Jun 2021 14:53:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:40:23
User entered 'Jan 2014'	System	20 Aug 2020 14:09:58

US3032249

Folder: Screening

Form: Medical History (11)

Generated On: 09 Jun 2021 14:53:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:40:23
User entered '2014'	System	20 Aug 2020 14:09:58

US3032249

Folder: Screening

Form: Medical History (12)

Generated On: 09 Jun 2021 14:53:49

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:40:23
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:50:49
User coded data point as SOC: Hepatobiliary disorders, HLGT: Gallbladder disorders, HLT: Cholecystitis and cholelithiasis, PT: Cholecystitis, LLT: Cholecystitis - version MedDRA\\23.0.	Coder Import (b) (4)	20 Aug 2020 14:12:19
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	20 Aug 2020 14:12:19
Data point term sent to Coder	System	20 Aug 2020 14:11:20
User entered 'Cholecystitis'	Samantha Wieseler (b) (4)	20 Aug 2020 14:11:02

US3032249

Folder: Screening

Form: Medical History (12)

Generated On: 09 Jun 2021 14:53:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:40:23
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:50:49
User entered 'UN UNK 2014'	Samantha Wieseler (b) (4)	20 Aug 2020 14:11:02

US3032249

Folder: Screening

Form: Medical History (12)

Generated On: 09 Jun 2021 14:53:49

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:40:23
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:50:49
User entered '0'	Samantha Wieseler (b) (4)	20 Aug 2020 14:11:02

US3032249

Folder: Screening

Form: Medical History (12)

Generated On: 09 Jun 2021 14:53:49

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:40:23
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:50:49
User entered 'No (N)'	Samantha Wieseler (b) (4)	20 Aug 2020 14:11:02

US3032249

Folder: Screening

Form: Medical History (12)

Generated On: 09 Jun 2021 14:53:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:40:23
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:50:49
User entered 'UN UNK 2014'	Samantha Wieseler (b) (4)	20 Aug 2020 14:11:02

US3032249

Folder: Screening

Form: Medical History (12)

Generated On: 09 Jun 2021 14:53:49

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:40:23
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:50:49
User entered '0'	Samantha Wieseler (b) (4)	20 Aug 2020 14:11:02

US3032249

Folder: Screening

Form: Medical History (12)

Generated On: 09 Jun 2021 14:53:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:40:23
User entered 'Jan 2014'	System	20 Aug 2020 14:11:02

US3032249

Folder: Screening

Form: Medical History (12)

Generated On: 09 Jun 2021 14:53:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:40:23
User entered '2014'	System	20 Aug 2020 14:11:02

US3032249

Folder: Screening

Form: Medical History (12)

Generated On: 09 Jun 2021 14:53:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:40:23
User entered 'Jan 2014'	System	20 Aug 2020 14:11:02

US3032249

Folder: Screening

Form: Medical History (12)

Generated On: 09 Jun 2021 14:53:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:40:23
User entered '2014'	System	20 Aug 2020 14:11:02

US3032249

Folder: Screening

Form: Medical History (13)

Generated On: 09 Jun 2021 14:53:49

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:40:23
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).		30 Sep 2020 09:21:56
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:50:49
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.' answered with 'Olmesartan HCTZ is added.' (Site from DM).	(b) (4) Kelsey Kelley (b) (4)	28 Sep 2020 15:24:20
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)	09 Sep 2020 04:17:11
User coded data point as SOC: Vascular disorders, HLGT: Vascular hypertensive disorders, HLT: Vascular hypertensive disorders NEC, PT: Hypertension, LLT: Hypertension - version MedDRA\\23.0.	Coder Import (b) (4)	20 Aug 2020 14:12:18
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	20 Aug 2020 14:12:18
Data point term sent to Coder	System	20 Aug 2020 14:11:20
User entered 'Hypertension'	Samantha Wieseler (b) (4)	20 Aug 2020 14:11:14

US3032249

Folder: Screening

Form: Medical History (13)

Generated On: 09 Jun 2021 14:53:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:40:23
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:50:49
User entered 'UN UNK 2017'	Samantha Wieseler (b) (4)	20 Aug 2020 14:11:14

US3032249

Folder: Screening

Form: Medical History (13)

Generated On: 09 Jun 2021 14:53:49

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:40:23
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:50:49
User entered '0'	Samantha Wieseler (b) (4)	20 Aug 2020 14:11:14

US3032249

Folder: Screening

Form: Medical History (13)

Generated On: 09 Jun 2021 14:53:49

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:40:23
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:50:49
User entered 'Yes (Y)'	Samantha Wieseler (b) (4)	20 Aug 2020 14:11:14

US3032249

Folder: Screening

Form: Medical History (13)

Generated On: 09 Jun 2021 14:53:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:40:23
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:50:49
User entered empty.	Samantha Wieseler (b) (4)	20 Aug 2020 14:11:14

US3032249

Folder: Screening

Form: Medical History (13)

Generated On: 09 Jun 2021 14:53:49

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:40:23
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:50:49
User entered '0'	Samantha Wieseler (b) (4)	20 Aug 2020 14:11:14

US3032249

Folder: Screening

Form: Medical History (13)

Generated On: 09 Jun 2021 14:53:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:40:23
User entered 'Jan 2017'	System	20 Aug 2020 14:11:14

US3032249

Folder: Screening

Form: Medical History (13)

Generated On: 09 Jun 2021 14:53:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:40:23
User entered '2017'	System	20 Aug 2020 14:11:14

US3032249

Folder: Screening

Form: Medical History (13)

Generated On: 09 Jun 2021 14:53:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:40:23
User entered empty.	System	20 Aug 2020 14:11:14

US3032249

Folder: Screening

Form: Medical History (13)

Generated On: 09 Jun 2021 14:53:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:40:23
User entered empty.	System	20 Aug 2020 14:11:14

US3032249

Folder: Screening

Form: Medical History (14)

Generated On: 09 Jun 2021 14:53:49

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:40:23
User signature succeeded.	Keith Vrbicky (b) (4)	24 Nov 2020 20:29:25
User coded data point as SOC: Gastrointestinal disorders, HLGT: Gastrointestinal motility and defaecation conditions, HLT: Gastrointestinal atonic and hypomotility disorders NEC, PT: Gastroesophageal reflux disease, LLT: Acid reflux (esophageal) - version MedDRA\\23.0.	Coder Import (b) (4)	23 Nov 2020 20:42:09
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	23 Nov 2020 20:42:09
Data point term sent to Coder	System	23 Nov 2020 20:40:35
Coding entries removed.	(b) (4), (b) (6)	23 Nov 2020 20:39:36
Signature has been broken.		23 Nov 2020 20:39:36
User entered 'Acid Reflux' reason for change: Data Entry Error		23 Nov 2020 20:39:36
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:50:49
User coded data point as SOC: Gastrointestinal disorders, HLGT: Gastrointestinal motility and defaecation conditions, HLT: Gastrointestinal atonic and hypomotility disorders NEC, PT: Gastroesophageal reflux disease, LLT: Gastroesophageal reflux disease - version MedDRA\\23.0.	Coder Import (b) (4)	20 Aug 2020 14:13:23
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	20 Aug 2020 14:13:23
Data point term sent to Coder	System	20 Aug 2020 14:12:22
User entered 'Gastroesophageal Reflux Disease'	Samantha Wieseler (b) (4)	20 Aug 2020 14:12:20

US3032249

Folder: Screening

Form: Medical History (14)

Generated On: 09 Jun 2021 14:53:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:40:23
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:50:49
User entered 'UN UNK 2017'	Samantha Wieseler (b) (4)	20 Aug 2020 14:12:20

US3032249

Folder: Screening

Form: Medical History (14)

Generated On: 09 Jun 2021 14:53:49

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:40:23
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:50:49
User entered '0'	Samantha Wieseler (b) (4)	20 Aug 2020 14:12:20

US3032249

Folder: Screening

Form: Medical History (14)

Generated On: 09 Jun 2021 14:53:49

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:40:23
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:50:49
User entered 'Yes (Y)'	Samantha Wieseler (b) (4)	20 Aug 2020 14:12:20

US3032249

Folder: Screening

Form: Medical History (14)

Generated On: 09 Jun 2021 14:53:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:40:23
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:50:49
User entered empty.	Samantha Wieseler (b) (4)	20 Aug 2020 14:12:20

US3032249

Folder: Screening

Form: Medical History (14)

Generated On: 09 Jun 2021 14:53:49

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:40:23
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:50:49
User entered '0'	Samantha Wieseler (b) (4)	20 Aug 2020 14:12:20

US3032249

Folder: Screening

Form: Medical History (14)

Generated On: 09 Jun 2021 14:53:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:40:23
User entered 'Jan 2017'	System	20 Aug 2020 14:12:20

US3032249

Folder: Screening

Form: Medical History (14)

Generated On: 09 Jun 2021 14:53:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:40:23
User entered '2017'	System	20 Aug 2020 14:12:20

US3032249

Folder: Screening

Form: Medical History (14)

Generated On: 09 Jun 2021 14:53:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:40:23
User entered empty.	System	20 Aug 2020 14:12:20

US3032249

Folder: Screening

Form: Medical History (14)

Generated On: 09 Jun 2021 14:53:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:40:23
User entered empty.	System	20 Aug 2020 14:12:20

US3032249

Folder: Screening

Form: Medical History (15)

Generated On: 09 Jun 2021 14:53:49

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:40:23
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).		30 Sep 2020 10:22:11
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:50:49
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.' answered with 'inhaler is added' (Site from DM).	Kelsey Kelley (b) (4)	28 Sep 2020 15:26:39
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)	09 Sep 2020 04:17:40
User coded data point as SOC: Respiratory, thoracic and mediastinal disorders, HLG: Bronchial disorders (excl neoplasms), HLT: Bronchospasm and obstruction, PT: Chronic obstructive pulmonary disease, LLT: Chronic obstructive pulmonary disease - version MedDRA\23.0.	Coder Import (b) (4)	20 Aug 2020 14:14:29
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4)	20 Aug 2020 14:14:29
Data point term sent to Coder	System	20 Aug 2020 14:13:23
User entered 'Chronic Obstructive Pulmonary Disorder'	Samantha Wieseler (b) (4)	20 Aug 2020 14:12:44

US3032249

Folder: Screening

Form: Medical History (15)

Generated On: 09 Jun 2021 14:53:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:40:23
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:50:49
User entered 'UN UNK 2015'	Samantha Wieseler (b) (4)	20 Aug 2020 14:12:44

US3032249

Folder: Screening

Form: Medical History (15)

Generated On: 09 Jun 2021 14:53:49

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:40:23
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:50:49
User entered '0'	Samantha Wieseler (b) (4)	20 Aug 2020 14:12:44

US3032249

Folder: Screening

Form: Medical History (15)

Generated On: 09 Jun 2021 14:53:49

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:40:23
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:50:49
User entered 'Yes (Y)'	Samantha Wieseler (b) (4)	20 Aug 2020 14:12:44

US3032249

Folder: Screening

Form: Medical History (15)

Generated On: 09 Jun 2021 14:53:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:40:23
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:50:49
User entered empty.	Samantha Wieseler (b) (4)	20 Aug 2020 14:12:44

US3032249

Folder: Screening

Form: Medical History (15)

Generated On: 09 Jun 2021 14:53:49

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:40:23
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:50:49
User entered '0'	Samantha Wieseler (b) (4)	20 Aug 2020 14:12:44

US3032249

Folder: Screening

Form: Medical History (15)

Generated On: 09 Jun 2021 14:53:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:40:23
User entered 'Jan 2015'	System	20 Aug 2020 14:12:44

US3032249

Folder: Screening

Form: Medical History (15)

Generated On: 09 Jun 2021 14:53:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:40:23
User entered '2015'	System	20 Aug 2020 14:12:44

US3032249

Folder: Screening

Form: Medical History (15)

Generated On: 09 Jun 2021 14:53:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:40:23
User entered empty.	System	20 Aug 2020 14:12:44

US3032249

Folder: Screening

Form: Medical History (15)

Generated On: 09 Jun 2021 14:53:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:40:23
User entered empty.	System	20 Aug 2020 14:12:44

US3032249

Folder: Screening

Form: Medical History (16)

Generated On: 09 Jun 2021 14:53:49

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:40:23
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).		30 Sep 2020 10:26:05
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:50:49
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.' answered with 'inhaler added' (Site from DM).	(b) (4)	
User opened query 'Per DM CLR: Please note that there is no Con Med listed for treatment of this condition. Please review and if applicable add a Con Med or provide an explanation for no medical treatment.' (Site from DM).	Kelsey Kelley (b) (4)	28 Sep 2020 15:27:15
	(b) (4)	
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)	09 Sep 2020 04:18:20
User coded data point as SOC: Respiratory, thoracic and mediastinal disorders, HLG: Bronchial disorders (excl neoplasms), HLT: Bronchospasm and obstruction, PT: Asthma, LLT: Asthma - version MedDRA\23.0.	(b) (4)	
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4)	20 Aug 2020 14:14:28
Data point term sent to Coder	(b) (4)	
User entered 'Asthma'	System	20 Aug 2020 14:13:22
	Samantha Wieseler (b) (4)	20 Aug 2020 14:13:00
	(b) (4)	

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Folder: Screening

Form: Medical History (16)

Generated On: 09 Jun 2021 14:53:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:40:23
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:50:49
User entered 'UN UNK 2015'	Samantha Wieseler (b) (4)	20 Aug 2020 14:13:00

US3032249

Folder: Screening

Form: Medical History (16)

Generated On: 09 Jun 2021 14:53:49

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:40:23
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:50:49
User entered '0'	Samantha Wieseler (b) (4)	20 Aug 2020 14:13:00

US3032249

Folder: Screening

Form: Medical History (16)

Generated On: 09 Jun 2021 14:53:49

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:40:23
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:50:49
User entered 'Yes (Y)'	Samantha Wieseler (b) (4)	20 Aug 2020 14:13:00

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Folder: Screening

Form: Medical History (16)

Generated On: 09 Jun 2021 14:53:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:40:23
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:50:49
User entered empty.	Samantha Wieseler (b) (4)	20 Aug 2020 14:13:00

US3032249

Folder: Screening

Form: Medical History (16)

Generated On: 09 Jun 2021 14:53:49

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:40:23
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:50:49
User entered '0'	Samantha Wieseler (b) (4)	20 Aug 2020 14:13:00

US3032249

Folder: Screening

Form: Medical History (16)

Generated On: 09 Jun 2021 14:53:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:40:23
User entered 'Jan 2015'	System	20 Aug 2020 14:13:00

US3032249

Folder: Screening

Form: Medical History (16)

Generated On: 09 Jun 2021 14:53:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:40:23
User entered '2015'	System	20 Aug 2020 14:13:00

US3032249

Folder: Screening

Form: Medical History (16)

Generated On: 09 Jun 2021 14:53:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:40:23
User entered empty.	System	20 Aug 2020 14:13:00

US3032249

Folder: Screening

Form: Medical History (16)

Generated On: 09 Jun 2021 14:53:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:40:23
User entered empty.	System	20 Aug 2020 14:13:00

US3032249

Folder: Screening

Form: Medical History (17)

Generated On: 09 Jun 2021 14:53:49

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:40:23
User closed query 'Per DM CLR: Please specify the location and/or type of Edema. Update Med History eCRF as appropriate. ' (Site from DM).		30 Sep 2020 10:26:18
User coded data point as SOC: General disorders and administration site conditions, HLGT: General system disorders NEC, HLT: Oedema NEC, PT: Oedema peripheral, LLT: Lower leg edema - version MedDRA\23.0.	Coder Import (b) (4)	29 Sep 2020 07:49:34
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\23.0.	(b) (4)	29 Sep 2020 07:49:34
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:50:49
Data point term sent to Coder	System (b) (4)	28 Sep 2020 15:52:31
Query 'Per DM CLR: Please specify the location and/or type of Edema. Update Med History eCRF as appropriate. ' answered with 'data updated' (Site from DM).	Kelsey Kelley (b) (4)	28 Sep 2020 15:51:51
Coding entries removed.	Kelsey Kelley (b) (4)	28 Sep 2020 15:51:43
User entered 'EDEMA bilateral lower leg' reason for change: Data Entry Error	(b) (4)	28 Sep 2020 15:51:43
User opened query 'Per DM CLR: Please specify the location and/or type of Edema. Update Med History eCRF as appropriate. ' (Site from DM).	(b) (4), (b) (6)	09 Sep 2020 04:18:43
User coded data point as SOC: General disorders and administration site conditions, HLGT: General system disorders NEC, HLT: Oedema NEC, PT: Oedema, LLT: Edema - version MedDRA\23.0.	Coder Import (b) (4)	20 Aug 2020 14:14:29
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4)	20 Aug 2020 14:14:29
Data point term sent to Coder	System	20 Aug 2020 14:13:23
User entered 'Edema'	Samantha Wieseler (b) (4)	20 Aug 2020 14:13:14

US3032249

Folder: Screening

Form: Medical History (17)

Generated On: 09 Jun 2021 14:53:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:40:23
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:50:49
User entered 'UN UNK 2017'	Samantha Wieseler (b) (4)	20 Aug 2020 14:13:14

US3032249

Folder: Screening

Form: Medical History (17)

Generated On: 09 Jun 2021 14:53:49

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:40:23
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:50:49
User entered '0'	Samantha Wieseler (b) (4)	20 Aug 2020 14:13:14

US3032249

Folder: Screening

Form: Medical History (17)

Generated On: 09 Jun 2021 14:53:49

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:40:23
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:50:49
User entered 'Yes (Y)'	Samantha Wieseler (b) (4)	20 Aug 2020 14:13:14

US3032249

Folder: Screening

Form: Medical History (17)

Generated On: 09 Jun 2021 14:53:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:40:23
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:50:49
User entered empty.	Samantha Wieseler (b) (4)	20 Aug 2020 14:13:14

US3032249

Folder: Screening

Form: Medical History (17)

Generated On: 09 Jun 2021 14:53:49

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:40:23
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:50:49
User entered '0'	Samantha Wieseler (b) (4)	20 Aug 2020 14:13:14

US3032249

Folder: Screening

Form: Medical History (17)

Generated On: 09 Jun 2021 14:53:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:40:23
User entered 'Jan 2017'	System	20 Aug 2020 14:13:14

US3032249

Folder: Screening

Form: Medical History (17)

Generated On: 09 Jun 2021 14:53:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:40:23
User entered '2017'	System	20 Aug 2020 14:13:14

US3032249

Folder: Screening

Form: Medical History (17)

Generated On: 09 Jun 2021 14:53:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:40:23
User entered empty.	System	20 Aug 2020 14:13:14

US3032249

Folder: Screening

Form: Medical History (17)

Generated On: 09 Jun 2021 14:53:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:40:23
User entered empty.	System	20 Aug 2020 14:13:14

US3032249

Folder: Screening

Form: Medical History (18)

Generated On: 09 Jun 2021 14:53:49

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:40:23
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:50:49
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)	20 Aug 2020 14:15:49
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	20 Aug 2020 14:15:49
Data point term sent to Coder	System	20 Aug 2020 14:14:24
User entered 'Over Active Bladder'	Samantha Wieseler (b) (4)	20 Aug 2020 14:13:35

US3032249

Folder: Screening

Form: Medical History (18)

Generated On: 09 Jun 2021 14:53:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:40:23
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:50:49
User entered 'UN UNK 2018'	Samantha Wieseler (b) (4)	20 Aug 2020 14:13:35

US3032249

Folder: Screening

Form: Medical History (18)

Generated On: 09 Jun 2021 14:53:49

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:40:23
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:50:49
User entered '0'	Samantha Wieseler (b) (4)	20 Aug 2020 14:13:35

US3032249

Folder: Screening

Form: Medical History (18)

Generated On: 09 Jun 2021 14:53:49

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:40:23
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:50:49
User entered 'Yes (Y)'	Samantha Wieseler (b) (4)	20 Aug 2020 14:13:35

US3032249

Folder: Screening

Form: Medical History (18)

Generated On: 09 Jun 2021 14:53:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:40:23
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:50:49
User entered empty.	Samantha Wieseler (b) (4)	20 Aug 2020 14:13:35

US3032249

Folder: Screening

Form: Medical History (18)

Generated On: 09 Jun 2021 14:53:49

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:40:23
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:50:49
User entered '0'	Samantha Wieseler (b) (4)	20 Aug 2020 14:13:35

US3032249

Folder: Screening

Form: Medical History (18)

Generated On: 09 Jun 2021 14:53:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:40:23
User entered 'Jan 2018'	System	20 Aug 2020 14:13:35

US3032249

Folder: Screening

Form: Medical History (18)

Generated On: 09 Jun 2021 14:53:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:40:23
User entered '2018'	System	20 Aug 2020 14:13:35

US3032249

Folder: Screening

Form: Medical History (18)

Generated On: 09 Jun 2021 14:53:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:40:23
User entered empty.	System	20 Aug 2020 14:13:35

US3032249

Folder: Screening

Form: Medical History (18)

Generated On: 09 Jun 2021 14:53:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:40:23
User entered empty.	System	20 Aug 2020 14:13:35

US3032249

Folder: Screening

Form: Medical History (19)

Generated On: 09 Jun 2021 14:53:49

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:40:23
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:41:55
User coded data point as SOC: Metabolism and nutrition disorders, HLGT: Lipid metabolism disorders, HLT: Lipid metabolism and deposit disorders NEC, PT: Dyslipidaemia, LLT: Dyslipidemia - version MedDRA\23.0.	Coder Import (b) (4)	25 Mar 2021 21:00:32
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4)	25 Mar 2021 21:00:32
Data point term sent to Coder	System	25 Mar 2021 20:59:28
User entered 'dyslipidemia'	Kelsey Kelley (b) (4)	25 Mar 2021 20:58:55

US3032249

Folder: Screening

Form: Medical History (19)

Generated On: 09 Jun 2021 14:53:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:40:23
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:41:55
User entered 'un UNK 2018'	(b) (4) Kelsey Kelley (b) (4)	25 Mar 2021 20:58:55

US3032249

Folder: Screening

Form: Medical History (19)

Generated On: 09 Jun 2021 14:53:49

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:40:23
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:41:55
User entered '0'	(b) (4) Kelsey Kelley (b) (4)	25 Mar 2021 20:58:55

US3032249

Folder: Screening

Form: Medical History (19)

Generated On: 09 Jun 2021 14:53:49

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:40:23
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:41:55
User entered 'Yes (Y)'	(b) (4) Kelsey Kelley (b) (4)	25 Mar 2021 20:58:55

US3032249

Folder: Screening

Form: Medical History (19)

Generated On: 09 Jun 2021 14:53:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:40:23
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:41:55
User entered empty.	Kelsey Kelley (b) (4)	25 Mar 2021 20:58:55

US3032249

Folder: Screening

Form: Medical History (19)

Generated On: 09 Jun 2021 14:53:49

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:40:23
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:41:55
User entered '0'	Kelsey Kelley (b) (4)	25 Mar 2021 20:58:55

US3032249

Folder: Screening

Form: Medical History (19)

Generated On: 09 Jun 2021 14:53:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:40:23
User entered 'Jan 2018'	System	25 Mar 2021 20:58:55

US3032249

Folder: Screening

Form: Medical History (19)

Generated On: 09 Jun 2021 14:53:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:40:23
User entered '2018'	System	25 Mar 2021 20:58:55

US3032249

Folder: Screening

Form: Medical History (19)

Generated On: 09 Jun 2021 14:53:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:40:23
User entered empty.	System	25 Mar 2021 20:58:55

US3032249

Folder: Screening

Form: Medical History (19)

Generated On: 09 Jun 2021 14:53:49

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:40:23
User entered empty.	System	25 Mar 2021 20:58:55

US3032249

Folder: Screening

Form: Medical History (20)

Generated On: 09 Jun 2021 14:53:49

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:40:23
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:41:55
User coded data point as SOC: Endocrine disorders, HLG: Endocrine disorders of gonadal function, HLT: Endocrine abnormalities of gonadal function NEC, PT: Oestrogen deficiency, LLT: Estrogen deficiency - version MedDRA\\23.0.	Coder Import (b) (4)	25 Mar 2021 21:00:31
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	25 Mar 2021 21:00:31
Data point term sent to Coder	System	25 Mar 2021 20:59:28
User entered 'estrogen deficiency'	Kelsey Kelley (b) (4)	25 Mar 2021 20:59:07

US3032249

Folder: Screening

Form: Medical History (20)

Generated On: 09 Jun 2021 14:53:49

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:40:23
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:41:55
User entered 'un UNK 2018'	Kelsey Kelley (b) (4)	25 Mar 2021 20:59:07

US3032249

Folder: Screening

Form: Medical History (20)

Generated On: 09 Jun 2021 14:53:49

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:40:23
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:41:55
User entered '0'	Kelsey Kelley (b) (4)	25 Mar 2021 20:59:07

US3032249

Folder: Screening

Form: Medical History (20)

Generated On: 09 Jun 2021 14:53:49

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:40:23
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:41:55
User entered 'Yes (Y)'	(b) (4) Kelsey Kelley (b) (4)	25 Mar 2021 20:59:07

US3032249

Folder: Screening

Form: Medical History (20)

Generated On: 09 Jun 2021 14:53:49

[If No, please specify the stop date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:40:23
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:41:55
User entered empty.	Kelsey Kelley (b) (4)	25 Mar 2021 20:59:07

US3032249

Folder: Screening

Form: Medical History (20)

Generated On: 09 Jun 2021 14:53:49

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:40:23
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:41:55
User entered '0'	(b) (4) Kelsey Kelley (b) (4)	25 Mar 2021 20:59:07

US3032249

Folder: Screening

Form: Medical History (20)

Generated On: 09 Jun 2021 14:53:49

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:40:23
User entered 'Jan 2018'	System	25 Mar 2021 20:59:07

US3032249

Folder: Screening

Form: Medical History (20)

Generated On: 09 Jun 2021 14:53:49

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:40:23
User entered '2018'	System	25 Mar 2021 20:59:07

US3032249

Folder: Screening

Form: Medical History (20)

Generated On: 09 Jun 2021 14:53:49

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:40:23
User entered empty.	System	25 Mar 2021 20:59:07

US3032249

Folder: Screening

Form: Medical History (20)

Generated On: 09 Jun 2021 14:53:49

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:40:23
User entered empty.	System	25 Mar 2021 20:59:07

US3032249

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 14:53:49

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:40:23
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:50:49
User entered 'Yes (Y)'	Samantha Wieseler (b) (4)	20 Aug 2020 12:56:31

US3032249

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 14:53:49

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:40:23
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:50:49
User entered '19 Aug 2020'	Samantha Wieseler (b) (4)	20 Aug 2020 12:56:31

US3032249

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 14:53:49

[Time of assessment \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:40:23
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:50:49
User entered '16:57'	Samantha Wieseler (b) (4)	20 Aug 2020 12:56:31

US3032249

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 14:53:49

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:40:23
User entered '19 Aug 2020 16:57'	System	20 Aug 2020 12:56:31

US3032249

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 14:53:49

[Height \(xxx.x\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:40:23
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:50:49
User entered '160' cm	(b) (4)	
	Samantha Wieseler (b) (4)	20 Aug 2020 12:56:31
DataPoint set to visible.	(b) (4)	
	System	19 Aug 2020 23:40:28

US3032249

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 14:53:49

Weight (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:40:23
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:50:49
User entered '96.6' kg	(b) (4)	
	Samantha Wieseler (b) (4)	20 Aug 2020 12:56:31
DataPoint set to visible.	(b) (4)	
	System	19 Aug 2020 23:40:28

US3032249

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 14:53:49

BMI (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:40:23
Amendment Manager: User entered '37.73438'	System	17 Sep 2020 00:15:14
User entered '37.7'	System	20 Aug 2020 12:56:31
DataPoint set to visible.	System	19 Aug 2020 23:40:28

US3032249

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 14:53:49

[BMI units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:40:23
User entered 'kg/m2'	System	20 Aug 2020 12:56:31
DataPoint set to visible.	System	19 Aug 2020 23:40:28

US3032249

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 14:53:49

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:40:23
User signature succeeded.	Keith Vrbicky (b) (4)	24 Nov 2020 20:29:25
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4) (b) (4), (b) (6)	23 Nov 2020 20:48:04
Signature has been broken.		23 Nov 2020 20:43:40
User entered '36.6' C reason for change: Data Entry Error		23 Nov 2020 20:43:40
User signature succeeded.	Keith Vrbicky (b) (4)	08 Oct 2020 15:43:04
User closed query 'Per CDM: Per CCGs V2.0 pages 16-17, if Screening and Visit 1 Day 1 are on the same day, ND should be recorded for TEMPERATURE, PULSE, RESPIRATORY RATE, SYSTOLIC BP, and DIASTOLIC BP on this page (ND for "Not done" and not left empty). Please note that when ND is recorded for TEMPERATURE, the unit should not remain. Please review and update as appropriate. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	08 Oct 2020 07:03:02
Query 'Per CDM: Per CCGs V2.0 pages 16-17, if Screening and Visit 1 Day 1 are on the same day, ND should be recorded for TEMPERATURE, PULSE, RESPIRATORY RATE, SYSTOLIC BP, and DIASTOLIC BP on this page (ND for "Not done" and not left empty). Please note that when ND is recorded for TEMPERATURE, the unit should not remain. Please review and update as appropriate. ' answered with 'DATA UPDATED' (Site from DM).	Linden DeBoer (b) (4) (b) (4)	07 Oct 2020 15:02:18
Signature has been broken.	Linden DeBoer (b) (4) (b) (4)	07 Oct 2020 15:02:12
User entered missing code ND - Not Done; reason for change Data Entry Error	Linden DeBoer (b) (4) (b) (4)	07 Oct 2020 15:02:12

US3032249

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 14:53:49

Temperature (xxx.x)

Audit	User	Time (GMT)
User opened query 'Per CDM: Per CCGs V2.0 pages 16-17, if Screening and Visit 1 Day 1 are on the same day, ND should be recorded for TEMPERATURE, PULSE, RESPIRATORY RATE, SYSTOLIC BP, and DIASTOLIC BP on this page (ND for “Not done” and not left empty). Please note that when ND is recorded for TEMPERATURE, the unit should not remain. Please review and update as appropriate. ' (Site from DM).	(b) (4), (b) (6)	07 Oct 2020 11:54:43
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:50:49
User entered '36.6' C	(b) (4) Samantha Wieseler (b) (4)	20 Aug 2020 12:56:31
	(b) (4)	

US3032249

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 14:53:49

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:40:23
User signature succeeded.	Keith Vrbicky (b) (4)	24 Nov 2020 20:29:25
User entered empty; reason for change Data Entry Error	(b) (4)	23 Nov 2020 20:48:04
Signature has been broken.	(b) (4), (b) (6)	23 Nov 2020 20:43:40
User entered 'Oral (Oral)' reason for change: Data Entry Error		23 Nov 2020 20:43:40
User signature succeeded.	Keith Vrbicky (b) (4)	08 Oct 2020 15:43:04
Signature has been broken.	(b) (4)	
	Linden DeBoer (b) (4)	07 Oct 2020 15:02:12
User entered empty; reason for change Data Entry Error	(b) (4)	
	Linden DeBoer (b) (4)	07 Oct 2020 15:02:12
User signature succeeded.	(b) (4)	
	Keith Vrbicky (b) (4)	28 Sep 2020 17:50:49
User entered 'Oral (Oral)'	(b) (4)	
	Samantha Wieseler (b) (4)	20 Aug 2020 12:56:31
	(b) (4)	

US3032249

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 14:53:49

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:40:23
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:50:49
User entered empty.	Samantha Wieseler (b) (4)	20 Aug 2020 12:56:31

US3032249

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 14:53:49

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:40:23
User signature succeeded.	Keith Vrbicky (b) (4)	24 Nov 2020 20:29:25
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4)	23 Nov 2020 20:48:04
Signature has been broken.	(b) (4), (b) (6)	23 Nov 2020 20:43:40
User entered '63' reason for change: Data Entry Error		23 Nov 2020 20:43:40
User signature succeeded.	Keith Vrbicky (b) (4)	08 Oct 2020 15:43:04
Signature has been broken.	(b) (4)	
	Linden DeBoer (b) (4)	07 Oct 2020 15:02:12
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4)	
User signature succeeded.	Linden DeBoer (b) (4)	07 Oct 2020 15:02:12
	(b) (4)	
	Keith Vrbicky (b) (4)	28 Sep 2020 17:50:49
	(b) (4)	
User entered '63'	Samantha Wieseler (b) (4)	20 Aug 2020 12:56:31
	(b) (4)	

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Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 14:53:49

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:40:23
User entered 'bpm'	System	20 Aug 2020 12:56:31

US3032249

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 14:53:49

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:40:23
User signature succeeded.	Keith Vrbicky (b) (4)	24 Nov 2020 20:29:25
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4)	23 Nov 2020 20:48:04
Signature has been broken.	(b) (4), (b) (6)	23 Nov 2020 20:43:40
User entered '18' reason for change: Data Entry Error	(b) (4)	23 Nov 2020 20:43:40
User signature succeeded.	Keith Vrbicky (b) (4)	08 Oct 2020 15:43:04
Signature has been broken.	(b) (4)	07 Oct 2020 15:02:12
User entered missing code ND - Not Done; reason for change Data Entry Error	Linden DeBoer (b) (4)	07 Oct 2020 15:02:12
User signature succeeded.	(b) (4)	28 Sep 2020 17:50:49
User entered '18'	Keith Vrbicky (b) (4)	(b) (4)
	Samantha Wieseler (b) (4)	20 Aug 2020 12:56:31
	(b) (4)	

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Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 14:53:49

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:40:23
User entered 'breaths/min'	System	20 Aug 2020 12:56:31

US3032249

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 14:53:49

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:40:23
User signature succeeded.	Keith Vrbicky (b) (4)	24 Nov 2020 20:29:25
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4)	23 Nov 2020 20:48:04
Signature has been broken.	(b) (4), (b) (6)	23 Nov 2020 20:43:40
User entered '135' reason for change: Data Entry Error	(b) (4), (b) (6)	23 Nov 2020 20:43:40
User signature succeeded.	Keith Vrbicky (b) (4)	08 Oct 2020 15:43:04
Signature has been broken.	(b) (4)	07 Oct 2020 15:02:12
User entered missing code ND - Not Done; reason for change Data Entry Error	Linden DeBoer (b) (4)	07 Oct 2020 15:02:12
User signature succeeded.	(b) (4)	28 Sep 2020 17:50:49
User entered '135'	Keith Vrbicky (b) (4)	(b) (4)
	Samantha Wieseler (b) (4)	20 Aug 2020 12:56:31
	(b) (4)	

US3032249

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 14:53:49

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:40:23
User entered 'mmHg'	System	20 Aug 2020 12:56:31

US3032249

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 14:53:49

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:40:23
User signature succeeded.	Keith Vrbicky (b) (4)	24 Nov 2020 20:29:25
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4)	23 Nov 2020 20:48:04
Signature has been broken.	(b) (4), (b) (6)	23 Nov 2020 20:43:40
User entered '70' reason for change: Data Entry Error	(b) (4), (b) (6)	23 Nov 2020 20:43:40
User signature succeeded.	Keith Vrbicky (b) (4)	08 Oct 2020 15:43:04
Signature has been broken.	(b) (4)	07 Oct 2020 15:02:12
User entered missing code ND - Not Done; reason for change Data Entry Error	Linden DeBoer (b) (4)	07 Oct 2020 15:02:12
User signature succeeded.	(b) (4)	28 Sep 2020 17:50:49
User entered '70'	Keith Vrbicky (b) (4)	(b) (4)
	Samantha Wieseler (b) (4)	20 Aug 2020 12:56:31
	(b) (4)	

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Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 14:53:49

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:40:23
User entered 'mmHg'	System	20 Aug 2020 12:56:31

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Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 14:53:49

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:40:23

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Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 14:53:49

[Weight \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:40:23

US3032249

Folder: Screening

Form: Physical Examination

Generated On: 09 Jun 2021 14:53:49

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:40:23
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:50:49
User entered 'Yes (Y)'	Samantha Wieseler (b) (4)	20 Aug 2020 14:00:08

US3032249

Folder: Screening

Form: Physical Examination

Generated On: 09 Jun 2021 14:53:49

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:40:23
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:50:49
User entered '19 Aug 2020'	Samantha Wieseler (b) (4)	20 Aug 2020 14:00:08

US3032249

Folder: Screening

Form: Childbearing Potential

Generated On: 09 Jun 2021 14:53:49

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:40:23
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:50:49
User entered '19 Aug 2020'	Samantha Wieseler (b) (4)	20 Aug 2020 14:00:44

US3032249

Folder: Screening

Form: Childbearing Potential

Generated On: 09 Jun 2021 14:53:49

[Is the participant of childbearing potential?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:40:23
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:50:49
User entered 'No (N)'	Samantha Wieseler (b) (4)	20 Aug 2020 14:00:44

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Folder: Screening

Form: Childbearing Potential

Generated On: 09 Jun 2021 14:53:49

[If No, what is the reason?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:40:23
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:50:49
User entered 'Surgically sterile (SURGICALLY STERILE)'	Samantha Wieseler (b) (4)	20 Aug 2020 14:00:44

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Folder: Screening

Form: Childbearing Potential

Generated On: 09 Jun 2021 14:53:49

[If Partner medically sterile or Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:40:23
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:50:49
User entered empty.	Samantha Wieseler (b) (4)	20 Aug 2020 14:00:44

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Folder: Screening

Form: Childbearing Potential

Generated On: 09 Jun 2021 14:53:49

If Surgically sterile, date of surgery (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:40:23
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:50:49
User entered 'UN UNK 1983'	Samantha Wieseler (b) (4)	20 Aug 2020 14:00:44

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Folder: Screening

Form: Childbearing Potential

Generated On: 09 Jun 2021 14:53:49

[Date of surgery unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:40:23
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:50:49
User entered '0'	Samantha Wieseler (b) (4)	20 Aug 2020 14:00:44

US3032249

Folder: Screening

Form: Childbearing Potential

Generated On: 09 Jun 2021 14:53:49

If Post-menopausal, date of last menstruation (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:40:23
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:50:49
User entered empty.	Samantha Wieseler (b) (4)	20 Aug 2020 14:00:44

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Folder: Screening

Form: Childbearing Potential

Generated On: 09 Jun 2021 14:53:49

[Date of last menstruation unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:40:23
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:50:49
User entered '0'	Samantha Wieseler (b) (4)	20 Aug 2020 14:00:44

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Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 14:53:49

[Healthcare workers](#) (e.g., doctors, nurses, dentists, hospital support staff, morgue/mortuary workers)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:40:23
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:50:49
User entered 'No (N)'	Samantha Wieseler (b) (4)	20 Aug 2020 14:01:36

US3032249

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 14:53:49

Emergency Response (e.g., Law enforcement officers, Firefighters, emergency medical service workers)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:40:23
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:50:49
User entered 'No (N)'	Samantha Wieseler (b) (4)	20 Aug 2020 14:01:36

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Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 14:53:49

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)	27 Apr 2021 15:40:23
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:50:49
User entered 'No (N)'	Samantha Wieseler (b) (4)	20 Aug 2020 14:01:36

US3032249

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 14:53:49

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)	27 Apr 2021 15:40:23
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:50:49
User entered 'No (N)'	Samantha Wieseler (b) (4)	20 Aug 2020 14:01:36

US3032249

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 14:53:49

Warehouse shipping and fulfillment centers and jobs (e.g., Amazon facilities)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:40:23
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:50:49
User entered 'No (N)'	Samantha Wieseler (b) (4)	20 Aug 2020 14:01:36

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Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 14:53:49

[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)	27 Apr 2021 15:40:23
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:50:49
User entered 'No (N)'	Samantha Wieseler (b) (4)	20 Aug 2020 14:01:36

US3032249

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 14:53:49

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)	27 Apr 2021 15:40:23
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:50:49
User entered 'No (N)'	Samantha Wieseler (b) (4)	20 Aug 2020 14:01:36

US3032249

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 14:53:49

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)	27 Apr 2021 15:40:23
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:50:49
User entered 'Yes (Y)'	Samantha Wieseler (b) (4)	20 Aug 2020 14:01:36

US3032249

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 14:53:49

[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)	27 Apr 2021 15:40:23
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:50:49
User entered 'No (N)'	Samantha Wieseler (b) (4)	20 Aug 2020 14:01:36

US3032249

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 14:53:49

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)	27 Apr 2021 15:40:23
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:50:49
User entered 'No (N)'	Samantha Wieseler (b) (4)	20 Aug 2020 14:01:36

US3032249

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 14:53:49

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)	27 Apr 2021 15:40:23
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:50:49
User entered 'No (N)'	Samantha Wieseler (b) (4)	20 Aug 2020 14:01:36

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Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 14:53:49

Other

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:40:23
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:50:49
User entered 'No (N)'	Samantha Wieseler (b) (4)	20 Aug 2020 14:01:36

US3032249

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 14:53:49

[Specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:40:23
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:50:49
User entered empty.	Samantha Wieseler (b) (4)	20 Aug 2020 14:01:36

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Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 14:53:49

No Risk Identified

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:40:23
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:50:49
User entered '0'	Samantha Wieseler (b) (4)	20 Aug 2020 14:01:36

US3032249

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 14:53:49

[Resides in Nursing Home or Assisted Living Facility](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:40:23
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:50:49
User entered '0'	Samantha Wieseler (b) (4)	20 Aug 2020 14:01:36

US3032249

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 14:53:49

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)	27 Apr 2021 15:40:23
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:50:49
User entered '0'	Samantha Wieseler (b) (4)	20 Aug 2020 14:01:36

US3032249

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 14:53:49

[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)	27 Apr 2021 15:40:23
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:50:49
User entered '0'	Samantha Wieseler (b) (4)	20 Aug 2020 14:01:36

US3032249

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 14:53:49

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)	27 Apr 2021 15:40:23
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:50:49
User entered '0'	Samantha Wieseler (b) (4)	20 Aug 2020 14:01:36

US3032249

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 14:53:49

[Resides in a single family home](#) (i.e., detached housing)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:40:23
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:50:49
User entered 'I'	Samantha Wieseler (b) (4)	20 Aug 2020 14:01:36

US3032249

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 14:53:49

Other

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:40:23
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:50:49
User entered '0'	Samantha Wieseler (b) (4)	20 Aug 2020 14:01:36

US3032249

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 14:53:49

[Specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:40:23
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:50:49
User entered empty.	Samantha Wieseler (b) (4)	20 Aug 2020 14:01:36

US3032249

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 09 Jun 2021 14:53:49

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:25:32
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:50:49
User entered 'Yes (Y)'	(b) (4) Kelsey Kelley (b) (4)	19 Aug 2020 23:40:10

US3032249

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 09 Jun 2021 14:53:49

[Visit date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:25:32
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:50:49
User entered '19 Aug 2020'	(b) (4) Kelsey Kelley (b) (4)	19 Aug 2020 23:40:10
	(b) (4)	

US3032249

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 09 Jun 2021 14:53:49

[Was visit performed at the participant's home or at the clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:25:32
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:50:49
User entered 'Clinic (Clinic)'	(b) (4) Kelsey Kelley (b) (4)	19 Aug 2020 23:40:10

US3032249

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 09 Jun 2021 14:53:49

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:25:32
User entered 'VISIT1'	System	19 Aug 2020 23:40:10

US3032249

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 14:53:49

What was the date of randomization? (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:25:32
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:50:49
User entered '19 AUG 2020'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	19 Aug 2020 23:04:10

US3032249

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 14:53:49

[What was the participant's randomization number?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:25:32
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:50:49
Amendment Manager: User closed query 'Data entered is non-conformant. Please correct.' (Site from System).	(b) (4) System	21 Aug 2020 05:44:47
Amendment Manager: Data point set to conformant.	System	21 Aug 2020 05:44:47
User opened query 'Data entered is non-conformant. Please correct.' (Site from System).	System	19 Aug 2020 23:04:10
User entered '187194' (non-conformant).	RWS_ENDPOINT ENDPOINT (b) (4)	19 Aug 2020 23:04:10

US3032249

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 14:53:49

[In what Cohort was the participant enrolled?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:25:32
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:50:49
User entered '>=65 years (3)'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	19 Aug 2020 23:04:10

US3032249

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 14:53:49

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)	27 Mar 2021 19:25:32
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:50:49
User entered 'Yes (Y)'	Samantha Wieseler (b) (4)	20 Aug 2020 14:02:09

US3032249

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 14:53:49

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)	27 Mar 2021 19:25:32
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:50:49
User entered 'No (N)'	Samantha Wieseler (b) (4)	20 Aug 2020 14:02:09

US3032249

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 14:53:49

Severe obesity (body mass index > or = 40kg/m2)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:25:32
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:50:49
User entered 'No (N)'	Samantha Wieseler (b) (4)	20 Aug 2020 14:02:09

US3032249

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 14:53:49

[Diabetes \(Type I, Type 2, or gestational\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:25:32
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:50:49
User entered 'No (N)'	Samantha Wieseler (b) (4)	20 Aug 2020 14:02:09

US3032249

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 14:53:49

[Liver Disease](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:25:32
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:50:49
User entered 'No (N)'	Samantha Wieseler (b) (4)	20 Aug 2020 14:02:09

US3032249

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 14:53:49

[Human Immunodeficiency Virus \(HIV\) infection](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:25:32
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:50:49
User entered 'No (N)'	(b) (4) Kelsey Kelley (b) (4)	28 Sep 2020 15:25:02
Amendment Manager: DataPoint set to visible.	(b) (4) System	19 Sep 2020 10:36:26
Amendment Manager inserted this DataPoint.	System	19 Sep 2020 01:39:09

US3032249

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 14:53:49

Height

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:25:32
User signature succeeded.	Keith Vrbicky (b) (4)	14 Oct 2020 19:37:33
User closed query 'Per CDM: Please note as the Screening and Visit 1 is done on the same day, Height and weight to be recorded in screening and updated to "NOT Done " in Visit 1. Kindly remove the units as well. Thanks.' (Site from DM).	(b) (4) (b) (4), (b) (6)	14 Oct 2020 03:39:59
Query 'Per CDM: Please note as the Screening and Visit 1 is done on the same day, Height and weight to be recorded in screening and updated to "NOT Done " in Visit 1. Kindly remove the units as well. Thanks.' answered with 'data updated' (Site from DM).	Linden DeBoer (b) (4) (b) (4)	13 Oct 2020 14:10:07
Signature has been broken.	Linden DeBoer (b) (4) (b) (4)	13 Oct 2020 14:10:01
User entered missing code ND - Not Done; reason for change Data Entry Error	Linden DeBoer (b) (4) (b) (4)	13 Oct 2020 14:10:01
User opened query 'Per CDM: Please note as the Screening and Visit 1 is done on the same day, Height and weight to be recorded in screening and updated to "NOT Done " in Visit 1. Kindly remove the units as well. Thanks.' (Site from DM).	(b) (4), (b) (6)	13 Oct 2020 09:11:22
User signature succeeded.	Keith Vrbicky (b) (4) (b) (4)	28 Sep 2020 17:50:49
User entered '160' cm	Samantha Wieseler (b) (4) (b) (4)	20 Aug 2020 14:03:36

US3032249

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 14:53:49

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:25:32
User signature succeeded.	Keith Vrbicky (b) (4)	14 Oct 2020 19:37:33
Signature has been broken.	(b) (4)	
	Linden DeBoer (b) (4)	13 Oct 2020 14:10:01
	(b) (4)	
User entered missing code ND - Not Done; reason for change Data Entry Error	Linden DeBoer (b) (4)	13 Oct 2020 14:10:01
User signature succeeded.	(b) (4)	
	Keith Vrbicky (b) (4)	28 Sep 2020 17:50:49
	(b) (4)	
User entered '96.6' kg	Samantha Wieseler (b) (4)	20 Aug 2020 14:03:36
	(b) (4)	

US3032249

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 14:53:49

Height

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:25:32
User signature succeeded.	Keith Vrbicky (b) (4)	14 Oct 2020 19:37:33
User closed query 'Per CDM: Please note as the Screening and Visit 1 is done on the same day, Height and weight to be recorded in screening and updated to "NOT Done " in Visit 1. Kindly remove the units as well. Thanks.' (Site from DM).	(b) (4) (b) (4), (b) (6)	14 Oct 2020 03:39:59
Query 'Per CDM: Please note as the Screening and Visit 1 is done on the same day, Height and weight to be recorded in screening and updated to "NOT Done " in Visit 1. Kindly remove the units as well. Thanks.' answered with 'data updated' (Site from DM).	Linden DeBoer (b) (4) (b) (4)	13 Oct 2020 14:10:07
Signature has been broken.	Linden DeBoer (b) (4) (b) (4)	13 Oct 2020 14:10:01
User entered missing code ND - Not Done; reason for change Data Entry Error	Linden DeBoer (b) (4) (b) (4)	13 Oct 2020 14:10:01
User opened query 'Per CDM: Please note as the Screening and Visit 1 is done on the same day, Height and weight to be recorded in screening and updated to "NOT Done " in Visit 1. Kindly remove the units as well. Thanks.' (Site from DM).	(b) (4), (b) (6)	13 Oct 2020 09:11:22
User signature succeeded.	Keith Vrbicky (b) (4) (b) (4)	28 Sep 2020 17:50:49
User entered '160' cm	Samantha Wieseler (b) (4) (b) (4)	20 Aug 2020 14:03:36

US3032249

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 14:53:49

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:25:32
User signature succeeded.	Keith Vrbicky (b) (4)	14 Oct 2020 19:37:33
Signature has been broken.	(b) (4)	
	Linden DeBoer (b) (4)	13 Oct 2020 14:10:01
	(b) (4)	
User entered missing code ND - Not Done; reason for change Data Entry Error	Linden DeBoer (b) (4)	13 Oct 2020 14:10:01
User signature succeeded.	(b) (4)	
	Keith Vrbicky (b) (4)	28 Sep 2020 17:50:49
	(b) (4)	
User entered '96.6' kg	Samantha Wieseler (b) (4)	20 Aug 2020 14:03:36
	(b) (4)	

US3032249

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:53:49

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:25:32
User accepted default value 'Pre-Dose (PREDOSE)'	Samantha Wieseler (b) (4)	20 Aug 2020 14:03:36

US3032249

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:53:49

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:25:32
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:50:49
User entered 'Yes (Y)'	(b) (4) Samantha Wieseler (b) (4)	20 Aug 2020 14:03:36
	(b) (4)	

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:53:49

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:25:32
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:50:49
User entered '19 Aug 2020'	Samantha Wieseler (b) (4)	20 Aug 2020 14:03:36

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:53:49

Time of assessment (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:25:32
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:50:49
User entered '16:57'	Samantha Wieseler (b) (4)	20 Aug 2020 14:03:36

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:53:49

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:25:32
User entered '19 Aug 2020 16:57'	System	20 Aug 2020 14:03:36

US3032249

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:53:49

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:25:32
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:50:49
User entered '36.6' C	Samantha Wieseler (b) (4)	20 Aug 2020 14:03:36

US3032249

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:53:49

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:25:32
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:50:49
User entered 'Oral (Oral)'	Samantha Wieseler (b) (4)	20 Aug 2020 14:03:36

US3032249

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:53:49

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:25:32
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:50:49
User entered empty.	Samantha Wieseler (b) (4)	20 Aug 2020 14:03:36

US3032249

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:53:49

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:25:32
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:50:49
User entered '63'	Samantha Wieseler (b) (4)	20 Aug 2020 14:03:36

US3032249

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:53:49

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:25:32
User entered 'bpm'	System	20 Aug 2020 14:03:36

US3032249

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:53:49

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:25:32
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:50:49
User entered '18'	Samantha Wieseler (b) (4)	20 Aug 2020 14:03:36

US3032249

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:53:49

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:25:32
User entered 'breaths/min'	System	20 Aug 2020 14:03:36

US3032249

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:53:49

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:25:32
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:50:49
User entered '135'	Samantha Wieseler (b) (4)	20 Aug 2020 14:03:36

US3032249

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:53:49

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:25:32
User entered 'mmHg'	System	20 Aug 2020 14:03:36

US3032249

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:53:49

[Diastolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:25:32
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:50:49
User entered '70'	Samantha Wieseler (b) (4)	20 Aug 2020 14:03:36

US3032249

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:53:49

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:25:32
User entered 'mmHg'	System	20 Aug 2020 14:03:36

US3032249

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 14:53:49

Height

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:25:32
User signature succeeded.	Keith Vrbicky (b) (4)	14 Oct 2020 19:37:33
User closed query 'Per CDM: Please note as the Screening and Visit 1 is done on the same day, Height and weight to be recorded in screening and updated to "NOT Done " in Visit 1. Kindly remove the units as well. Thanks.' (Site from DM).	(b) (4) (b) (4), (b) (6)	14 Oct 2020 03:39:59
Query 'Per CDM: Please note as the Screening and Visit 1 is done on the same day, Height and weight to be recorded in screening and updated to "NOT Done " in Visit 1. Kindly remove the units as well. Thanks.' answered with 'data updated' (Site from DM).	Linden DeBoer (b) (4) (b) (4)	13 Oct 2020 14:10:07
Signature has been broken.	Linden DeBoer (b) (4) (b) (4)	13 Oct 2020 14:10:01
User entered missing code ND - Not Done; reason for change Data Entry Error	Linden DeBoer (b) (4) (b) (4)	13 Oct 2020 14:10:01
User opened query 'Per CDM: Please note as the Screening and Visit 1 is done on the same day, Height and weight to be recorded in screening and updated to "NOT Done " in Visit 1. Kindly remove the units as well. Thanks.' (Site from DM).	(b) (4), (b) (6)	13 Oct 2020 09:11:22
User signature succeeded.	Keith Vrbicky (b) (4) (b) (4)	28 Sep 2020 17:50:49
User entered '160' cm	Samantha Wieseler (b) (4) (b) (4)	20 Aug 2020 14:03:36

US3032249

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 14:53:49

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:25:32
User signature succeeded.	Keith Vrbicky (b) (4)	14 Oct 2020 19:37:33
Signature has been broken.	(b) (4)	
	Linden DeBoer (b) (4)	13 Oct 2020 14:10:01
	(b) (4)	
User entered missing code ND - Not Done; reason for change Data Entry Error	Linden DeBoer (b) (4)	13 Oct 2020 14:10:01
User signature succeeded.	(b) (4)	
	Keith Vrbicky (b) (4)	28 Sep 2020 17:50:49
	(b) (4)	
User entered '96.6' kg	Samantha Wieseler (b) (4)	20 Aug 2020 14:03:36
	(b) (4)	

US3032249

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:53:49

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:25:32
User accepted default value 'Post-Dose (POSTDOSE)'	Samantha Wieseler (b) (4)	20 Aug 2020 14:03:36

US3032249

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:53:49

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:25:32
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:50:49
User entered 'Yes (Y)'	(b) (4) Samantha Wieseler (b) (4)	20 Aug 2020 14:03:36
	(b) (4)	

US3032249

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:53:49

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:25:32
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:50:49
User entered '19 Aug 2020'	(b) (4) Samantha Wieseler (b) (4)	20 Aug 2020 14:03:36
	(b) (4)	

US3032249

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:53:49

Time of assessment (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:25:32
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:50:49
Amendment Manager: Query closed during migration process because the edit check no longer exists in target version.	(b) (4)	21 Aug 2020 05:44:45
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 minutes per protocol' (Site from System).	Samantha Wieseler (b) (4)	20 Aug 2020 14:03:56
User opened 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)	20 Aug 2020 14:03:36
User entered '19:11'	Samantha Wieseler (b) (4)	20 Aug 2020 14:03:36

US3032249

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:53:49

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:25:32
User entered '19 Aug 2020 19:11'	System	20 Aug 2020 14:03:36

US3032249

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:53:49

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:25:32
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:50:49
User entered '36.6' C	Samantha Wieseler (b) (4)	20 Aug 2020 14:03:36

US3032249

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:53:49

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:25:32
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:50:49
User entered 'Oral (Oral)'	Samantha Wieseler (b) (4)	20 Aug 2020 14:03:36

US3032249

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:53:49

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:25:32
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:50:49
User entered empty.	Samantha Wieseler (b) (4)	20 Aug 2020 14:03:36

US3032249

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:53:49

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:25:32
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:50:49
User entered '68'	Samantha Wieseler (b) (4)	20 Aug 2020 14:03:36

US3032249

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:53:49

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:25:32
User entered 'bpm'	System	20 Aug 2020 14:03:36

US3032249

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:53:49

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:25:32
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:50:49
User entered '16'	Samantha Wieseler (b) (4)	20 Aug 2020 14:03:36

US3032249

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:53:49

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:25:32
User entered 'breaths/min'	System	20 Aug 2020 14:03:36

US3032249

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:53:49

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:25:32
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:50:49
User entered '128'	Samantha Wieseler (b) (4)	20 Aug 2020 14:03:36

US3032249

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:53:49

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:25:32
User entered 'mmHg'	System	20 Aug 2020 14:03:36

US3032249

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:53:49

[Diastolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:25:32
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:50:49
User entered '76'	Samantha Wieseler (b) (4)	20 Aug 2020 14:03:36

US3032249

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:53:49

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:25:32
User entered 'mmHg'	System	20 Aug 2020 14:03:36

US3032249

Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 09 Jun 2021 14:53:49

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:25:32
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:50:49
User entered 'Yes (Y)'	Samantha Wieseler (b) (4)	20 Aug 2020 14:04:07

US3032249

Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 09 Jun 2021 14:53:49

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:25:32
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:50:49
User entered '19 Aug 2020'	Samantha Wieseler (b) (4)	20 Aug 2020 14:04:07

US3032249

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 14:53:49

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:25:26
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:50:49
User entered 'Yes (Y)'	(b) (4) Kelsey Kelley (b) (4)	19 Aug 2020 23:40:48

US3032249

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 14:53:49

[If No, reason not given](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:25:26
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:50:49
User entered empty.	(b) (4) Kelsey Kelley (b) (4)	19 Aug 2020 23:40:48

US3032249

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 14:53:49

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)	27 Mar 2021 19:25:26
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:50:49
User entered empty.	(b) (4) Kelsey Kelley (b) (4)	19 Aug 2020 23:40:48
	(b) (4)	

US3032249

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 14:53:49

[What was the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:25:26
User entered 'MRNA-1273 OR PLACEBO'	System	19 Aug 2020 23:40:48

US3032249

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 14:53:49

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:25:26
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:50:49
User entered '19 Aug 2020'	Kelsey Kelley (b) (4)	19 Aug 2020 23:40:48

US3032249

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 14:53:49

[What was the treatment time? \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:25:26
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:50:49
User entered '18:35'	(b) (4) Kelsey Kelley (b) (4)	19 Aug 2020 23:40:48

US3032249

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 14:53:49

[Treatment Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:25:26
User entered '19 Aug 2020 18:35'	System	19 Aug 2020 23:40:48

US3032249

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 14:53:49

[Which arm was used to give treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:25:26
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:50:49
User entered 'Left Arm (LEFT ARM)'	Kelsey Kelley (b) (4)	19 Aug 2020 23:40:48

US3032249

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 14:53:49

What was the frequency of the study treatment dosing?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:25:26
User entered 'ONCE'	System	19 Aug 2020 23:40:48

US3032249

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 14:53:49

[What was the route of administration for the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:25:26
User entered 'INTRAMUSCULAR'	System	19 Aug 2020 23:40:48

US3032249

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 14:53:49

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:25:26
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:50:49
User entered 'Yes (Y)'	(b) (4) Samantha Wieseler (b) (4)	20 Aug 2020 14:04:48

US3032249

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 14:53:49

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:25:26
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:50:49
User entered '19 Aug 2020'	Samantha Wieseler (b) (4)	20 Aug 2020 14:04:48

US3032249

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 14:53:49

[Collection time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:25:26
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:50:49
User entered '17:53'	Samantha Wieseler (b) (4)	20 Aug 2020 14:04:48

US3032249

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 14:53:49

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:25:26
User entered '19 Aug 2020 17:53'	System	20 Aug 2020 14:04:48

US3032249

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 09 Jun 2021 14:53:49

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:25:26
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:50:49
User entered '19 Aug 2020'	Samantha Wieseler (b) (4)	20 Aug 2020 14:05:04

US3032249

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 14:53:49

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:25:26
User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)'	Samantha Wieseler (b) (4)	20 Aug 2020 14:05:04

US3032249

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 14:53:49

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:25:26
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:50:49
User entered 'Yes (Y)'	Samantha Wieseler (b) (4)	20 Aug 2020 14:05:04

US3032249

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 14:53:49

[Collection time \(00:00 - 23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:25:26
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:50:49
User entered '17:42'	Samantha Wieseler (b) (4)	20 Aug 2020 14:05:04

US3032249

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 14:53:49

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:25:26
User entered '19 Aug 2020 17:42'	System	20 Aug 2020 14:05:04

US3032249

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 14:53:49

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:25:26
User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)'	Samantha Wieseler (b) (4)	20 Aug 2020 14:05:04

US3032249

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 14:53:49

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:25:26
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:50:49
User entered 'Yes (Y)'	Samantha Wieseler (b) (4)	20 Aug 2020 14:05:04

US3032249

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 14:53:49

[Collection time \(00:00 - 23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:25:26
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:50:49
User entered '17:42'	Samantha Wieseler (b) (4)	20 Aug 2020 14:05:04

US3032249

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 14:53:49

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:25:26
User entered '19 Aug 2020 17:42'	System	20 Aug 2020 14:05:04

US3032249

Folder: Visit 1 Day 1

Form: Continuing

Generated On: 09 Jun 2021 14:53:49

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:25:26
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:50:49
User entered 'Yes (Y)'	Samantha Wieseler (b) (4)	20 Aug 2020 14:05:24

US3032249

Folder: Visit 1 Day 1

Form: Continuing

Generated On: 09 Jun 2021 14:53:49

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:25:26
User entered 'I'	System	20 Aug 2020 14:05:24

US3032249

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 14:53:49

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:43:07
Data entry locked.	System	19 Aug 2020 23:40:48
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	19 Aug 2020 23:40:48

US3032249

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 14:53:49

Was TEMPERATURE taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:43:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5a55dca4933e096f)', Time: '2020-08-19T19:12:59', User OID: 'PatientReportedOutcome (US3032249)', ODM File OID: 'dce7056e-65c7-4c5c-b9f2-e833547146d2'	System	20 Aug 2020 00:14:03
User entered 'Yes (Y)'	System	20 Aug 2020 00:14:03

US3032249

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 14:53:49

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:43:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5a55dca4933e096f)', Time: '2020-08-19T19:13:11', User OID: 'PatientReportedOutcome (US3032249)', ODM File OID: 'dce7056e-65c7-4c5c-b9f2-e833547146d2'	System	20 Aug 2020 00:14:03
User entered '97.9'	System	20 Aug 2020 00:14:03

US3032249

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 14:53:49

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:43:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5a55dca4933e096f)', Time: '2020-08-19T19:13:19', User OID: 'PatientReportedOutcome (US3032249)', ODM File OID: 'dce7056e-65c7-4c5c-b9f2-e833547146d2'	System	20 Aug 2020 00:14:03
User entered 'No (N)'	System	20 Aug 2020 00:14:03

US3032249

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 14:53:49

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:43:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5a55dca4933e096f)', Time: '2020-08-19T19:14:00', User OID: 'PatientReportedOutcome (US3032249)', ODM File OID: 'dce7056e-65c7-4c5c-b9f2-e833547146d2'	System	20 Aug 2020 00:14:03
User entered '19 Aug 2020 19:14'	System	20 Aug 2020 00:14:03

US3032249

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 14:53:49

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:43:07
User entered '19 Aug 2020 18:55'	System	19 Aug 2020 23:40:48

US3032249

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 14:53:49

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:43:07
User entered '19 Aug 2020 21:25'	System	19 Aug 2020 23:40:48

US3032249

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 14:53:49

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:43:07
Data entry locked.	System	19 Aug 2020 23:40:48
User entered 'Day 1, after vaccination (at home)'	System	19 Aug 2020 23:40:48

US3032249

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 14:53:49

Was TEMPERATURE taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:43:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5a55dca4933e096f)', Time: '2020-08-19T22:23:46', User OID: 'PatientReportedOutcome (US3032249)', ODM File OID: '9630634f-320d-42b4-9b79-4e6a10fb4037'	System	20 Aug 2020 03:24:18
User entered 'Yes (Y)'	System	20 Aug 2020 03:24:18

US3032249

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 14:53:49

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:43:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5a55dca4933e096f)', Time: '2020-08-19T22:23:55', User OID: 'PatientReportedOutcome (US3032249)', ODM File OID: '9630634f-320d-42b4-9b79-4e6a10fb4037'	System	20 Aug 2020 03:24:18
User entered '98.0'	System	20 Aug 2020 03:24:18

US3032249

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 14:53:49

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:43:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5a55dca4933e096f)', Time: '2020-08-19T22:24:00', User OID: 'PatientReportedOutcome (US3032249)', ODM File OID: '9630634f-320d-42b4-9b79-4e6a10fb4037'	System	20 Aug 2020 03:24:18
User entered 'No (N)'	System	20 Aug 2020 03:24:18

US3032249

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 14:53:49

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:43:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5a55dca4933e096f)', Time: '2020-08-19T22:24:15', User OID: 'PatientReportedOutcome (US3032249)', ODM File OID: '9630634f-320d-42b4-9b79-4e6a10fb4037'	System	20 Aug 2020 03:24:18
User entered '19 Aug 2020 22:24'	System	20 Aug 2020 03:24:18

US3032249

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 14:53:49

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:43:07
User entered '19 Aug 2020 22:20'	System	19 Aug 2020 23:40:48

US3032249

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 14:53:49

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:43:07
User entered '20 Aug 2020 11:59'	System	19 Aug 2020 23:40:48

US3032249

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 14:53:49

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:43:07
Data entry locked.	System	19 Aug 2020 23:40:48
User entered 'Day 2'	System	19 Aug 2020 23:40:48

US3032249

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 14:53:49

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:43:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5a55dca4933e096f)', Time: '2020-08-20T13:15:11', User OID: 'PatientReportedOutcome (US3032249)', ODM File OID: '356cd6c0-b2f0-4135-930e-5d6e7c749d49'	System	20 Aug 2020 18:15:48
User entered 'Yes (Y)'	System	20 Aug 2020 18:15:48

US3032249

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 14:53:49

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:43:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5a55dca4933e096f)', Time: '2020-08-20T13:15:23', User OID: 'PatientReportedOutcome (US3032249)', ODM File OID: '356cd6c0-b2f0-4135-930e-5d6e7c749d49'	System	20 Aug 2020 18:15:48
User entered '97.1'	System	20 Aug 2020 18:15:48

US3032249

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 14:53:49

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:43:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5a55dca4933e096f)', Time: '2020-08-20T13:15:29', User OID: 'PatientReportedOutcome (US3032249)', ODM File OID: '356cd6c0-b2f0-4135-930e-5d6e7c749d49'	System	20 Aug 2020 18:15:48
User entered 'No (N)'	System	20 Aug 2020 18:15:48

US3032249

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 14:53:49

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:43:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5a55dca4933e096f)', Time: '2020-08-20T13:15:44', User OID: 'PatientReportedOutcome (US3032249)', ODM File OID: '356cd6c0-b2f0-4135-930e-5d6e7c749d49'	System	20 Aug 2020 18:15:48
User entered '20 Aug 2020 13:15'	System	20 Aug 2020 18:15:48

US3032249

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 14:53:49

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:43:07
User entered '20 Aug 2020 12:00'	System	19 Aug 2020 23:40:48

US3032249

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 14:53:49

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:43:07
User entered '21 Aug 2020 11:59'	System	19 Aug 2020 23:40:48

US3032249

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 14:53:49

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:43:07
Data entry locked.	System	19 Aug 2020 23:40:48
User entered 'Day 3'	System	19 Aug 2020 23:40:48

US3032249

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 14:53:49

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:43:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5a55dca4933e096f)', Time: '2020-08-21T22:27:38', User OID: 'PatientReportedOutcome (US3032249)', ODM File OID: 'fa390549-c6ab-475e-ac18-c9e3dd2344e2'	System	22 Aug 2020 03:28:06
User entered 'Yes (Y)'	System	22 Aug 2020 03:28:06

US3032249

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 14:53:49

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:43:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5a55dca4933e096f)', Time: '2020-08-21T22:27:47', User OID: 'PatientReportedOutcome (US3032249)', ODM File OID: 'fa390549-c6ab-475e-ac18-c9e3dd2344e2'	System	22 Aug 2020 03:28:06
User entered '98.1'	System	22 Aug 2020 03:28:06

US3032249

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 14:53:49

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:43:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5a55dca4933e096f)', Time: '2020-08-21T22:27:52', User OID: 'PatientReportedOutcome (US3032249)', ODM File OID: 'fa390549-c6ab-475e-ac18-c9e3dd2344e2'	System	22 Aug 2020 03:28:06
User entered 'No (N)'	System	22 Aug 2020 03:28:06

US3032249

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 14:53:49

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:43:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5a55dca4933e096f)', Time: '2020-08-21T22:28:01', User OID: 'PatientReportedOutcome (US3032249)', ODM File OID: 'fa390549-c6ab-475e-ac18-c9e3dd2344e2'	System	22 Aug 2020 03:28:06
User entered '21 Aug 2020 22:28'	System	22 Aug 2020 03:28:06

US3032249

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 14:53:49

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:43:07
User entered '21 Aug 2020 12:00'	System	19 Aug 2020 23:40:48

US3032249

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 14:53:49

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:43:07
User entered '22 Aug 2020 11:59'	System	19 Aug 2020 23:40:48

US3032249

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 14:53:49

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:43:07
Data entry locked.	System	19 Aug 2020 23:40:48
User entered 'Day 4'	System	19 Aug 2020 23:40:48

US3032249

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 14:53:49

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:43:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5a55dca4933e096f)', Time: '2020-08-22T19:44:31', User OID: 'PatientReportedOutcome (US3032249)', ODM File OID: '3e0e6409-03ff-4200-af3f-84c51ecd6194'	System	23 Aug 2020 00:45:25
User entered 'Yes (Y)'	System	23 Aug 2020 00:45:25

US3032249

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 14:53:49

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:43:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5a55dca4933e096f)', Time: '2020-08-22T19:44:51', User OID: 'PatientReportedOutcome (US3032249)', ODM File OID: '3e0e6409-03ff-4200-af3f-84c51ecd6194'	System	23 Aug 2020 00:45:25
User entered '97.8'	System	23 Aug 2020 00:45:25

US3032249

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 14:53:49

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:43:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5a55dca4933e096f)', Time: '2020-08-22T19:45:03', User OID: 'PatientReportedOutcome (US3032249)', ODM File OID: '3e0e6409-03ff-4200-af3f-84c51ecd6194'	System	23 Aug 2020 00:45:25
User entered 'No (N)'	System	23 Aug 2020 00:45:25

US3032249

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 14:53:49

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:43:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5a55dca4933e096f)', Time: '2020-08-22T19:45:22', User OID: 'PatientReportedOutcome (US3032249)', ODM File OID: '3e0e6409-03ff-4200-af3f-84c51ecd6194'	System	23 Aug 2020 00:45:25
User entered '22 Aug 2020 19:45'	System	23 Aug 2020 00:45:25

US3032249

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 14:53:49

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:43:07
User entered '22 Aug 2020 12:00'	System	19 Aug 2020 23:40:48

US3032249

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 14:53:49

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:43:07
User entered '23 Aug 2020 11:59'	System	19 Aug 2020 23:40:48

US3032249

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 14:53:49

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:43:07
Data entry locked.	System	19 Aug 2020 23:40:48
User entered 'Day 5'	System	19 Aug 2020 23:40:48

US3032249

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 14:53:49

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:43:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5a55dca4933e096f)', Time: '2020-08-23T22:37:10', User OID: 'PatientReportedOutcome (US3032249)', ODM File OID: 'fab2c3a2-a40d-4213-bd1f-c6aff204e585'	System	24 Aug 2020 03:37:47
User entered 'Yes (Y)'	System	24 Aug 2020 03:37:47

US3032249

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 14:53:49

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:43:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5a55dca4933e096f)', Time: '2020-08-23T22:37:29', User OID: 'PatientReportedOutcome (US3032249)', ODM File OID: 'fab2c3a2-a40d-4213-bd1f-c6aff204e585'	System	24 Aug 2020 03:37:47
User entered '98.1'	System	24 Aug 2020 03:37:47

US3032249

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 14:53:49

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:43:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5a55dca4933e096f)', Time: '2020-08-23T22:37:34', User OID: 'PatientReportedOutcome (US3032249)', ODM File OID: 'fab2c3a2-a40d-4213-bd1f-c6aff204e585'	System	24 Aug 2020 03:37:47
User entered 'No (N)'	System	24 Aug 2020 03:37:47

US3032249

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 14:53:49

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:43:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5a55dca4933e096f)', Time: '2020-08-23T22:37:42', User OID: 'PatientReportedOutcome (US3032249)', ODM File OID: 'fab2c3a2-a40d-4213-bd1f-c6aff204e585'	System	24 Aug 2020 03:37:47
User entered '23 Aug 2020 22:37'	System	24 Aug 2020 03:37:47

US3032249

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 14:53:49

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:43:07
User entered '23 Aug 2020 12:00'	System	19 Aug 2020 23:40:48

US3032249

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 14:53:49

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:43:07
User entered '24 Aug 2020 11:59'	System	19 Aug 2020 23:40:48

US3032249

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 14:53:49

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:43:07
Data entry locked.	System	19 Aug 2020 23:40:48
User entered 'Day 6'	System	19 Aug 2020 23:40:48

US3032249

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 14:53:49

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:43:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5a55dca4933e096f)', Time: '2020-08-25T04:48:28', User OID: 'PatientReportedOutcome (US3032249)', ODM File OID: '9511a682-2f34-4437-8102-fd7a5281ac95'	System	25 Aug 2020 09:49:07
User entered 'Yes (Y)'	System	25 Aug 2020 09:49:07

US3032249

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 14:53:49

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:43:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5a55dca4933e096f)', Time: '2020-08-25T04:48:45', User OID: 'PatientReportedOutcome (US3032249)', ODM File OID: '9511a682-2f34-4437-8102-fd7a5281ac95'	System	25 Aug 2020 09:49:07
User entered '97.8'	System	25 Aug 2020 09:49:07

US3032249

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 14:53:49

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:43:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5a55dca4933e096f)', Time: '2020-08-25T04:48:51', User OID: 'PatientReportedOutcome (US3032249)', ODM File OID: '9511a682-2f34-4437-8102-fd7a5281ac95'	System	25 Aug 2020 09:49:07
User entered 'No (N)'	System	25 Aug 2020 09:49:07

US3032249

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 14:53:49

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:43:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5a55dca4933e096f)', Time: '2020-08-25T04:49:04', User OID: 'PatientReportedOutcome (US3032249)', ODM File OID: '9511a682-2f34-4437-8102-fd7a5281ac95'	System	25 Aug 2020 09:49:07
User entered '25 Aug 2020 04:49'	System	25 Aug 2020 09:49:07

US3032249

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 14:53:49

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:43:07
User entered '24 Aug 2020 12:00'	System	19 Aug 2020 23:40:48

US3032249

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 14:53:49

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:43:07
User entered '25 Aug 2020 11:59'	System	19 Aug 2020 23:40:48

US3032249

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 14:53:49

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:43:07
Data entry locked.	System	19 Aug 2020 23:40:48
User entered 'Day 7'	System	19 Aug 2020 23:40:48

US3032249

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 14:53:49

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:43:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5a55dca4933e096f)', Time: '2020-08-25T23:32:04', User OID: 'PatientReportedOutcome (US3032249)', ODM File OID: 'ee2bf2cb-f160-45fd-8e9d-6b0955a67e0c'	System	26 Aug 2020 04:32:37
User entered 'Yes (Y)'	System	26 Aug 2020 04:32:37

US3032249

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 14:53:49

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:43:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5a55dca4933e096f)', Time: '2020-08-25T23:32:18', User OID: 'PatientReportedOutcome (US3032249)', ODM File OID: 'ee2bf2cb-f160-45fd-8e9d-6b0955a67e0c'	System	26 Aug 2020 04:32:37
User entered '97.4'	System	26 Aug 2020 04:32:37

US3032249

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 14:53:49

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:43:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5a55dca4933e096f)', Time: '2020-08-25T23:32:22', User OID: 'PatientReportedOutcome (US3032249)', ODM File OID: 'ee2bf2cb-f160-45fd-8e9d-6b0955a67e0c'	System	26 Aug 2020 04:32:37
User entered 'No (N)'	System	26 Aug 2020 04:32:37

US3032249

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 14:53:49

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:43:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5a55dca4933e096f)', Time: '2020-08-25T23:32:30', User OID: 'PatientReportedOutcome (US3032249)', ODM File OID: 'ee2bf2cb-f160-45fd-8e9d-6b0955a67e0c'	System	26 Aug 2020 04:32:37
User entered '25 Aug 2020 23:32'	System	26 Aug 2020 04:32:37

US3032249

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 14:53:49

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:43:07
User entered '25 Aug 2020 12:00'	System	19 Aug 2020 23:40:48

US3032249

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 14:53:49

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:43:07
User entered '26 Aug 2020 11:59'	System	19 Aug 2020 23:40:48

US3032249

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 14:53:49

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:43:07
Data entry locked.	System	19 Aug 2020 23:40:48
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	19 Aug 2020 23:40:48

US3032249

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 14:53:49

Please record - **PAIN AT INJECTION SITE.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:43:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5a55dca4933e096f)', Time: '2020-08-19T19:14:12', User OID: 'PatientReportedOutcome (US3032249)', ODM File OID: 'bcc23e8e-5904-482d-b92e-88249b4d1299'	System	20 Aug 2020 00:14:46
User entered 'None (1)'	System	20 Aug 2020 00:14:46

US3032249

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 14:53:49

Is there any **REDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:43:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5a55dca4933e096f)', Time: '2020-08-19T19:14:20', User OID: 'PatientReportedOutcome (US3032249)', ODM File OID: 'bcc23e8e-5904-482d-b92e-88249b4d1299'	System	20 Aug 2020 00:14:46
User entered 'No (N)'	System	20 Aug 2020 00:14:46

US3032249

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 14:53:49

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:43:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5a55dca4933e096f)', Time: '2020-08-19T19:14:23', User OID: 'PatientReportedOutcome (US3032249)', ODM File OID: 'bcc23e8e-5904-482d-b92e-88249b4d1299'	System	20 Aug 2020 00:14:46
User entered 'No (N)'	System	20 Aug 2020 00:14:46

US3032249

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 14:53:49

Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:43:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5a55dca4933e096f)', Time: '2020-08-19T19:14:35', User OID: 'PatientReportedOutcome (US3032249)', ODM File OID: 'bcc23e8e-5904-482d-b92e-88249b4d1299'	System	20 Aug 2020 00:14:46
User entered 'None (1)'	System	20 Aug 2020 00:14:46

US3032249

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 14:53:49

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:43:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5a55dca4933e096f)', Time: '2020-08-19T19:14:44', User OID: 'PatientReportedOutcome (US3032249)', ODM File OID: 'bcc23e8e-5904-482d-b92e-88249b4d1299'	System	20 Aug 2020 00:14:46
User entered '19 Aug 2020 19:14'	System	20 Aug 2020 00:14:46

US3032249

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 14:53:49

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:43:07
User entered '19 Aug 2020 18:55'	System	19 Aug 2020 23:40:48

US3032249

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 14:53:49

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:43:07
User entered '19 Aug 2020 21:25'	System	19 Aug 2020 23:40:48

US3032249

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 14:53:49

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:43:07
Data entry locked.	System	19 Aug 2020 23:40:48
User entered 'Day 1, after vaccination (at home)'	System	19 Aug 2020 23:40:48

US3032249

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 14:53:49

Please record - **PAIN AT INJECTION SITE.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:43:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5a55dca4933e096f)', Time: '2020-08-19T22:24:25', User OID: 'PatientReportedOutcome (US3032249)', ODM File OID: '57a09ee3-63ed-4aa9-9dde-d8ba9e624dbd'	System	20 Aug 2020 03:25:17
User entered 'None (1)'	System	20 Aug 2020 03:25:17

US3032249

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 14:53:49

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:43:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5a55dca4933e096f)', Time: '2020-08-19T22:24:32', User OID: 'PatientReportedOutcome (US3032249)', ODM File OID: '57a09ee3-63ed-4aa9-9dde-d8ba9e624dbd'	System	20 Aug 2020 03:25:17
User entered 'No (N)'	System	20 Aug 2020 03:25:17

US3032249

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 14:53:49

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:43:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5a55dca4933e096f)', Time: '2020-08-19T22:24:40', User OID: 'PatientReportedOutcome (US3032249)', ODM File OID: '57a09ee3-63ed-4aa9-9dde-d8ba9e624dbd'	System	20 Aug 2020 03:25:17
User entered 'No (N)'	System	20 Aug 2020 03:25:17

US3032249

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 14:53:49

Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:43:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5a55dca4933e096f)', Time: '2020-08-19T22:24:57', User OID: 'PatientReportedOutcome (US3032249)', ODM File OID: '57a09ee3-63ed-4aa9-9dde-d8ba9e624dbd'	System	20 Aug 2020 03:25:17
User entered 'None (1)'	System	20 Aug 2020 03:25:17

US3032249

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 14:53:49

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:43:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5a55dca4933e096f)', Time: '2020-08-19T22:25:13', User OID: 'PatientReportedOutcome (US3032249)', ODM File OID: '57a09ee3-63ed-4aa9-9dde-d8ba9e624dbd'	System	20 Aug 2020 03:25:17
User entered '19 Aug 2020 22:25'	System	20 Aug 2020 03:25:17

US3032249

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 14:53:49

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:43:07
User entered '19 Aug 2020 22:20'	System	19 Aug 2020 23:40:48

US3032249

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 14:53:49

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:43:07
User entered '20 Aug 2020 11:59'	System	19 Aug 2020 23:40:48

US3032249

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 14:53:49

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:43:07
Data entry locked.	System	19 Aug 2020 23:40:48
User entered 'Day 2'	System	19 Aug 2020 23:40:48

US3032249

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 14:53:49

Please record - **PAIN AT INJECTION SITE.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:43:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5a55dca4933e096f)', Time: '2020-08-20T13:15:58', User OID: 'PatientReportedOutcome (US3032249)', ODM File OID: '71db4253-f485-4baa-8992-b1c6cfbda718'	System	20 Aug 2020 18:16:33
User entered 'None (1)'	System	20 Aug 2020 18:16:33

US3032249

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 14:53:49

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:43:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5a55dca4933e096f)', Time: '2020-08-20T13:16:04', User OID: 'PatientReportedOutcome (US3032249)', ODM File OID: '71db4253-f485-4baa-8992-b1c6cfbda718'	System	20 Aug 2020 18:16:33
User entered 'No (N)'	System	20 Aug 2020 18:16:33

US3032249

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 14:53:49

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:43:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5a55dca4933e096f)', Time: '2020-08-20T13:16:10', User OID: 'PatientReportedOutcome (US3032249)', ODM File OID: '71db4253-f485-4baa-8992-b1c6cfbda718'	System	20 Aug 2020 18:16:33
User entered 'No (N)'	System	20 Aug 2020 18:16:33

US3032249

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 14:53:49

Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:43:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5a55dca4933e096f)', Time: '2020-08-20T13:16:17', User OID: 'PatientReportedOutcome (US3032249)', ODM File OID: '71db4253-f485-4baa-8992-b1c6cfbda718'	System	20 Aug 2020 18:16:33
User entered 'None (1)'	System	20 Aug 2020 18:16:33

US3032249

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 14:53:49

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:43:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5a55dca4933e096f)', Time: '2020-08-20T13:16:31', User OID: 'PatientReportedOutcome (US3032249)', ODM File OID: '71db4253-f485-4baa-8992-b1c6cfbda718'	System	20 Aug 2020 18:16:33
User entered '20 Aug 2020 13:16'	System	20 Aug 2020 18:16:33

US3032249

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 14:53:49

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:43:07
User entered '20 Aug 2020 12:00'	System	19 Aug 2020 23:40:48

US3032249

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 14:53:49

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:43:07
User entered '21 Aug 2020 11:59'	System	19 Aug 2020 23:40:48

US3032249

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 14:53:49

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:43:07
Data entry locked.	System	19 Aug 2020 23:40:48
User entered 'Day 3'	System	19 Aug 2020 23:40:48

US3032249

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 14:53:49

Please record - **PAIN AT INJECTION SITE.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:43:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5a55dca4933e096f)', Time: '2020-08-21T22:28:10', User OID: 'PatientReportedOutcome (US3032249)', ODM File OID: '070ef027-3136-4970-936b-3405e99e80a5'	System	22 Aug 2020 03:28:34
User entered 'None (1)'	System	22 Aug 2020 03:28:34

US3032249

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 14:53:49

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:43:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5a55dca4933e096f)', Time: '2020-08-21T22:28:14', User OID: 'PatientReportedOutcome (US3032249)', ODM File OID: '070ef027-3136-4970-936b-3405e99e80a5'	System	22 Aug 2020 03:28:34
User entered 'No (N)'	System	22 Aug 2020 03:28:34

US3032249

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 14:53:49

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:43:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5a55dca4933e096f)', Time: '2020-08-21T22:28:18', User OID: 'PatientReportedOutcome (US3032249)', ODM File OID: '070ef027-3136-4970-936b-3405e99e80a5'	System	22 Aug 2020 03:28:34
User entered 'No (N)'	System	22 Aug 2020 03:28:34

US3032249

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 14:53:49

Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:43:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5a55dca4933e096f)', Time: '2020-08-21T22:28:22', User OID: 'PatientReportedOutcome (US3032249)', ODM File OID: '070ef027-3136-4970-936b-3405e99e80a5'	System	22 Aug 2020 03:28:34
User entered 'None (1)'	System	22 Aug 2020 03:28:34

US3032249

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 14:53:49

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:43:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5a55dca4933e096f)', Time: '2020-08-21T22:28:30', User OID: 'PatientReportedOutcome (US3032249)', ODM File OID: '070ef027-3136-4970-936b-3405e99e80a5'	System	22 Aug 2020 03:28:34
User entered '21 Aug 2020 22:28'	System	22 Aug 2020 03:28:34

US3032249

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 14:53:49

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:43:07
User entered '21 Aug 2020 12:00'	System	19 Aug 2020 23:40:48

US3032249

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 14:53:49

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:43:07
User entered '22 Aug 2020 11:59'	System	19 Aug 2020 23:40:48

US3032249

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 14:53:49

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:43:07
Data entry locked.	System	19 Aug 2020 23:40:48
User entered 'Day 4'	System	19 Aug 2020 23:40:48

US3032249

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 14:53:49

Please record - **PAIN AT INJECTION SITE.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:43:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5a55dca4933e096f)', Time: '2020-08-22T19:45:31', User OID: 'PatientReportedOutcome (US3032249)', ODM File OID: '88ccce58-20f1-4244-948d-64780b445641'	System	23 Aug 2020 00:46:25
User entered 'None (1)'	System	23 Aug 2020 00:46:25

US3032249

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 14:53:49

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:43:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5a55dca4933e096f)', Time: '2020-08-22T19:45:47', User OID: 'PatientReportedOutcome (US3032249)', ODM File OID: '88ccce58-20f1-4244-948d-64780b445641'	System	23 Aug 2020 00:46:25
User entered 'No (N)'	System	23 Aug 2020 00:46:25

US3032249

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 14:53:49

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:43:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5a55dca4933e096f)', Time: '2020-08-22T19:45:53', User OID: 'PatientReportedOutcome (US3032249)', ODM File OID: '88ccce58-20f1-4244-948d-64780b445641'	System	23 Aug 2020 00:46:25
User entered 'No (N)'	System	23 Aug 2020 00:46:25

US3032249

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 14:53:49

Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:43:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5a55dca4933e096f)', Time: '2020-08-22T19:46:01', User OID: 'PatientReportedOutcome (US3032249)', ODM File OID: '88ccce58-20f1-4244-948d-64780b445641'	System	23 Aug 2020 00:46:25
User entered 'None (1)'	System	23 Aug 2020 00:46:25

US3032249

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 14:53:49

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:43:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5a55dca4933e096f)', Time: '2020-08-22T19:46:23', User OID: 'PatientReportedOutcome (US3032249)', ODM File OID: '88ccce58-20f1-4244-948d-64780b445641'	System	23 Aug 2020 00:46:25
User entered '22 Aug 2020 19:46'	System	23 Aug 2020 00:46:25

US3032249

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 14:53:49

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:43:07
User entered '22 Aug 2020 12:00'	System	19 Aug 2020 23:40:48

US3032249

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 14:53:49

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:43:07
User entered '23 Aug 2020 11:59'	System	19 Aug 2020 23:40:48

US3032249

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 14:53:49

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:43:07
Data entry locked.	System	19 Aug 2020 23:40:48
User entered 'Day 5'	System	19 Aug 2020 23:40:48

US3032249

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 14:53:49

Please record - **PAIN AT INJECTION SITE.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:43:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5a55dca4933e096f)', Time: '2020-08-23T22:37:57', User OID: 'PatientReportedOutcome (US3032249)', ODM File OID: '5eb2bc07-3b10-49a0-88b4-bb92ac02c656'	System	24 Aug 2020 03:38:26
User entered 'None (1)'	System	24 Aug 2020 03:38:26

US3032249

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 14:53:49

Is there any **REDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:43:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5a55dca4933e096f)', Time: '2020-08-23T22:38:01', User OID: 'PatientReportedOutcome (US3032249)', ODM File OID: '5eb2bc07-3b10-49a0-88b4-bb92ac02c656'	System	24 Aug 2020 03:38:26
User entered 'No (N)'	System	24 Aug 2020 03:38:26

US3032249

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 14:53:49

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:43:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5a55dca4933e096f)', Time: '2020-08-23T22:38:05', User OID: 'PatientReportedOutcome (US3032249)', ODM File OID: '5eb2bc07-3b10-49a0-88b4-bb92ac02c656'	System	24 Aug 2020 03:38:26
User entered 'No (N)'	System	24 Aug 2020 03:38:26

US3032249

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 14:53:49

Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:43:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5a55dca4933e096f)', Time: '2020-08-23T22:38:11', User OID: 'PatientReportedOutcome (US3032249)', ODM File OID: '5eb2bc07-3b10-49a0-88b4-bb92ac02c656'	System	24 Aug 2020 03:38:26
User entered 'None (1)'	System	24 Aug 2020 03:38:26

US3032249

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 14:53:49

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:43:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5a55dca4933e096f)', Time: '2020-08-23T22:38:21', User OID: 'PatientReportedOutcome (US3032249)', ODM File OID: '5eb2bc07-3b10-49a0-88b4-bb92ac02c656'	System	24 Aug 2020 03:38:26
User entered '23 Aug 2020 22:38'	System	24 Aug 2020 03:38:26

US3032249

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 14:53:49

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:43:07
User entered '23 Aug 2020 12:00'	System	19 Aug 2020 23:40:48

US3032249

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 14:53:49

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:43:07
User entered '24 Aug 2020 11:59'	System	19 Aug 2020 23:40:48

US3032249

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 14:53:49

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:43:07
Data entry locked.	System	19 Aug 2020 23:40:48
User entered 'Day 6'	System	19 Aug 2020 23:40:48

US3032249

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 14:53:49

Please record - **PAIN AT INJECTION SITE.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:43:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5a55dca4933e096f)', Time: '2020-08-25T04:49:12', User OID: 'PatientReportedOutcome (US3032249)', ODM File OID: 'fd9d66e1-1832-42d3-b3d9-4d95c3bc6905'	System	25 Aug 2020 09:49:43
User entered 'None (1)'	System	25 Aug 2020 09:49:43

US3032249

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 14:53:49

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:43:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5a55dca4933e096f)', Time: '2020-08-25T04:49:16', User OID: 'PatientReportedOutcome (US3032249)', ODM File OID: 'fd9d66e1-1832-42d3-b3d9-4d95c3bc6905'	System	25 Aug 2020 09:49:43
User entered 'No (N)'	System	25 Aug 2020 09:49:43

US3032249

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 14:53:49

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:43:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5a55dca4933e096f)', Time: '2020-08-25T04:49:22', User OID: 'PatientReportedOutcome (US3032249)', ODM File OID: 'fd9d66e1-1832-42d3-b3d9-4d95c3bc6905'	System	25 Aug 2020 09:49:43
User entered 'No (N)'	System	25 Aug 2020 09:49:43

US3032249

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 14:53:49

Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:43:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5a55dca4933e096f)', Time: '2020-08-25T04:49:26', User OID: 'PatientReportedOutcome (US3032249)', ODM File OID: 'fd9d66e1-1832-42d3-b3d9-4d95c3bc6905'	System	25 Aug 2020 09:49:43
User entered 'None (1)'	System	25 Aug 2020 09:49:43

US3032249

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 14:53:49

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:43:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5a55dca4933e096f)', Time: '2020-08-25T04:49:37', User OID: 'PatientReportedOutcome (US3032249)', ODM File OID: 'fd9d66e1-1832-42d3-b3d9-4d95c3bc6905'	System	25 Aug 2020 09:49:43
User entered '25 Aug 2020 04:49'	System	25 Aug 2020 09:49:43

US3032249

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 14:53:49

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:43:07
User entered '24 Aug 2020 12:00'	System	19 Aug 2020 23:40:48

US3032249

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 14:53:49

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:43:07
User entered '25 Aug 2020 11:59'	System	19 Aug 2020 23:40:48

US3032249

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 14:53:49

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:43:07
Data entry locked.	System	19 Aug 2020 23:40:48
User entered 'Day 7'	System	19 Aug 2020 23:40:48

US3032249

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 14:53:49

Please record - **PAIN AT INJECTION SITE.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:43:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5a55dca4933e096f)', Time: '2020-08-25T23:32:37', User OID: 'PatientReportedOutcome (US3032249)', ODM File OID: '54185bae-6bfa-48cf-94b7-8dc1ea471e62'	System	26 Aug 2020 04:33:04
User entered 'None (1)'	System	26 Aug 2020 04:33:04

US3032249

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 14:53:49

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:43:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5a55dca4933e096f)', Time: '2020-08-25T23:32:41', User OID: 'PatientReportedOutcome (US3032249)', ODM File OID: '54185bae-6bfa-48cf-94b7-8dc1ea471e62'	System	26 Aug 2020 04:33:04
User entered 'No (N)'	System	26 Aug 2020 04:33:04

US3032249

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 14:53:49

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:43:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5a55dca4933e096f)', Time: '2020-08-25T23:32:45', User OID: 'PatientReportedOutcome (US3032249)', ODM File OID: '54185bae-6bfa-48cf-94b7-8dc1ea471e62'	System	26 Aug 2020 04:33:04
User entered 'No (N)'	System	26 Aug 2020 04:33:04

US3032249

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 14:53:49

Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:43:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5a55dca4933e096f)', Time: '2020-08-25T23:32:49', User OID: 'PatientReportedOutcome (US3032249)', ODM File OID: '54185bae-6bfa-48cf-94b7-8dc1ea471e62'	System	26 Aug 2020 04:33:04
User entered 'None (1)'	System	26 Aug 2020 04:33:04

US3032249

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 14:53:49

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:43:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5a55dca4933e096f)', Time: '2020-08-25T23:32:59', User OID: 'PatientReportedOutcome (US3032249)', ODM File OID: '54185bae-6bfa-48cf-94b7-8dc1ea471e62'	System	26 Aug 2020 04:33:04
User entered '25 Aug 2020 23:32'	System	26 Aug 2020 04:33:04

US3032249

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 14:53:49

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:43:07
User entered '25 Aug 2020 12:00'	System	19 Aug 2020 23:40:48

US3032249

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 14:53:49

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:43:07
User entered '26 Aug 2020 11:59'	System	19 Aug 2020 23:40:48

US3032249

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 14:53:49

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:43:07
Data entry locked.	System	19 Aug 2020 23:40:48
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	19 Aug 2020 23:40:48

US3032249

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 14:53:49

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:43:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5a55dca4933e096f)', Time: '2020-08-19T19:15:31', User OID: 'PatientReportedOutcome (US3032249)', ODM File OID: 'ac8ec07a-674f-4954-9fc0-52440c074495'	System	20 Aug 2020 00:16:21
User entered 'None (0)'	System	20 Aug 2020 00:16:21

US3032249

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 14:53:49

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:43:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5a55dca4933e096f)', Time: '2020-08-19T19:15:39', User OID: 'PatientReportedOutcome (US3032249)', ODM File OID: 'ac8ec07a-674f-4954-9fc0-52440c074495'	System	20 Aug 2020 00:16:21
User entered 'None (0)'	System	20 Aug 2020 00:16:21

US3032249

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 14:53:49

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:43:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5a55dca4933e096f)', Time: '2020-08-19T19:15:48', User OID: 'PatientReportedOutcome (US3032249)', ODM File OID: 'ac8ec07a-674f-4954-9fc0-52440c074495'	System	20 Aug 2020 00:16:21
User entered 'None (0)'	System	20 Aug 2020 00:16:21

US3032249

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 14:53:49

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:43:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5a55dca4933e096f)', Time: '2020-08-19T19:15:52', User OID: 'PatientReportedOutcome (US3032249)', ODM File OID: 'ac8ec07a-674f-4954-9fc0-52440c074495'	System	20 Aug 2020 00:16:21
User entered 'None (0)'	System	20 Aug 2020 00:16:21

US3032249

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 14:53:49

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:43:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5a55dca4933e096f)', Time: '2020-08-19T19:15:58', User OID: 'PatientReportedOutcome (US3032249)', ODM File OID: 'ac8ec07a-674f-4954-9fc0-52440c074495'	System	20 Aug 2020 00:16:21
User entered 'None (0)'	System	20 Aug 2020 00:16:21

US3032249

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 14:53:49

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:43:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5a55dca4933e096f)', Time: '2020-08-19T19:16:05', User OID: 'PatientReportedOutcome (US3032249)', ODM File OID: 'ac8ec07a-674f-4954-9fc0-52440c074495'	System	20 Aug 2020 00:16:21
User entered 'None (0)'	System	20 Aug 2020 00:16:21

US3032249

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 14:53:49

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)	27 Mar 2021 20:43:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5a55dca4933e096f)', Time: '2020-08-19T19:16:13', User OID: 'PatientReportedOutcome (US3032249)', ODM File OID: 'ac8ec07a-674f-4954-9fc0-52440c074495'	System	20 Aug 2020 00:16:21
User entered 'No (N)'	System	20 Aug 2020 00:16:21

US3032249

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 14:53:49

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:43:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5a55dca4933e096f)', Time: '2020-08-19T19:16:18', User OID: 'PatientReportedOutcome (US3032249)', ODM File OID: 'ac8ec07a-674f-4954-9fc0-52440c074495'	System	20 Aug 2020 00:16:21
User entered '19 Aug 2020 19:16'	System	20 Aug 2020 00:16:21

US3032249

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 14:53:49

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:43:07
User entered '19 Aug 2020 18:55'	System	19 Aug 2020 23:40:48

US3032249

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 14:53:49

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:43:07
User entered '19 Aug 2020 21:25'	System	19 Aug 2020 23:40:48

US3032249

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 14:53:49

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:43:07
Data entry locked.	System	19 Aug 2020 23:40:48
User entered 'Day 1, after vaccination (at home)'	System	19 Aug 2020 23:40:48

US3032249

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 14:53:49

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:43:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5a55dca4933e096f)', Time: '2020-08-19T22:25:36', User OID: 'PatientReportedOutcome (US3032249)', ODM File OID: '454c3920-51aa-45f8-894f-b6b788d5cea4'	System	20 Aug 2020 03:26:53
User entered 'None (0)'	System	20 Aug 2020 03:26:53

US3032249

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 14:53:49

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:43:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5a55dca4933e096f)', Time: '2020-08-19T22:25:47', User OID: 'PatientReportedOutcome (US3032249)', ODM File OID: '454c3920-51aa-45f8-894f-b6b788d5cea4'	System	20 Aug 2020 03:26:53
User entered 'None (0)'	System	20 Aug 2020 03:26:53

US3032249

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 14:53:49

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:43:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5a55dca4933e096f)', Time: '2020-08-19T22:26:01', User OID: 'PatientReportedOutcome (US3032249)', ODM File OID: '454c3920-51aa-45f8-894f-b6b788d5cea4'	System	20 Aug 2020 03:26:53
User entered 'None (0)'	System	20 Aug 2020 03:26:53

US3032249

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 14:53:49

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:43:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5a55dca4933e096f)', Time: '2020-08-19T22:26:10', User OID: 'PatientReportedOutcome (US3032249)', ODM File OID: '454c3920-51aa-45f8-894f-b6b788d5cea4'	System	20 Aug 2020 03:26:53
User entered 'None (0)'	System	20 Aug 2020 03:26:53

US3032249

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 14:53:49

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:43:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5a55dca4933e096f)', Time: '2020-08-19T22:26:14', User OID: 'PatientReportedOutcome (US3032249)', ODM File OID: '454c3920-51aa-45f8-894f-b6b788d5cea4'	System	20 Aug 2020 03:26:53
User entered 'None (0)'	System	20 Aug 2020 03:26:53

US3032249

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 14:53:49

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:43:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5a55dca4933e096f)', Time: '2020-08-19T22:26:21', User OID: 'PatientReportedOutcome (US3032249)', ODM File OID: '454c3920-51aa-45f8-894f-b6b788d5cea4'	System	20 Aug 2020 03:26:53
User entered 'None (0)'	System	20 Aug 2020 03:26:53

US3032249

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 14:53:49

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)	27 Mar 2021 20:43:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5a55dca4933e096f)', Time: '2020-08-19T22:26:32', User OID: 'PatientReportedOutcome (US3032249)', ODM File OID: '454c3920-51aa-45f8-894f-b6b788d5cea4'	System	20 Aug 2020 03:26:53
User entered 'No (N)'	System	20 Aug 2020 03:26:53

US3032249

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 14:53:49

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:43:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5a55dca4933e096f)', Time: '2020-08-19T22:26:52', User OID: 'PatientReportedOutcome (US3032249)', ODM File OID: '454c3920-51aa-45f8-894f-b6b788d5cea4'	System	20 Aug 2020 03:26:53
User entered '19 Aug 2020 22:26'	System	20 Aug 2020 03:26:53

US3032249

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 14:53:49

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:43:07
User entered '19 Aug 2020 22:20'	System	19 Aug 2020 23:40:48

US3032249

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 14:53:49

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:43:07
User entered '20 Aug 2020 11:59'	System	19 Aug 2020 23:40:48

US3032249

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 14:53:49

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:43:07
Data entry locked.	System	19 Aug 2020 23:40:48
User entered 'Day 2'	System	19 Aug 2020 23:40:48

US3032249

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 14:53:49

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:43:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5a55dca4933e096f)', Time: '2020-08-20T13:17:00', User OID: 'PatientReportedOutcome (US3032249)', ODM File OID: 'f3b684d7-4fc9-4b6d-b8e7-04db0af5eeb5'	System	20 Aug 2020 18:18:33
User entered 'None (0)'	System	20 Aug 2020 18:18:33

US3032249

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 14:53:49

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:43:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5a55dca4933e096f)', Time: '2020-08-20T13:17:10', User OID: 'PatientReportedOutcome (US3032249)', ODM File OID: 'f3b684d7-4fc9-4b6d-b8e7-04db0af5eeb5'	System	20 Aug 2020 18:18:33
User entered 'None (0)'	System	20 Aug 2020 18:18:33

US3032249

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 14:53:49

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:43:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5a55dca4933e096f)', Time: '2020-08-20T13:17:25', User OID: 'PatientReportedOutcome (US3032249)', ODM File OID: 'f3b684d7-4fc9-4b6d-b8e7-04db0af5eeb5'	System	20 Aug 2020 18:18:33
User entered 'None (0)'	System	20 Aug 2020 18:18:33

US3032249

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 14:53:49

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:43:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5a55dca4933e096f)', Time: '2020-08-20T13:17:35', User OID: 'PatientReportedOutcome (US3032249)', ODM File OID: 'f3b684d7-4fc9-4b6d-b8e7-04db0af5eeb5'	System	20 Aug 2020 18:18:33
User entered 'None (0)'	System	20 Aug 2020 18:18:33

US3032249

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 14:53:49

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:43:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5a55dca4933e096f)', Time: '2020-08-20T13:17:45', User OID: 'PatientReportedOutcome (US3032249)', ODM File OID: 'f3b684d7-4fc9-4b6d-b8e7-04db0af5eeb5'	System	20 Aug 2020 18:18:33
User entered 'None (0)'	System	20 Aug 2020 18:18:33

US3032249

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 14:53:49

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:43:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5a55dca4933e096f)', Time: '2020-08-20T13:17:53', User OID: 'PatientReportedOutcome (US3032249)', ODM File OID: 'f3b684d7-4fc9-4b6d-b8e7-04db0af5eeb5'	System	20 Aug 2020 18:18:33
User entered 'None (0)'	System	20 Aug 2020 18:18:33

US3032249

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 14:53:49

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)	27 Mar 2021 20:43:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5a55dca4933e096f)', Time: '2020-08-20T13:18:01', User OID: 'PatientReportedOutcome (US3032249)', ODM File OID: 'f3b684d7-4fc9-4b6d-b8e7-04db0af5eeb5'	System	20 Aug 2020 18:18:33
User entered 'No (N)'	System	20 Aug 2020 18:18:33

US3032249

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 14:53:49

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:43:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5a55dca4933e096f)', Time: '2020-08-20T13:18:28', User OID: 'PatientReportedOutcome (US3032249)', ODM File OID: 'f3b684d7-4fc9-4b6d-b8e7-04db0af5eeb5'	System	20 Aug 2020 18:18:33
User entered '20 Aug 2020 13:18'	System	20 Aug 2020 18:18:33

US3032249

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 14:53:49

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:43:07
User entered '20 Aug 2020 12:00'	System	19 Aug 2020 23:40:48

US3032249

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 14:53:49

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:43:07
User entered '21 Aug 2020 11:59'	System	19 Aug 2020 23:40:48

US3032249

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 14:53:49

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:43:07
Data entry locked.	System	19 Aug 2020 23:40:48
User entered 'Day 3'	System	19 Aug 2020 23:40:48

US3032249

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 14:53:49

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:43:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5a55dca4933e096f)', Time: '2020-08-21T22:28:37', User OID: 'PatientReportedOutcome (US3032249)', ODM File OID: '76b4f00a-563c-4326-8ebd-a7c55256eeb5'	System	22 Aug 2020 03:29:48
User entered 'None (0)'	System	22 Aug 2020 03:29:48

US3032249

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 14:53:49

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:43:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5a55dca4933e096f)', Time: '2020-08-21T22:28:47', User OID: 'PatientReportedOutcome (US3032249)', ODM File OID: '76b4f00a-563c-4326-8ebd-a7c55256eeb5'	System	22 Aug 2020 03:29:48
User entered 'None (0)'	System	22 Aug 2020 03:29:48

US3032249

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 14:53:49

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:43:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5a55dca4933e096f)', Time: '2020-08-21T22:28:56', User OID: 'PatientReportedOutcome (US3032249)', ODM File OID: '76b4f00a-563c-4326-8ebd-a7c55256eeb5'	System	22 Aug 2020 03:29:48
User entered 'None (0)'	System	22 Aug 2020 03:29:48

US3032249

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 14:53:49

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:43:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5a55dca4933e096f)', Time: '2020-08-21T22:29:13', User OID: 'PatientReportedOutcome (US3032249)', ODM File OID: '76b4f00a-563c-4326-8ebd-a7c55256eeb5'	System	22 Aug 2020 03:29:48
User entered 'None (0)'	System	22 Aug 2020 03:29:48

US3032249

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 14:53:49

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:43:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5a55dca4933e096f)', Time: '2020-08-21T22:29:18', User OID: 'PatientReportedOutcome (US3032249)', ODM File OID: '76b4f00a-563c-4326-8ebd-a7c55256eeb5'	System	22 Aug 2020 03:29:48
User entered 'None (0)'	System	22 Aug 2020 03:29:48

US3032249

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 14:53:49

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:43:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5a55dca4933e096f)', Time: '2020-08-21T22:29:27', User OID: 'PatientReportedOutcome (US3032249)', ODM File OID: '76b4f00a-563c-4326-8ebd-a7c55256eeb5'	System	22 Aug 2020 03:29:48
User entered 'None (0)'	System	22 Aug 2020 03:29:48

US3032249

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 14:53:49

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)	27 Mar 2021 20:43:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5a55dca4933e096f)', Time: '2020-08-21T22:29:33', User OID: 'PatientReportedOutcome (US3032249)', ODM File OID: '76b4f00a-563c-4326-8ebd-a7c55256eeb5'	System	22 Aug 2020 03:29:48
User entered 'No (N)'	System	22 Aug 2020 03:29:48

US3032249

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 14:53:49

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:43:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5a55dca4933e096f)', Time: '2020-08-21T22:29:45', User OID: 'PatientReportedOutcome (US3032249)', ODM File OID: '76b4f00a-563c-4326-8ebd-a7c55256eeb5'	System	22 Aug 2020 03:29:48
User entered '21 Aug 2020 22:29'	System	22 Aug 2020 03:29:48

US3032249

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 14:53:49

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:43:07
User entered '21 Aug 2020 12:00'	System	19 Aug 2020 23:40:48

US3032249

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 14:53:49

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:43:07
User entered '22 Aug 2020 11:59'	System	19 Aug 2020 23:40:48

US3032249

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 14:53:49

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:43:07
Data entry locked.	System	19 Aug 2020 23:40:48
User entered 'Day 4'	System	19 Aug 2020 23:40:48

US3032249

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 14:53:49

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:43:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5a55dca4933e096f)', Time: '2020-08-22T19:46:45', User OID: 'PatientReportedOutcome (US3032249)', ODM File OID: '7844a223-7c80-4d98-b19e-ce7e4e9f403f'	System	23 Aug 2020 00:48:26
User entered 'None (0)'	System	23 Aug 2020 00:48:26

US3032249

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 14:53:49

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:43:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5a55dca4933e096f)', Time: '2020-08-22T19:46:51', User OID: 'PatientReportedOutcome (US3032249)', ODM File OID: '7844a223-7c80-4d98-b19e-ce7e4e9f403f'	System	23 Aug 2020 00:48:26
User entered 'None (0)'	System	23 Aug 2020 00:48:26

US3032249

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 14:53:49

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:43:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5a55dca4933e096f)', Time: '2020-08-22T19:47:03', User OID: 'PatientReportedOutcome (US3032249)', ODM File OID: '7844a223-7c80-4d98-b19e-ce7e4e9f403f'	System	23 Aug 2020 00:48:26
User entered 'None (0)'	System	23 Aug 2020 00:48:26

US3032249

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 14:53:49

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:43:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5a55dca4933e096f)', Time: '2020-08-22T19:47:20', User OID: 'PatientReportedOutcome (US3032249)', ODM File OID: '7844a223-7c80-4d98-b19e-ce7e4e9f403f'	System	23 Aug 2020 00:48:26
User entered 'None (0)'	System	23 Aug 2020 00:48:26

US3032249

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 14:53:49

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:43:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5a55dca4933e096f)', Time: '2020-08-22T19:47:25', User OID: 'PatientReportedOutcome (US3032249)', ODM File OID: '7844a223-7c80-4d98-b19e-ce7e4e9f403f'	System	23 Aug 2020 00:48:26
User entered 'None (0)'	System	23 Aug 2020 00:48:26

US3032249

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 14:53:49

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:43:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5a55dca4933e096f)', Time: '2020-08-22T19:47:35', User OID: 'PatientReportedOutcome (US3032249)', ODM File OID: '7844a223-7c80-4d98-b19e-ce7e4e9f403f'	System	23 Aug 2020 00:48:26
User entered 'None (0)'	System	23 Aug 2020 00:48:26

US3032249

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 14:53:49

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)	27 Mar 2021 20:43:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5a55dca4933e096f)', Time: '2020-08-22T19:47:44', User OID: 'PatientReportedOutcome (US3032249)', ODM File OID: '7844a223-7c80-4d98-b19e-ce7e4e9f403f'	System	23 Aug 2020 00:48:26
User entered 'No (N)'	System	23 Aug 2020 00:48:26

US3032249

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 14:53:49

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:43:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5a55dca4933e096f)', Time: '2020-08-22T19:48:23', User OID: 'PatientReportedOutcome (US3032249)', ODM File OID: '7844a223-7c80-4d98-b19e-ce7e4e9f403f'	System	23 Aug 2020 00:48:26
User entered '22 Aug 2020 19:48'	System	23 Aug 2020 00:48:26

US3032249

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 14:53:49

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:43:07
User entered '22 Aug 2020 12:00'	System	19 Aug 2020 23:40:48

US3032249

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 14:53:49

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:43:07
User entered '23 Aug 2020 11:59'	System	19 Aug 2020 23:40:48

US3032249

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 14:53:49

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:43:07
Data entry locked.	System	19 Aug 2020 23:40:48
User entered 'Day 5'	System	19 Aug 2020 23:40:48

US3032249

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 14:53:49

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:43:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5a55dca4933e096f)', Time: '2020-08-23T22:38:28', User OID: 'PatientReportedOutcome (US3032249)', ODM File OID: 'a9ec474e-bb5f-4894-ae1a-b26133fe9969'	System	24 Aug 2020 03:39:35
User entered 'None (0)'	System	24 Aug 2020 03:39:35

US3032249

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 14:53:49

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:43:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5a55dca4933e096f)', Time: '2020-08-23T22:38:35', User OID: 'PatientReportedOutcome (US3032249)', ODM File OID: 'a9ec474e-bb5f-4894-ae1a-b26133fe9969'	System	24 Aug 2020 03:39:35
User entered 'None (0)'	System	24 Aug 2020 03:39:35

US3032249

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 14:53:49

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:43:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5a55dca4933e096f)', Time: '2020-08-23T22:38:43', User OID: 'PatientReportedOutcome (US3032249)', ODM File OID: 'a9ec474e-bb5f-4894-ae1a-b26133fe9969'	System	24 Aug 2020 03:39:35
User entered 'None (0)'	System	24 Aug 2020 03:39:35

US3032249

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 14:53:49

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:43:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5a55dca4933e096f)', Time: '2020-08-23T22:38:53', User OID: 'PatientReportedOutcome (US3032249)', ODM File OID: 'a9ec474e-bb5f-4894-ae1a-b26133fe9969'	System	24 Aug 2020 03:39:35
User entered 'None (0)'	System	24 Aug 2020 03:39:35

US3032249

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 14:53:49

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:43:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5a55dca4933e096f)', Time: '2020-08-23T22:39:00', User OID: 'PatientReportedOutcome (US3032249)', ODM File OID: 'a9ec474e-bb5f-4894-ae1a-b26133fe9969'	System	24 Aug 2020 03:39:35
User entered 'None (0)'	System	24 Aug 2020 03:39:35

US3032249

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 14:53:49

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:43:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5a55dca4933e096f)', Time: '2020-08-23T22:39:05', User OID: 'PatientReportedOutcome (US3032249)', ODM File OID: 'a9ec474e-bb5f-4894-ae1a-b26133fe9969'	System	24 Aug 2020 03:39:35
User entered 'None (0)'	System	24 Aug 2020 03:39:35

US3032249

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 14:53:49

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)	27 Mar 2021 20:43:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5a55dca4933e096f)', Time: '2020-08-23T22:39:18', User OID: 'PatientReportedOutcome (US3032249)', ODM File OID: 'a9ec474e-bb5f-4894-ae1a-b26133fe9969'	System	24 Aug 2020 03:39:35
User entered 'No (N)'	System	24 Aug 2020 03:39:35

US3032249

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 14:53:49

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:43:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5a55dca4933e096f)', Time: '2020-08-23T22:39:31', User OID: 'PatientReportedOutcome (US3032249)', ODM File OID: 'a9ec474e-bb5f-4894-ae1a-b26133fe9969'	System	24 Aug 2020 03:39:35
User entered '23 Aug 2020 22:39'	System	24 Aug 2020 03:39:35

US3032249

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 14:53:49

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:43:07
User entered '23 Aug 2020 12:00'	System	19 Aug 2020 23:40:48

US3032249

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 14:53:49

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:43:07
User entered '24 Aug 2020 11:59'	System	19 Aug 2020 23:40:48

US3032249

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 14:53:49

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:43:07
Data entry locked.	System	19 Aug 2020 23:40:48
User entered 'Day 6'	System	19 Aug 2020 23:40:48

US3032249

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 14:53:49

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:43:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5a55dca4933e096f)', Time: '2020-08-25T04:49:45', User OID: 'PatientReportedOutcome (US3032249)', ODM File OID: '37b6bc23-1235-4d28-8d30-29f615b04926'	System	25 Aug 2020 09:50:31
User entered 'None (0)'	System	25 Aug 2020 09:50:31

US3032249

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 14:53:49

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:43:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5a55dca4933e096f)', Time: '2020-08-25T04:49:54', User OID: 'PatientReportedOutcome (US3032249)', ODM File OID: '37b6bc23-1235-4d28-8d30-29f615b04926'	System	25 Aug 2020 09:50:31
User entered 'None (0)'	System	25 Aug 2020 09:50:31

US3032249

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 14:53:49

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:43:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5a55dca4933e096f)', Time: '2020-08-25T04:49:59', User OID: 'PatientReportedOutcome (US3032249)', ODM File OID: '37b6bc23-1235-4d28-8d30-29f615b04926'	System	25 Aug 2020 09:50:31
User entered 'None (0)'	System	25 Aug 2020 09:50:31

US3032249

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 14:53:49

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:43:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5a55dca4933e096f)', Time: '2020-08-25T04:50:03', User OID: 'PatientReportedOutcome (US3032249)', ODM File OID: '37b6bc23-1235-4d28-8d30-29f615b04926'	System	25 Aug 2020 09:50:31
User entered 'None (0)'	System	25 Aug 2020 09:50:31

US3032249

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 14:53:49

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:43:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5a55dca4933e096f)', Time: '2020-08-25T04:50:07', User OID: 'PatientReportedOutcome (US3032249)', ODM File OID: '37b6bc23-1235-4d28-8d30-29f615b04926'	System	25 Aug 2020 09:50:31
User entered 'None (0)'	System	25 Aug 2020 09:50:31

US3032249

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 14:53:49

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:43:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5a55dca4933e096f)', Time: '2020-08-25T04:50:10', User OID: 'PatientReportedOutcome (US3032249)', ODM File OID: '37b6bc23-1235-4d28-8d30-29f615b04926'	System	25 Aug 2020 09:50:31
User entered 'None (0)'	System	25 Aug 2020 09:50:31

US3032249

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 14:53:49

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)	27 Mar 2021 20:43:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5a55dca4933e096f)', Time: '2020-08-25T04:50:16', User OID: 'PatientReportedOutcome (US3032249)', ODM File OID: '37b6bc23-1235-4d28-8d30-29f615b04926'	System	25 Aug 2020 09:50:31
User entered 'No (N)'	System	25 Aug 2020 09:50:31

US3032249

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 14:53:49

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:43:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5a55dca4933e096f)', Time: '2020-08-25T04:50:27', User OID: 'PatientReportedOutcome (US3032249)', ODM File OID: '37b6bc23-1235-4d28-8d30-29f615b04926'	System	25 Aug 2020 09:50:31
User entered '25 Aug 2020 04:50'	System	25 Aug 2020 09:50:31

US3032249

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 14:53:49

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:43:07
User entered '24 Aug 2020 12:00'	System	19 Aug 2020 23:40:48

US3032249

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 14:53:49

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:43:07
User entered '25 Aug 2020 11:59'	System	19 Aug 2020 23:40:48

US3032249

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 14:53:49

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:43:07
Data entry locked.	System	19 Aug 2020 23:40:48
User entered 'Day 7'	System	19 Aug 2020 23:40:48

US3032249

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 14:53:49

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:43:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5a55dca4933e096f)', Time: '2020-08-25T23:33:05', User OID: 'PatientReportedOutcome (US3032249)', ODM File OID: 'c387ac73-4438-40bf-abf8-fe1833acdc72'	System	26 Aug 2020 04:39:25
User entered 'None (0)'	System	26 Aug 2020 04:39:25

US3032249

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 14:53:49

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:43:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5a55dca4933e096f)', Time: '2020-08-25T23:33:09', User OID: 'PatientReportedOutcome (US3032249)', ODM File OID: 'c387ac73-4438-40bf-abf8-fe1833acdc72'	System	26 Aug 2020 04:39:25
User entered 'None (0)'	System	26 Aug 2020 04:39:25

US3032249

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 14:53:49

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:43:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5a55dca4933e096f)', Time: '2020-08-25T23:33:12', User OID: 'PatientReportedOutcome (US3032249)', ODM File OID: 'c387ac73-4438-40bf-abf8-fe1833acdc72'	System	26 Aug 2020 04:39:25
User entered 'None (0)'	System	26 Aug 2020 04:39:25

US3032249

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 14:53:49

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:43:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5a55dca4933e096f)', Time: '2020-08-25T23:33:17', User OID: 'PatientReportedOutcome (US3032249)', ODM File OID: 'c387ac73-4438-40bf-abf8-fe1833acdc72'	System	26 Aug 2020 04:39:25
User entered 'None (0)'	System	26 Aug 2020 04:39:25

US3032249

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 14:53:49

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:43:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5a55dca4933e096f)', Time: '2020-08-25T23:33:21', User OID: 'PatientReportedOutcome (US3032249)', ODM File OID: 'c387ac73-4438-40bf-abf8-fe1833acdc72'	System	26 Aug 2020 04:39:25
User entered 'None (0)'	System	26 Aug 2020 04:39:25

US3032249

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 14:53:49

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:43:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5a55dca4933e096f)', Time: '2020-08-25T23:33:24', User OID: 'PatientReportedOutcome (US3032249)', ODM File OID: 'c387ac73-4438-40bf-abf8-fe1833acdc72'	System	26 Aug 2020 04:39:25
User entered 'None (0)'	System	26 Aug 2020 04:39:25

US3032249

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 14:53:49

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)	27 Mar 2021 20:43:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5a55dca4933e096f)', Time: '2020-08-25T23:33:28', User OID: 'PatientReportedOutcome (US3032249)', ODM File OID: 'c387ac73-4438-40bf-abf8-fe1833acdc72'	System	26 Aug 2020 04:39:25
User entered 'No (N)'	System	26 Aug 2020 04:39:25

US3032249

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 14:53:49

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:43:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5a55dca4933e096f)', Time: '2020-08-25T23:33:38', User OID: 'PatientReportedOutcome (US3032249)', ODM File OID: 'c387ac73-4438-40bf-abf8-fe1833acdc72'	System	26 Aug 2020 04:39:25
User entered '25 Aug 2020 23:33'	System	26 Aug 2020 04:39:25

US3032249

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 14:53:49

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:43:07
User entered '25 Aug 2020 12:00'	System	19 Aug 2020 23:40:48

US3032249

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 14:53:49

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:43:07
User entered '26 Aug 2020 11:59'	System	19 Aug 2020 23:40:48

US3032249

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 14:53:49

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:25:26
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:50:49
User entered 'Yes (Y)'	Samantha Wieseler (b) (4)	09 Sep 2020 17:39:27

US3032249

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 14:53:49

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:25:26
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:50:49
User entered '26 Aug 2020'	(b) (4) Samantha Wieseler (b) (4)	09 Sep 2020 17:39:27

US3032249

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 14:53:49

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:25:26
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:50:49
User entered 'Contact Made (CONTACT MADE)'	(b) (4) Samantha Wieseler (b) (4)	09 Sep 2020 17:39:27

US3032249

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 14:53:49

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:25:26
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:50:49
User entered empty.	Samantha Wieseler (b) (4)	09 Sep 2020 17:39:27

US3032249

Folder: Safety Call Day 8 (1)

Form: Continuing

Generated On: 09 Jun 2021 14:53:49

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:25:26
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:50:49
User entered 'Yes (Y)'	Samantha Wieseler (b) (4)	09 Sep 2020 17:39:33

US3032249

Folder: Safety Call Day 8 (1)

Form: Continuing

Generated On: 09 Jun 2021 14:53:49

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:25:26
User entered 'I'	System	09 Sep 2020 17:39:33

US3032249

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 09 Jun 2021 14:53:49

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:25:26
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:50:49
User entered 'Yes (Y)'	Samantha Wieseler (b) (4)	09 Sep 2020 17:39:43

US3032249

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 09 Jun 2021 14:53:49

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:25:26
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:50:49
User entered '02 Sep 2020'	(b) (4) Samantha Wieseler (b) (4)	09 Sep 2020 17:39:43

US3032249

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 09 Jun 2021 14:53:49

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:25:26
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:50:49
User entered 'Contact Made (CONTACT MADE)'	(b) (4) Samantha Wieseler (b) (4)	09 Sep 2020 17:39:43

US3032249

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 09 Jun 2021 14:53:49

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:25:26
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:50:49
User entered empty.	Samantha Wieseler (b) (4)	09 Sep 2020 17:39:43

US3032249

Folder: Safety Call Day 15 (1)

Form: Continuing

Generated On: 09 Jun 2021 14:53:49

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:25:26
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:50:49
User entered 'Yes (Y)'	Samantha Wieseler (b) (4)	09 Sep 2020 17:39:48

US3032249

Folder: Safety Call Day 15 (1)

Form: Continuing

Generated On: 09 Jun 2021 14:53:49

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:25:26
User entered 'I'	System	09 Sep 2020 17:39:48

US3032249

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 09 Jun 2021 14:53:49

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:25:26
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:50:49
User entered 'Yes (Y)'	(b) (4) Samantha Wieseler (b) (4)	09 Sep 2020 17:39:59

US3032249

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 09 Jun 2021 14:53:49

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:25:26
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:50:49
User entered '09 Sep 2020'	Samantha Wieseler (b) (4)	09 Sep 2020 17:39:59

US3032249

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 09 Jun 2021 14:53:49

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:25:26
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:50:49
User entered 'Contact Made (CONTACT MADE)'	(b) (4) Samantha Wieseler (b) (4)	09 Sep 2020 17:39:59

US3032249

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 09 Jun 2021 14:53:49

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:25:26
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:50:49
User entered empty.	Samantha Wieseler (b) (4)	09 Sep 2020 17:39:59

US3032249

Folder: Safety Call Day 22 (1)

Form: Continuing

Generated On: 09 Jun 2021 14:53:49

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:25:26
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:50:49
User entered 'Yes (Y)'	Samantha Wieseler (b) (4)	09 Sep 2020 17:40:04

US3032249

Folder: Safety Call Day 22 (1)

Form: Continuing

Generated On: 09 Jun 2021 14:53:49

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:25:26
User entered 'I'	System	09 Sep 2020 17:40:04

US3032249

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 09 Jun 2021 14:53:49

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:25:32
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:50:49
User entered 'Yes (Y)'	Linden DeBoer (b) (4)	21 Sep 2020 16:42:21

US3032249

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 09 Jun 2021 14:53:49

[Visit date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:25:32
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:50:49
User entered '21 Sep 2020'	Linden DeBoer (b) (4)	21 Sep 2020 16:42:21

US3032249

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 09 Jun 2021 14:53:49

[Was visit performed at the participant's home or at the clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:25:32
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:50:49
User entered 'Clinic (Clinic)'	Linden DeBoer (b) (4)	21 Sep 2020 16:42:21

US3032249

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 09 Jun 2021 14:53:49

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:25:32
User entered 'VISIT2'	System	21 Sep 2020 16:42:21

US3032249

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:53:49

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:25:32
User accepted default value 'Pre-Dose (PREDOSE)'	Kelsey Kelley (b) (4) (b) (4)	21 Sep 2020 17:20:16

US3032249

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:53:49

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:25:32
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:50:49
User entered 'Yes (Y)'	(b) (4) Kelsey Kelley (b) (4)	21 Sep 2020 17:20:16

US3032249

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:53:49

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:25:32
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:50:49
User entered '21 Sep 2020'	(b) (4) Kelsey Kelley (b) (4)	21 Sep 2020 17:20:16
	(b) (4)	

US3032249

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:53:49

[Time of assessment \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:25:32
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:50:49
User entered '10:27'	(b) (4) Kelsey Kelley (b) (4)	21 Sep 2020 17:20:16

US3032249

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:53:49

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:25:32
User entered '21 Sep 2020 10:27'	System	21 Sep 2020 17:20:16

US3032249

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:53:49

[Temperature \(xxx.x\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:25:32
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:50:49
User entered '36.5' C	(b) (4) Kelsey Kelley (b) (4)	21 Sep 2020 17:20:16

US3032249

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:53:49

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:25:32
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:50:49
User entered 'Oral (Oral)'	(b) (4) Kelsey Kelley (b) (4)	21 Sep 2020 17:20:16
	(b) (4)	

US3032249

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:53:49

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:25:32
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:50:49
User entered empty.	(b) (4) Kelsey Kelley (b) (4)	21 Sep 2020 17:20:16

US3032249

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:53:49

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:25:32
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:50:49
User entered '62'	(b) (4) Kelsey Kelley (b) (4)	21 Sep 2020 17:20:16

US3032249

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:53:49

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:25:32
User entered 'bpm'	System	21 Sep 2020 17:20:16

US3032249

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:53:49

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:25:32
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:50:49
User entered '16'	(b) (4) Kelsey Kelley (b) (4)	21 Sep 2020 17:20:16

US3032249

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:53:49

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:25:32
User entered 'breaths/min'	System	21 Sep 2020 17:20:16

US3032249

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:53:49

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:25:32
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:50:49
User entered '123'	(b) (4) Kelsey Kelley (b) (4)	21 Sep 2020 17:20:16

US3032249

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:53:49

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:25:32
User entered 'mmHg'	System	21 Sep 2020 17:20:16

US3032249

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:53:49

[Diastolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:25:32
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:50:49
User entered '76'	(b) (4) Kelsey Kelley (b) (4)	21 Sep 2020 17:20:16

US3032249

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:53:49

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:25:32
User entered 'mmHg'	System	21 Sep 2020 17:20:16

US3032249

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:53:49

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:25:32
User accepted default value 'Post-Dose (POSTDOSE)'	Kelsey Kelley (b) (4) (b) (4)	21 Sep 2020 17:21:16

US3032249

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:53:49

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:25:32
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:50:49
User entered 'Yes (Y)'	(b) (4) Kelsey Kelley (b) (4)	21 Sep 2020 17:21:16

US3032249

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:53:49

[Date of assessment \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:25:32
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:50:49
User entered '21 Sep 2020'	(b) (4) Kelsey Kelley (b) (4)	21 Sep 2020 17:21:16

US3032249

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:53:49

[Time of assessment \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:25:32
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:50:49
User entered '12:06'	(b) (4) Kelsey Kelley (b) (4)	21 Sep 2020 17:21:16

US3032249

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:53:49

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:25:32
User entered '21 Sep 2020 12:06'	System	21 Sep 2020 17:21:16

US3032249

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:53:49

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:25:32
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:50:49
User entered '36.7' C	(b) (4) Kelsey Kelley (b) (4)	21 Sep 2020 17:21:16

US3032249

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:53:49

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:25:32
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:50:49
User entered 'Oral (Oral)'	(b) (4) Kelsey Kelley (b) (4)	21 Sep 2020 17:21:16
	(b) (4)	

US3032249

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:53:49

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:25:32
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:50:49
User entered empty.	(b) (4) Kelsey Kelley (b) (4)	21 Sep 2020 17:21:16

US3032249

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:53:49

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:25:32
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:50:49
User entered '60'	(b) (4) Kelsey Kelley (b) (4)	21 Sep 2020 17:21:16

US3032249

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:53:49

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:25:32
User entered 'bpm'	System	21 Sep 2020 17:21:16

US3032249

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:53:49

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:25:32
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:50:49
User entered '14'	(b) (4) Kelsey Kelley (b) (4)	21 Sep 2020 17:21:16

US3032249

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:53:49

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:25:32
User entered 'breaths/min'	System	21 Sep 2020 17:21:16

US3032249

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:53:49

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:25:32
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:50:49
User entered '129'	(b) (4) Kelsey Kelley (b) (4)	21 Sep 2020 17:21:16

US3032249

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:53:49

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:25:32
User entered 'mmHg'	System	21 Sep 2020 17:21:16

US3032249

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:53:49

[Diastolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:25:32
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:50:49
User entered '74'	(b) (4) Kelsey Kelley (b) (4)	21 Sep 2020 17:21:16

US3032249

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:53:49

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:25:32
User entered 'mmHg'	System	21 Sep 2020 17:21:16

US3032249

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 14:53:49

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:25:32
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:50:49
User entered 'Yes (Y)'	Linden DeBoer (b) (4)	21 Sep 2020 16:42:31

US3032249

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 14:53:49

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:25:32
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:50:49
User entered '21 Sep 2020'	Linden DeBoer (b) (4)	21 Sep 2020 16:42:31

US3032249

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 14:53:49

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:25:32
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:50:49
User entered 'Yes (Y)'	Linden DeBoer (b) (4)	21 Sep 2020 16:44:17

US3032249

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 14:53:49

[If No, reason not given](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:25:32
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:50:49
User entered empty.	Linden DeBoer (b) (4)	21 Sep 2020 16:44:17

US3032249

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 14:53:49

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)	27 Mar 2021 19:25:32
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:50:49
User entered empty.	Linden DeBoer (b) (4)	21 Sep 2020 16:44:17

US3032249

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 14:53:49

[What was the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:25:32
User entered 'MRNA-1273 OR PLACEBO'	System	21 Sep 2020 16:44:17

US3032249

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 14:53:49

[What was the treatment date? \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:25:32
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:50:49
User entered '21 Sep 2020'	Linden DeBoer (b) (4)	21 Sep 2020 16:44:17

US3032249

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 14:53:49

[What was the treatment time? \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:25:32
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:50:49
User entered '11:35'	Linden DeBoer (b) (4)	21 Sep 2020 16:44:17

US3032249

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 14:53:49

[Treatment Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:25:32
User entered '21 Sep 2020 11:35'	System	21 Sep 2020 16:44:17

US3032249

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 14:53:49

[Which arm was used to give treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:25:32
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:50:49
User entered 'Left Arm (LEFT ARM)'	Linden DeBoer (b) (4)	21 Sep 2020 16:44:17

US3032249

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 14:53:49

[What was the frequency of the study treatment dosing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:25:32
User entered 'ONCE'	System	21 Sep 2020 16:44:17

US3032249

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 14:53:49

[What was the route of administration for the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:25:32
User entered 'INTRAMUSCULAR'	System	21 Sep 2020 16:44:17

US3032249

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 14:53:49

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:25:32
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:50:49
User entered 'Yes (Y)'	Linden DeBoer (b) (4)	21 Sep 2020 16:44:59

US3032249

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 14:53:49

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:25:32
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:50:49
User entered '21 Sep 2020'	Linden DeBoer (b) (4)	21 Sep 2020 16:44:59

US3032249

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 14:53:49

[Collection time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:25:32
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:50:49
User entered '11:02'	Linden DeBoer (b) (4)	21 Sep 2020 16:44:59

US3032249

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 14:53:49

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:25:32
User entered '21 Sep 2020 11:02'	System	21 Sep 2020 16:44:59

US3032249

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 09 Jun 2021 14:53:49

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:25:32
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:50:49
User entered '21 Sep 2020'	Linden DeBoer (b) (4)	21 Sep 2020 16:45:09

US3032249

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 14:53:49

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:25:32
User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)'	Linden DeBoer (b) (4) (b) (4)	21 Sep 2020 16:45:09

US3032249

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 14:53:49

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:25:32
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:50:49
User entered 'Yes (Y)'	Linden DeBoer (b) (4)	21 Sep 2020 16:45:09

US3032249

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 14:53:49

[Collection time \(00:00 - 23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:25:32
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:50:49
User entered '10:42'	Linden DeBoer (b) (4)	21 Sep 2020 16:45:09

US3032249

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 14:53:49

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:25:32
User entered '21 Sep 2020 10:42'	System	21 Sep 2020 16:45:09

US3032249

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 14:53:49

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:25:32
User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)'	Linden DeBoer (b) (4)	21 Sep 2020 16:45:09

US3032249

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 14:53:49

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:25:32
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:50:49
User entered 'No (N)'	Linden DeBoer (b) (4)	21 Sep 2020 16:45:09

US3032249

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 14:53:49

[Collection time \(00:00 - 23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:25:32
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:50:49
User entered empty.	Linden DeBoer (b) (4)	21 Sep 2020 16:45:09

US3032249

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 14:53:49

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:25:32
User entered empty.	System	21 Sep 2020 16:45:09

US3032249

Folder: Visit 2 Day 29 (1)

Form: Continuing

Generated On: 09 Jun 2021 14:53:49

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:25:32
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:50:49
User entered 'Yes (Y)'	Linden DeBoer (b) (4)	21 Sep 2020 16:45:13

US3032249

Folder: Visit 2 Day 29 (1)

Form: Continuing

Generated On: 09 Jun 2021 14:53:49

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:25:32
User entered 'I'	System	21 Sep 2020 16:45:13

US3032249

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 14:53:49

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:43:07
Data entry locked.	System	21 Sep 2020 16:44:17
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	21 Sep 2020 16:44:17

US3032249

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 14:53:49

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:43:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5a55dca4933e096f)', Time: '2020-09-21T12:08:22', User OID: 'PatientReportedOutcome (US3032249)', ODM File OID: '39106722-7911-444b-bace-1aaaecdbb574'	System	21 Sep 2020 17:12:52
User entered 'Yes (Y)'	System	21 Sep 2020 17:12:52

US3032249

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 14:53:49

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:43:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5a55dca4933e096f)', Time: '2020-09-21T12:08:33', User OID: 'PatientReportedOutcome (US3032249)', ODM File OID: '39106722-7911-444b-bace-1aaaecdbb574'	System	21 Sep 2020 17:12:52
User entered '98.1'	System	21 Sep 2020 17:12:52

US3032249

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 14:53:49

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:43:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5a55dca4933e096f)', Time: '2020-09-21T12:08:43', User OID: 'PatientReportedOutcome (US3032249)', ODM File OID: '39106722-7911-444b-bace-1aaaecdbb574'	System	21 Sep 2020 17:12:52
User entered 'No (N)'	System	21 Sep 2020 17:12:52

US3032249

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 14:53:49

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:43:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5a55dca4933e096f)', Time: '2020-09-21T12:08:59', User OID: 'PatientReportedOutcome (US3032249)', ODM File OID: '39106722-7911-444b-bace-1aaaecdbb574'	System	21 Sep 2020 17:12:52
User entered '21 Sep 2020 12:08'	System	21 Sep 2020 17:12:52

US3032249

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 14:53:49

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:43:07
User entered '21 Sep 2020 11:55'	System	21 Sep 2020 16:44:17

US3032249

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 14:53:49

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:43:07
User entered '21 Sep 2020 14:25'	System	21 Sep 2020 16:44:17

US3032249

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 14:53:49

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:43:07
Data entry locked.	System	21 Sep 2020 16:44:17
User entered 'Day 1, after vaccination (at home)'	System	21 Sep 2020 16:44:17

US3032249

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 14:53:49

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:43:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5a55dca4933e096f)', Time: '2020-09-21T20:15:06', User OID: 'PatientReportedOutcome (US3032249)', ODM File OID: '9014bfe5-20f8-42e1-bd8a-47d984b4a260'	System	22 Sep 2020 01:15:44
User entered 'Yes (Y)'	System	22 Sep 2020 01:15:44

US3032249

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 14:53:49

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:43:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5a55dca4933e096f)', Time: '2020-09-21T20:15:20', User OID: 'PatientReportedOutcome (US3032249)', ODM File OID: '9014bfe5-20f8-42e1-bd8a-47d984b4a260'	System	22 Sep 2020 01:15:44
User entered '97.9'	System	22 Sep 2020 01:15:44

US3032249

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 14:53:49

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:43:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5a55dca4933e096f)', Time: '2020-09-21T20:15:28', User OID: 'PatientReportedOutcome (US3032249)', ODM File OID: '9014bfe5-20f8-42e1-bd8a-47d984b4a260'	System	22 Sep 2020 01:15:44
User entered 'No (N)'	System	22 Sep 2020 01:15:44

US3032249

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 14:53:49

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:43:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5a55dca4933e096f)', Time: '2020-09-21T20:15:40', User OID: 'PatientReportedOutcome (US3032249)', ODM File OID: '9014bfe5-20f8-42e1-bd8a-47d984b4a260'	System	22 Sep 2020 01:15:44
User entered '21 Sep 2020 20:15'	System	22 Sep 2020 01:15:44

US3032249

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 14:53:49

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:43:07
User entered '21 Sep 2020 15:20'	System	21 Sep 2020 16:44:17

US3032249

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 14:53:49

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:43:07
User entered '22 Sep 2020 11:59'	System	21 Sep 2020 16:44:17

US3032249

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 14:53:49

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:43:07
Data entry locked.	System	21 Sep 2020 16:44:17
User entered 'Day 2'	System	21 Sep 2020 16:44:17

US3032249

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 14:53:49

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:43:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5a55dca4933e096f)', Time: '2020-09-22T22:09:13', User OID: 'PatientReportedOutcome (US3032249)', ODM File OID: '35c34268-23ee-4fe7-9e6e-d050ebbf00c5'	System	23 Sep 2020 03:09:41
User entered 'Yes (Y)'	System	23 Sep 2020 03:09:41

US3032249

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 14:53:49

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:43:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5a55dca4933e096f)', Time: '2020-09-22T22:09:25', User OID: 'PatientReportedOutcome (US3032249)', ODM File OID: '35c34268-23ee-4fe7-9e6e-d050ebbf00c5'	System	23 Sep 2020 03:09:41
User entered '97.7'	System	23 Sep 2020 03:09:41

US3032249

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 14:53:49

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:43:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5a55dca4933e096f)', Time: '2020-09-22T22:09:29', User OID: 'PatientReportedOutcome (US3032249)', ODM File OID: '35c34268-23ee-4fe7-9e6e-d050ebbf00c5'	System	23 Sep 2020 03:09:41
User entered 'No (N)'	System	23 Sep 2020 03:09:41

US3032249

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 14:53:49

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:43:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5a55dca4933e096f)', Time: '2020-09-22T22:09:39', User OID: 'PatientReportedOutcome (US3032249)', ODM File OID: '35c34268-23ee-4fe7-9e6e-d050ebbf00c5'	System	23 Sep 2020 03:09:41
User entered '22 Sep 2020 22:09'	System	23 Sep 2020 03:09:41

US3032249

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 14:53:49

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:43:07
User entered '22 Sep 2020 12:00'	System	21 Sep 2020 16:44:17

US3032249

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 14:53:49

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:43:07
User entered '23 Sep 2020 11:59'	System	21 Sep 2020 16:44:17

US3032249

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 14:53:49

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:43:07
Data entry locked.	System	21 Sep 2020 16:44:17
User entered 'Day 3'	System	21 Sep 2020 16:44:17

US3032249

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 14:53:49

Was TEMPERATURE taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:43:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5a55dca4933e096f)', Time: '2020-09-23T19:06:22', User OID: 'PatientReportedOutcome (US3032249)', ODM File OID: '9c78c3d8-71c8-4b32-873f-e0c6645d1200'	System	24 Sep 2020 00:07:12
User entered 'Yes (Y)'	System	24 Sep 2020 00:07:12

US3032249

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 14:53:49

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:43:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5a55dca4933e096f)', Time: '2020-09-23T19:06:59', User OID: 'PatientReportedOutcome (US3032249)', ODM File OID: '9c78c3d8-71c8-4b32-873f-e0c6645d1200'	System	24 Sep 2020 00:07:12
User entered '97.7'	System	24 Sep 2020 00:07:12

US3032249

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 14:53:49

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:43:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5a55dca4933e096f)', Time: '2020-09-23T19:07:04', User OID: 'PatientReportedOutcome (US3032249)', ODM File OID: '9c78c3d8-71c8-4b32-873f-e0c6645d1200'	System	24 Sep 2020 00:07:12
User entered 'No (N)'	System	24 Sep 2020 00:07:12

US3032249

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 14:53:49

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:43:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5a55dca4933e096f)', Time: '2020-09-23T19:07:09', User OID: 'PatientReportedOutcome (US3032249)', ODM File OID: '9c78c3d8-71c8-4b32-873f-e0c6645d1200'	System	24 Sep 2020 00:07:12
User entered '23 Sep 2020 19:07'	System	24 Sep 2020 00:07:12

US3032249

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 14:53:49

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:43:07
User entered '23 Sep 2020 12:00'	System	21 Sep 2020 16:44:17

US3032249

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 14:53:49

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:43:07
User entered '24 Sep 2020 11:59'	System	21 Sep 2020 16:44:17

US3032249

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 14:53:49

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:43:07
Data entry locked.	System	21 Sep 2020 16:44:17
User entered 'Day 4'	System	21 Sep 2020 16:44:17

US3032249

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 14:53:49

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:43:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5a55dca4933e096f)', Time: '2020-09-25T00:02:38', User OID: 'PatientReportedOutcome (US3032249)', ODM File OID: 'f4fd24b2-488a-4451-9111-ced22998d4de'	System	25 Sep 2020 05:03:11
User entered 'Yes (Y)'	System	25 Sep 2020 05:03:11

US3032249

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 14:53:49

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:43:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5a55dca4933e096f)', Time: '2020-09-25T00:02:53', User OID: 'PatientReportedOutcome (US3032249)', ODM File OID: 'f4fd24b2-488a-4451-9111-ced22998d4de'	System	25 Sep 2020 05:03:11
User entered '97.7'	System	25 Sep 2020 05:03:11

US3032249

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 14:53:49

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:43:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5a55dca4933e096f)', Time: '2020-09-25T00:02:57', User OID: 'PatientReportedOutcome (US3032249)', ODM File OID: 'f4fd24b2-488a-4451-9111-ced22998d4de'	System	25 Sep 2020 05:03:11
User entered 'No (N)'	System	25 Sep 2020 05:03:11

US3032249

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 14:53:49

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:43:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5a55dca4933e096f)', Time: '2020-09-25T00:03:07', User OID: 'PatientReportedOutcome (US3032249)', ODM File OID: 'f4fd24b2-488a-4451-9111-ced22998d4de'	System	25 Sep 2020 05:03:11
User entered '25 Sep 2020 00:03'	System	25 Sep 2020 05:03:11

US3032249

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 14:53:49

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:43:07
User entered '24 Sep 2020 12:00'	System	21 Sep 2020 16:44:17

US3032249

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 14:53:49

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:43:07
User entered '25 Sep 2020 11:59'	System	21 Sep 2020 16:44:17

US3032249

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 14:53:49

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:43:07
Data entry locked.	System	21 Sep 2020 16:44:17
User entered 'Day 5'	System	21 Sep 2020 16:44:17

US3032249

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 14:53:49

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:43:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5a55dca4933e096f)', Time: '2020-09-25T12:02:45', User OID: 'PatientReportedOutcome (US3032249)', ODM File OID: 'd0159c05-224b-4ab4-8856-cd22149c3087'	System	25 Sep 2020 17:04:28
User entered 'Yes (Y)'	System	25 Sep 2020 17:04:28

US3032249

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 14:53:49

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:43:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5a55dca4933e096f)', Time: '2020-09-25T12:03:01', User OID: 'PatientReportedOutcome (US3032249)', ODM File OID: 'd0159c05-224b-4ab4-8856-cd22149c3087'	System	25 Sep 2020 17:04:28
User entered '98.1'	System	25 Sep 2020 17:04:28

US3032249

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 14:53:49

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:43:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5a55dca4933e096f)', Time: '2020-09-25T12:03:07', User OID: 'PatientReportedOutcome (US3032249)', ODM File OID: 'd0159c05-224b-4ab4-8856-cd22149c3087'	System	25 Sep 2020 17:04:28
User entered 'No (N)'	System	25 Sep 2020 17:04:28

US3032249

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 14:53:49

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:43:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5a55dca4933e096f)', Time: '2020-09-25T12:03:18', User OID: 'PatientReportedOutcome (US3032249)', ODM File OID: 'd0159c05-224b-4ab4-8856-cd22149c3087'	System	25 Sep 2020 17:04:28
User entered '25 Sep 2020 12:03'	System	25 Sep 2020 17:04:28

US3032249

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 14:53:49

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:43:07
User entered '25 Sep 2020 12:00'	System	21 Sep 2020 16:44:17

US3032249

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 14:53:49

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:43:07
User entered '26 Sep 2020 11:59'	System	21 Sep 2020 16:44:17

US3032249

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 14:53:49

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:43:07
Data entry locked.	System	21 Sep 2020 16:44:17
User entered 'Day 6'	System	21 Sep 2020 16:44:17

US3032249

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 14:53:49

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:43:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5a55dca4933e096f)', Time: '2020-09-26T12:00:42', User OID: 'PatientReportedOutcome (US3032249)', ODM File OID: 'd26672d0-afe5-40f6-b4db-49749011681f'	System	26 Sep 2020 17:01:42
User entered 'Yes (Y)'	System	26 Sep 2020 17:01:42

US3032249

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 14:53:49

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:43:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5a55dca4933e096f)', Time: '2020-09-26T12:00:54', User OID: 'PatientReportedOutcome (US3032249)', ODM File OID: 'd26672d0-afe5-40f6-b4db-49749011681f' User entered '97.8'	System	26 Sep 2020 17:01:42
	System	26 Sep 2020 17:01:42

US3032249

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 14:53:49

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:43:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5a55dca4933e096f)', Time: '2020-09-26T12:00:58', User OID: 'PatientReportedOutcome (US3032249)', ODM File OID: 'd26672d0-afe5-40f6-b4db-49749011681f'	System	26 Sep 2020 17:01:42
User entered 'No (N)'	System	26 Sep 2020 17:01:42

US3032249

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 14:53:49

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:43:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5a55dca4933e096f)', Time: '2020-09-26T12:01:08', User OID: 'PatientReportedOutcome (US3032249)', ODM File OID: 'd26672d0-afe5-40f6-b4db-49749011681f'	System	26 Sep 2020 17:01:42
User entered '26 Sep 2020 12:01'	System	26 Sep 2020 17:01:42

US3032249

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 14:53:49

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:43:07
User entered '26 Sep 2020 12:00'	System	21 Sep 2020 16:44:17

US3032249

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 14:53:49

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:43:07
User entered '27 Sep 2020 11:59'	System	21 Sep 2020 16:44:17

US3032249

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 14:53:49

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:43:07
Data entry locked.	System	21 Sep 2020 16:44:17
User entered 'Day 7'	System	21 Sep 2020 16:44:17

US3032249

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 14:53:49

Was TEMPERATURE taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:43:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5a55dca4933e096f)', Time: '2020-09-27T12:31:37', User OID: 'PatientReportedOutcome (US3032249)', ODM File OID: 'd3e9342d-0e36-46e2-ae06-499b856f1da7'	System	27 Sep 2020 17:32:39
User entered 'Yes (Y)'	System	27 Sep 2020 17:32:39

US3032249

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 14:53:49

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:43:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5a55dca4933e096f)', Time: '2020-09-27T12:31:50', User OID: 'PatientReportedOutcome (US3032249)', ODM File OID: 'd3e9342d-0e36-46e2-ae06-499b856f1da7'	System	27 Sep 2020 17:32:39
User entered '97.8'	System	27 Sep 2020 17:32:39

US3032249

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 14:53:49

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:43:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5a55dca4933e096f)', Time: '2020-09-27T12:32:17', User OID: 'PatientReportedOutcome (US3032249)', ODM File OID: 'd3e9342d-0e36-46e2-ae06-499b856f1da7'	System	27 Sep 2020 17:32:39
User entered 'No (N)'	System	27 Sep 2020 17:32:39

US3032249

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 14:53:49

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:43:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5a55dca4933e096f)', Time: '2020-09-27T12:32:37', User OID: 'PatientReportedOutcome (US3032249)', ODM File OID: 'd3e9342d-0e36-46e2-ae06-499b856f1da7'	System	27 Sep 2020 17:32:39
User entered '27 Sep 2020 12:32'	System	27 Sep 2020 17:32:39

US3032249

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 14:53:49

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:43:07
User entered '27 Sep 2020 12:00'	System	21 Sep 2020 16:44:17

US3032249

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 14:53:49

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:43:07
User entered '28 Sep 2020 11:59'	System	21 Sep 2020 16:44:17

US3032249

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 14:53:49

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:43:07
Data entry locked.	System	21 Sep 2020 16:44:17
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	21 Sep 2020 16:44:17

US3032249

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 14:53:49

Please record - **PAIN AT INJECTION SITE.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:43:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5a55dca4933e096f)', Time: '2020-09-21T12:09:18', User OID: 'PatientReportedOutcome (US3032249)', ODM File OID: 'f40939b5-cb4a-431b-8685-14ab8351e0f7'	System	21 Sep 2020 17:13:03
User entered 'None (1)'	System	21 Sep 2020 17:13:03

US3032249

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 14:53:49

Is there any **REDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:43:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5a55dca4933e096f)', Time: '2020-09-21T12:09:23', User OID: 'PatientReportedOutcome (US3032249)', ODM File OID: 'f40939b5-cb4a-431b-8685-14ab8351e0f7'	System	21 Sep 2020 17:13:03
User entered 'No (N)'	System	21 Sep 2020 17:13:03

US3032249

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 14:53:49

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:43:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5a55dca4933e096f)', Time: '2020-09-21T12:09:27', User OID: 'PatientReportedOutcome (US3032249)', ODM File OID: 'f40939b5-cb4a-431b-8685-14ab8351e0f7'	System	21 Sep 2020 17:13:03
User entered 'No (N)'	System	21 Sep 2020 17:13:03

US3032249

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 14:53:49

Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:43:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5a55dca4933e096f)', Time: '2020-09-21T12:09:34', User OID: 'PatientReportedOutcome (US3032249)', ODM File OID: 'f40939b5-cb4a-431b-8685-14ab8351e0f7'	System	21 Sep 2020 17:13:03
User entered 'None (1)'	System	21 Sep 2020 17:13:03

US3032249

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 14:53:49

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:43:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5a55dca4933e096f)', Time: '2020-09-21T12:09:40', User OID: 'PatientReportedOutcome (US3032249)', ODM File OID: 'f40939b5-cb4a-431b-8685-14ab8351e0f7'	System	21 Sep 2020 17:13:03
User entered '21 Sep 2020 12:09'	System	21 Sep 2020 17:13:03

US3032249

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 14:53:49

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:43:07
User entered '21 Sep 2020 11:55'	System	21 Sep 2020 16:44:17

US3032249

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 14:53:49

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:43:07
User entered '21 Sep 2020 14:25'	System	21 Sep 2020 16:44:17

US3032249

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 14:53:49

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:43:07
Data entry locked.	System	21 Sep 2020 16:44:17
User entered 'Day 1, after vaccination (at home)'	System	21 Sep 2020 16:44:17

US3032249

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 14:53:49

Please record - **PAIN AT INJECTION SITE.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:43:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5a55dca4933e096f)', Time: '2020-09-21T20:15:48', User OID: 'PatientReportedOutcome (US3032249)', ODM File OID: '9203566e-4486-40ea-bf98-3038e58db2d4'	System	22 Sep 2020 01:16:19
User entered 'None (1)'	System	22 Sep 2020 01:16:19

US3032249

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 14:53:49

Is there any **REDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:43:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5a55dca4933e096f)', Time: '2020-09-21T20:15:53', User OID: 'PatientReportedOutcome (US3032249)', ODM File OID: '9203566e-4486-40ea-bf98-3038e58db2d4'	System	22 Sep 2020 01:16:19
User entered 'No (N)'	System	22 Sep 2020 01:16:19

US3032249

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 14:53:49

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:43:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5a55dca4933e096f)', Time: '2020-09-21T20:16:00', User OID: 'PatientReportedOutcome (US3032249)', ODM File OID: '9203566e-4486-40ea-bf98-3038e58db2d4'	System	22 Sep 2020 01:16:19
User entered 'No (N)'	System	22 Sep 2020 01:16:19

US3032249

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 14:53:49

Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:43:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5a55dca4933e096f)', Time: '2020-09-21T20:16:06', User OID: 'PatientReportedOutcome (US3032249)', ODM File OID: '9203566e-4486-40ea-bf98-3038e58db2d4'	System	22 Sep 2020 01:16:19
User entered 'None (1)'	System	22 Sep 2020 01:16:19

US3032249

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 14:53:49

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:43:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5a55dca4933e096f)', Time: '2020-09-21T20:16:16', User OID: 'PatientReportedOutcome (US3032249)', ODM File OID: '9203566e-4486-40ea-bf98-3038e58db2d4'	System	22 Sep 2020 01:16:19
User entered '21 Sep 2020 20:16'	System	22 Sep 2020 01:16:19

US3032249

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 14:53:49

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:43:07
User entered '21 Sep 2020 15:20'	System	21 Sep 2020 16:44:17

US3032249

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 14:53:49

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:43:07
User entered '22 Sep 2020 11:59'	System	21 Sep 2020 16:44:17

US3032249

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 14:53:49

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:43:07
Data entry locked.	System	21 Sep 2020 16:44:17
User entered 'Day 2'	System	21 Sep 2020 16:44:17

US3032249

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 14:53:49

Please record - **PAIN AT INJECTION SITE.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:43:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5a55dca4933e096f)', Time: '2020-09-22T22:09:47', User OID: 'PatientReportedOutcome (US3032249)', ODM File OID: '6b2ded1b-f791-45b8-94e8-74985ef1d346'	System	23 Sep 2020 03:10:14
User entered 'None (1)'	System	23 Sep 2020 03:10:14

US3032249

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 14:53:49

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:43:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5a55dca4933e096f)', Time: '2020-09-22T22:09:51', User OID: 'PatientReportedOutcome (US3032249)', ODM File OID: '6b2ded1b-f791-45b8-94e8-74985ef1d346'	System	23 Sep 2020 03:10:14
User entered 'No (N)'	System	23 Sep 2020 03:10:14

US3032249

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 14:53:49

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:43:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5a55dca4933e096f)', Time: '2020-09-22T22:10:02', User OID: 'PatientReportedOutcome (US3032249)', ODM File OID: '6b2ded1b-f791-45b8-94e8-74985ef1d346'	System	23 Sep 2020 03:10:14
User entered 'No (N)'	System	23 Sep 2020 03:10:14

US3032249

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 14:53:49

Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:43:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5a55dca4933e096f)', Time: '2020-09-22T22:10:06', User OID: 'PatientReportedOutcome (US3032249)', ODM File OID: '6b2ded1b-f791-45b8-94e8-74985ef1d346'	System	23 Sep 2020 03:10:14
User entered 'None (1)'	System	23 Sep 2020 03:10:14

US3032249

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 14:53:49

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:43:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5a55dca4933e096f)', Time: '2020-09-22T22:10:12', User OID: 'PatientReportedOutcome (US3032249)', ODM File OID: '6b2ded1b-f791-45b8-94e8-74985ef1d346'	System	23 Sep 2020 03:10:14
User entered '22 Sep 2020 22:10'	System	23 Sep 2020 03:10:14

US3032249

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 14:53:49

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:43:07
User entered '22 Sep 2020 12:00'	System	21 Sep 2020 16:44:17

US3032249

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 14:53:49

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:43:07
User entered '23 Sep 2020 11:59'	System	21 Sep 2020 16:44:17

US3032249

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 14:53:49

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:43:07
Data entry locked.	System	21 Sep 2020 16:44:17
User entered 'Day 3'	System	21 Sep 2020 16:44:17

US3032249

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 14:53:49

Please record - **PAIN AT INJECTION SITE.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:43:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5a55dca4933e096f)', Time: '2020-09-23T19:07:16', User OID: 'PatientReportedOutcome (US3032249)', ODM File OID: 'e3303db2-444e-4cad-8057-08de147cfa10'	System	24 Sep 2020 00:07:44
User entered 'None (1)'	System	24 Sep 2020 00:07:44

US3032249

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 14:53:49

Is there any **REDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:43:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5a55dca4933e096f)', Time: '2020-09-23T19:07:21', User OID: 'PatientReportedOutcome (US3032249)', ODM File OID: 'e3303db2-444e-4cad-8057-08de147cfa10'	System	24 Sep 2020 00:07:44
User entered 'No (N)'	System	24 Sep 2020 00:07:44

US3032249

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 14:53:49

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:43:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5a55dca4933e096f)', Time: '2020-09-23T19:07:26', User OID: 'PatientReportedOutcome (US3032249)', ODM File OID: 'e3303db2-444e-4cad-8057-08de147cfa10'	System	24 Sep 2020 00:07:44
User entered 'No (N)'	System	24 Sep 2020 00:07:44

US3032249

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 14:53:49

Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:43:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5a55dca4933e096f)', Time: '2020-09-23T19:07:31', User OID: 'PatientReportedOutcome (US3032249)', ODM File OID: 'e3303db2-444e-4cad-8057-08de147cfa10'	System	24 Sep 2020 00:07:44
User entered 'None (1)'	System	24 Sep 2020 00:07:44

US3032249

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 14:53:49

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:43:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5a55dca4933e096f)', Time: '2020-09-23T19:07:40', User OID: 'PatientReportedOutcome (US3032249)', ODM File OID: 'e3303db2-444e-4cad-8057-08de147cfa10'	System	24 Sep 2020 00:07:44
User entered '23 Sep 2020 19:07'	System	24 Sep 2020 00:07:44

US3032249

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 14:53:49

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:43:07
User entered '23 Sep 2020 12:00'	System	21 Sep 2020 16:44:17

US3032249

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 14:53:49

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:43:07
User entered '24 Sep 2020 11:59'	System	21 Sep 2020 16:44:17

US3032249

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 14:53:49

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:43:07
Data entry locked.	System	21 Sep 2020 16:44:17
User entered 'Day 4'	System	21 Sep 2020 16:44:17

US3032249

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 14:53:49

Please record - **PAIN AT INJECTION SITE.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:43:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5a55dca4933e096f)', Time: '2020-09-25T00:03:14', User OID: 'PatientReportedOutcome (US3032249)', ODM File OID: '4119f864-bf8d-44d0-875a-34be52f5639c'	System	25 Sep 2020 05:03:44
User entered 'None (1)'	System	25 Sep 2020 05:03:44

US3032249

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 14:53:49

Is there any **REDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:43:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5a55dca4933e096f)', Time: '2020-09-25T00:03:19', User OID: 'PatientReportedOutcome (US3032249)', ODM File OID: '4119f864-bf8d-44d0-875a-34be52f5639c'	System	25 Sep 2020 05:03:44
User entered 'No (N)'	System	25 Sep 2020 05:03:44

US3032249

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 14:53:49

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:43:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5a55dca4933e096f)', Time: '2020-09-25T00:03:23', User OID: 'PatientReportedOutcome (US3032249)', ODM File OID: '4119f864-bf8d-44d0-875a-34be52f5639c'	System	25 Sep 2020 05:03:44
User entered 'No (N)'	System	25 Sep 2020 05:03:44

US3032249

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 14:53:49

Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:43:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5a55dca4933e096f)', Time: '2020-09-25T00:03:29', User OID: 'PatientReportedOutcome (US3032249)', ODM File OID: '4119f864-bf8d-44d0-875a-34be52f5639c'	System	25 Sep 2020 05:03:44
User entered 'None (1)'	System	25 Sep 2020 05:03:44

US3032249

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 14:53:49

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:43:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5a55dca4933e096f)', Time: '2020-09-25T00:03:41', User OID: 'PatientReportedOutcome (US3032249)', ODM File OID: '4119f864-bf8d-44d0-875a-34be52f5639c'	System	25 Sep 2020 05:03:44
User entered '25 Sep 2020 00:03'	System	25 Sep 2020 05:03:44

US3032249

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 14:53:49

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:43:07
User entered '24 Sep 2020 12:00'	System	21 Sep 2020 16:44:17

US3032249

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 14:53:49

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:43:07
User entered '25 Sep 2020 11:59'	System	21 Sep 2020 16:44:17

US3032249

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 14:53:49

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:43:07
Data entry locked.	System	21 Sep 2020 16:44:17
User entered 'Day 5'	System	21 Sep 2020 16:44:17

US3032249

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 14:53:49

Please record - **PAIN AT INJECTION SITE.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:43:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5a55dca4933e096f)', Time: '2020-09-25T12:03:27', User OID: 'PatientReportedOutcome (US3032249)', ODM File OID: '47d4ec47-650d-4432-b662-c838fa543f53'	System	25 Sep 2020 17:04:52
User entered 'None (1)'	System	25 Sep 2020 17:04:52

US3032249

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 14:53:49

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:43:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5a55dca4933e096f)', Time: '2020-09-25T12:03:31', User OID: 'PatientReportedOutcome (US3032249)', ODM File OID: '47d4ec47-650d-4432-b662-c838fa543f53'	System	25 Sep 2020 17:04:52
User entered 'No (N)'	System	25 Sep 2020 17:04:52

US3032249

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 14:53:49

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:43:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5a55dca4933e096f)', Time: '2020-09-25T12:03:34', User OID: 'PatientReportedOutcome (US3032249)', ODM File OID: '47d4ec47-650d-4432-b662-c838fa543f53'	System	25 Sep 2020 17:04:52
User entered 'No (N)'	System	25 Sep 2020 17:04:52

US3032249

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 14:53:49

Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:43:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5a55dca4933e096f)', Time: '2020-09-25T12:03:38', User OID: 'PatientReportedOutcome (US3032249)', ODM File OID: '47d4ec47-650d-4432-b662-c838fa543f53'	System	25 Sep 2020 17:04:52
User entered 'None (1)'	System	25 Sep 2020 17:04:52

US3032249

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 14:53:49

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:43:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5a55dca4933e096f)', Time: '2020-09-25T12:03:46', User OID: 'PatientReportedOutcome (US3032249)', ODM File OID: '47d4ec47-650d-4432-b662-c838fa543f53'	System	25 Sep 2020 17:04:52
User entered '25 Sep 2020 12:03'	System	25 Sep 2020 17:04:52

US3032249

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 14:53:49

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:43:07
User entered '25 Sep 2020 12:00'	System	21 Sep 2020 16:44:17

US3032249

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 14:53:49

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:43:07
User entered '26 Sep 2020 11:59'	System	21 Sep 2020 16:44:17

US3032249

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 14:53:49

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:43:07
Data entry locked.	System	21 Sep 2020 16:44:17
User entered 'Day 6'	System	21 Sep 2020 16:44:17

US3032249

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 14:53:49

Please record - **PAIN AT INJECTION SITE.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:43:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5a55dca4933e096f)', Time: '2020-09-26T12:01:16', User OID: 'PatientReportedOutcome (US3032249)', ODM File OID: '741df0ec-b35e-4dac-be47-79de14964ece'	System	26 Sep 2020 17:02:18
User entered 'None (1)'	System	26 Sep 2020 17:02:18

US3032249

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 14:53:49

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:43:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5a55dca4933e096f)', Time: '2020-09-26T12:01:21', User OID: 'PatientReportedOutcome (US3032249)', ODM File OID: '741df0ec-b35e-4dac-be47-79de14964ece'	System	26 Sep 2020 17:02:18
User entered 'No (N)'	System	26 Sep 2020 17:02:18

US3032249

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 14:53:49

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:43:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5a55dca4933e096f)', Time: '2020-09-26T12:01:26', User OID: 'PatientReportedOutcome (US3032249)', ODM File OID: '741df0ec-b35e-4dac-be47-79de14964ece'	System	26 Sep 2020 17:02:18
User entered 'No (N)'	System	26 Sep 2020 17:02:18

US3032249

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 14:53:49

Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:43:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5a55dca4933e096f)', Time: '2020-09-26T12:01:31', User OID: 'PatientReportedOutcome (US3032249)', ODM File OID: '741df0ec-b35e-4dac-be47-79de14964ece'	System	26 Sep 2020 17:02:18
User entered 'None (1)'	System	26 Sep 2020 17:02:18

US3032249

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 14:53:49

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:43:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5a55dca4933e096f)', Time: '2020-09-26T12:01:40', User OID: 'PatientReportedOutcome (US3032249)', ODM File OID: '741df0ec-b35e-4dac-be47-79de14964ece'	System	26 Sep 2020 17:02:18
User entered '26 Sep 2020 12:01'	System	26 Sep 2020 17:02:18

US3032249

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 14:53:49

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:43:07
User entered '26 Sep 2020 12:00'	System	21 Sep 2020 16:44:17

US3032249

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 14:53:49

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:43:07
User entered '27 Sep 2020 11:59'	System	21 Sep 2020 16:44:17

US3032249

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 14:53:49

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:43:07
Data entry locked.	System	21 Sep 2020 16:44:17
User entered 'Day 7'	System	21 Sep 2020 16:44:17

US3032249

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 14:53:49

Please record - **PAIN AT INJECTION SITE.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:43:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5a55dca4933e096f)', Time: '2020-09-27T12:32:52', User OID: 'PatientReportedOutcome (US3032249)', ODM File OID: 'f86d5689-9a01-4216-853c-86dbd5cac73a'	System	27 Sep 2020 17:33:17
User entered 'None (1)'	System	27 Sep 2020 17:33:17

US3032249

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 14:53:49

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:43:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5a55dca4933e096f)', Time: '2020-09-27T12:32:56', User OID: 'PatientReportedOutcome (US3032249)', ODM File OID: 'f86d5689-9a01-4216-853c-86dbd5cac73a'	System	27 Sep 2020 17:33:17
User entered 'No (N)'	System	27 Sep 2020 17:33:17

US3032249

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 14:53:49

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:43:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5a55dca4933e096f)', Time: '2020-09-27T12:33:00', User OID: 'PatientReportedOutcome (US3032249)', ODM File OID: 'f86d5689-9a01-4216-853c-86dbd5cac73a'	System	27 Sep 2020 17:33:17
User entered 'No (N)'	System	27 Sep 2020 17:33:17

US3032249

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 14:53:49

Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:43:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5a55dca4933e096f)', Time: '2020-09-27T12:33:04', User OID: 'PatientReportedOutcome (US3032249)', ODM File OID: 'f86d5689-9a01-4216-853c-86dbd5cac73a'	System	27 Sep 2020 17:33:17
User entered 'None (1)'	System	27 Sep 2020 17:33:17

US3032249

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 14:53:49

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:43:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5a55dca4933e096f)', Time: '2020-09-27T12:33:12', User OID: 'PatientReportedOutcome (US3032249)', ODM File OID: 'f86d5689-9a01-4216-853c-86dbd5cac73a'	System	27 Sep 2020 17:33:17
User entered '27 Sep 2020 12:33'	System	27 Sep 2020 17:33:17

US3032249

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 14:53:49

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:43:07
User entered '27 Sep 2020 12:00'	System	21 Sep 2020 16:44:17

US3032249

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 14:53:49

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:43:07
User entered '28 Sep 2020 11:59'	System	21 Sep 2020 16:44:17

US3032249

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 14:53:49

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:43:07
Data entry locked.	System	21 Sep 2020 16:44:17
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	21 Sep 2020 16:44:17

US3032249

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 14:53:49

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:43:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5a55dca4933e096f)', Time: '2020-09-21T12:09:49', User OID: 'PatientReportedOutcome (US3032249)', ODM File OID: 'b6c22259-8e26-466c-ab78-27c86914c143'	System	21 Sep 2020 17:13:19
User entered 'None (0)'	System	21 Sep 2020 17:13:19

US3032249

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 14:53:49

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:43:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5a55dca4933e096f)', Time: '2020-09-21T12:09:54', User OID: 'PatientReportedOutcome (US3032249)', ODM File OID: 'b6c22259-8e26-466c-ab78-27c86914c143'	System	21 Sep 2020 17:13:19
User entered 'None (0)'	System	21 Sep 2020 17:13:19

US3032249

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 14:53:49

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:43:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5a55dca4933e096f)', Time: '2020-09-21T12:09:56', User OID: 'PatientReportedOutcome (US3032249)', ODM File OID: 'b6c22259-8e26-466c-ab78-27c86914c143'	System	21 Sep 2020 17:13:19
User entered 'None (0)'	System	21 Sep 2020 17:13:19

US3032249

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 14:53:49

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:43:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5a55dca4933e096f)', Time: '2020-09-21T12:10:00', User OID: 'PatientReportedOutcome (US3032249)', ODM File OID: 'b6c22259-8e26-466c-ab78-27c86914c143'	System	21 Sep 2020 17:13:19
User entered 'None (0)'	System	21 Sep 2020 17:13:19

US3032249

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 14:53:49

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:43:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5a55dca4933e096f)', Time: '2020-09-21T12:10:03', User OID: 'PatientReportedOutcome (US3032249)', ODM File OID: 'b6c22259-8e26-466c-ab78-27c86914c143'	System	21 Sep 2020 17:13:19
User entered 'None (0)'	System	21 Sep 2020 17:13:19

US3032249

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 14:53:49

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:43:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5a55dca4933e096f)', Time: '2020-09-21T12:10:06', User OID: 'PatientReportedOutcome (US3032249)', ODM File OID: 'b6c22259-8e26-466c-ab78-27c86914c143'	System	21 Sep 2020 17:13:19
User entered 'None (0)'	System	21 Sep 2020 17:13:19

US3032249

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 14:53:49

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)	27 Mar 2021 20:43:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5a55dca4933e096f)', Time: '2020-09-21T12:10:09', User OID: 'PatientReportedOutcome (US3032249)', ODM File OID: 'b6c22259-8e26-466c-ab78-27c86914c143'	System	21 Sep 2020 17:13:19
User entered 'No (N)'	System	21 Sep 2020 17:13:19

US3032249

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 14:53:49

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:43:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5a55dca4933e096f)', Time: '2020-09-21T12:10:14', User OID: 'PatientReportedOutcome (US3032249)', ODM File OID: 'b6c22259-8e26-466c-ab78-27c86914c143'	System	21 Sep 2020 17:13:19
User entered '21 Sep 2020 12:10'	System	21 Sep 2020 17:13:19

US3032249

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 14:53:49

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:43:07
User entered '21 Sep 2020 11:55'	System	21 Sep 2020 16:44:17

US3032249

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 14:53:49

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:43:07
User entered '21 Sep 2020 14:25'	System	21 Sep 2020 16:44:17

US3032249

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 14:53:49

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:43:07
Data entry locked.	System	21 Sep 2020 16:44:17
User entered 'Day 1, after vaccination (at home)'	System	21 Sep 2020 16:44:17

US3032249

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 14:53:49

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:43:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5a55dca4933e096f)', Time: '2020-09-21T20:16:57', User OID: 'PatientReportedOutcome (US3032249)', ODM File OID: 'aa6138d2-eea8-4d15-8c7e-63f19c2aa51d'	System	22 Sep 2020 01:18:18
User entered 'None (0)'	System	22 Sep 2020 01:18:18

US3032249

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 14:53:49

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:43:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5a55dca4933e096f)', Time: '2020-09-21T20:17:04', User OID: 'PatientReportedOutcome (US3032249)', ODM File OID: 'aa6138d2-eea8-4d15-8c7e-63f19c2aa51d'	System	22 Sep 2020 01:18:18
User entered 'None (0)'	System	22 Sep 2020 01:18:18

US3032249

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 14:53:49

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:43:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5a55dca4933e096f)', Time: '2020-09-21T20:17:18', User OID: 'PatientReportedOutcome (US3032249)', ODM File OID: 'aa6138d2-eea8-4d15-8c7e-63f19c2aa51d'	System	22 Sep 2020 01:18:18
User entered 'None (0)'	System	22 Sep 2020 01:18:18

US3032249

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 14:53:49

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:43:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5a55dca4933e096f)', Time: '2020-09-21T20:17:30', User OID: 'PatientReportedOutcome (US3032249)', ODM File OID: 'aa6138d2-eea8-4d15-8c7e-63f19c2aa51d'	System	22 Sep 2020 01:18:18
User entered 'None (0)'	System	22 Sep 2020 01:18:18

US3032249

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 14:53:49

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:43:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5a55dca4933e096f)', Time: '2020-09-21T20:17:36', User OID: 'PatientReportedOutcome (US3032249)', ODM File OID: 'aa6138d2-eea8-4d15-8c7e-63f19c2aa51d'	System	22 Sep 2020 01:18:18
User entered 'None (0)'	System	22 Sep 2020 01:18:18

US3032249

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 14:53:49

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:43:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5a55dca4933e096f)', Time: '2020-09-21T20:17:42', User OID: 'PatientReportedOutcome (US3032249)', ODM File OID: 'aa6138d2-eea8-4d15-8c7e-63f19c2aa51d'	System	22 Sep 2020 01:18:18
User entered 'None (0)'	System	22 Sep 2020 01:18:18

US3032249

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 14:53:49

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)	27 Mar 2021 20:43:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5a55dca4933e096f)', Time: '2020-09-21T20:17:52', User OID: 'PatientReportedOutcome (US3032249)', ODM File OID: 'aa6138d2-eea8-4d15-8c7e-63f19c2aa51d'	System	22 Sep 2020 01:18:18
User entered 'No (N)'	System	22 Sep 2020 01:18:18

US3032249

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 14:53:49

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:43:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5a55dca4933e096f)', Time: '2020-09-21T20:18:13', User OID: 'PatientReportedOutcome (US3032249)', ODM File OID: 'aa6138d2-eea8-4d15-8c7e-63f19c2aa51d'	System	22 Sep 2020 01:18:18
User entered '21 Sep 2020 20:18'	System	22 Sep 2020 01:18:18

US3032249

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 14:53:49

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:43:07
User entered '21 Sep 2020 15:20'	System	21 Sep 2020 16:44:17

US3032249

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 14:53:49

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:43:07
User entered '22 Sep 2020 11:59'	System	21 Sep 2020 16:44:17

US3032249

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 14:53:49

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:43:07
Data entry locked.	System	21 Sep 2020 16:44:17
User entered 'Day 2'	System	21 Sep 2020 16:44:17

US3032249

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 14:53:49

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:43:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5a55dca4933e096f)', Time: '2020-09-22T22:10:20', User OID: 'PatientReportedOutcome (US3032249)', ODM File OID: '4962bab5-41ef-44c8-bd41-651bd1c576bf'	System	23 Sep 2020 03:11:14
User entered 'None (0)'	System	23 Sep 2020 03:11:14

US3032249

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 14:53:49

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:43:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5a55dca4933e096f)', Time: '2020-09-22T22:10:25', User OID: 'PatientReportedOutcome (US3032249)', ODM File OID: '4962bab5-41ef-44c8-bd41-651bd1c576bf'	System	23 Sep 2020 03:11:14
User entered 'None (0)'	System	23 Sep 2020 03:11:14

US3032249

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 14:53:49

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:43:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5a55dca4933e096f)', Time: '2020-09-22T22:10:32', User OID: 'PatientReportedOutcome (US3032249)', ODM File OID: '4962bab5-41ef-44c8-bd41-651bd1c576bf'	System	23 Sep 2020 03:11:14
User entered 'None (0)'	System	23 Sep 2020 03:11:14

US3032249

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 14:53:49

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:43:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5a55dca4933e096f)', Time: '2020-09-22T22:10:37', User OID: 'PatientReportedOutcome (US3032249)', ODM File OID: '4962bab5-41ef-44c8-bd41-651bd1c576bf'	System	23 Sep 2020 03:11:14
User entered 'None (0)'	System	23 Sep 2020 03:11:14

US3032249

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 14:53:49

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:43:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5a55dca4933e096f)', Time: '2020-09-22T22:10:46', User OID: 'PatientReportedOutcome (US3032249)', ODM File OID: '4962bab5-41ef-44c8-bd41-651bd1c576bf'	System	23 Sep 2020 03:11:14
User entered 'None (0)'	System	23 Sep 2020 03:11:14

US3032249

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 14:53:49

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:43:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5a55dca4933e096f)', Time: '2020-09-22T22:10:51', User OID: 'PatientReportedOutcome (US3032249)', ODM File OID: '4962bab5-41ef-44c8-bd41-651bd1c576bf'	System	23 Sep 2020 03:11:14
User entered 'None (0)'	System	23 Sep 2020 03:11:14

US3032249

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 14:53:49

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)	27 Mar 2021 20:43:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5a55dca4933e096f)', Time: '2020-09-22T22:10:58', User OID: 'PatientReportedOutcome (US3032249)', ODM File OID: '4962bab5-41ef-44c8-bd41-651bd1c576bf'	System	23 Sep 2020 03:11:14
User entered 'No (N)'	System	23 Sep 2020 03:11:14

US3032249

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 14:53:49

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:43:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5a55dca4933e096f)', Time: '2020-09-22T22:11:11', User OID: 'PatientReportedOutcome (US3032249)', ODM File OID: '4962bab5-41ef-44c8-bd41-651bd1c576bf'	System	23 Sep 2020 03:11:14
User entered '22 Sep 2020 22:11'	System	23 Sep 2020 03:11:14

US3032249

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 14:53:49

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:43:07
User entered '22 Sep 2020 12:00'	System	21 Sep 2020 16:44:17

US3032249

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 14:53:49

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:43:07
User entered '23 Sep 2020 11:59'	System	21 Sep 2020 16:44:17

US3032249

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 14:53:49

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:43:07
Data entry locked.	System	21 Sep 2020 16:44:17
User entered 'Day 3'	System	21 Sep 2020 16:44:17

US3032249

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 14:53:49

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:43:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5a55dca4933e096f)', Time: '2020-09-23T19:07:47', User OID: 'PatientReportedOutcome (US3032249)', ODM File OID: '42714bd2-e20c-436d-9ab0-fe0a692626ee'	System	24 Sep 2020 00:08:30
User entered 'None (0)'	System	24 Sep 2020 00:08:30

US3032249

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 14:53:49

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:43:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5a55dca4933e096f)', Time: '2020-09-23T19:07:52', User OID: 'PatientReportedOutcome (US3032249)', ODM File OID: '42714bd2-e20c-436d-9ab0-fe0a692626ee'	System	24 Sep 2020 00:08:30
User entered 'None (0)'	System	24 Sep 2020 00:08:30

US3032249

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 14:53:49

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:43:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5a55dca4933e096f)', Time: '2020-09-23T19:07:58', User OID: 'PatientReportedOutcome (US3032249)', ODM File OID: '42714bd2-e20c-436d-9ab0-fe0a692626ee'	System	24 Sep 2020 00:08:30
User entered 'None (0)'	System	24 Sep 2020 00:08:30

US3032249

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 14:53:49

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:43:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5a55dca4933e096f)', Time: '2020-09-23T19:08:03', User OID: 'PatientReportedOutcome (US3032249)', ODM File OID: '42714bd2-e20c-436d-9ab0-fe0a692626ee'	System	24 Sep 2020 00:08:30
User entered 'None (0)'	System	24 Sep 2020 00:08:30

US3032249

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 14:53:49

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:43:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5a55dca4933e096f)', Time: '2020-09-23T19:08:08', User OID: 'PatientReportedOutcome (US3032249)', ODM File OID: '42714bd2-e20c-436d-9ab0-fe0a692626ee'	System	24 Sep 2020 00:08:30
User entered 'None (0)'	System	24 Sep 2020 00:08:30

US3032249

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 14:53:49

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:43:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5a55dca4933e096f)', Time: '2020-09-23T19:08:12', User OID: 'PatientReportedOutcome (US3032249)', ODM File OID: '42714bd2-e20c-436d-9ab0-fe0a692626ee'	System	24 Sep 2020 00:08:30
User entered 'None (0)'	System	24 Sep 2020 00:08:30

US3032249

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 14:53:49

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)	27 Mar 2021 20:43:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5a55dca4933e096f)', Time: '2020-09-23T19:08:19', User OID: 'PatientReportedOutcome (US3032249)', ODM File OID: '42714bd2-e20c-436d-9ab0-fe0a692626ee'	System	24 Sep 2020 00:08:30
User entered 'No (N)'	System	24 Sep 2020 00:08:30

US3032249

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 14:53:49

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:43:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5a55dca4933e096f)', Time: '2020-09-23T19:08:28', User OID: 'PatientReportedOutcome (US3032249)', ODM File OID: '42714bd2-e20c-436d-9ab0-fe0a692626ee'	System	24 Sep 2020 00:08:30
User entered '23 Sep 2020 19:08'	System	24 Sep 2020 00:08:30

US3032249

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 14:53:49

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:43:07
User entered '23 Sep 2020 12:00'	System	21 Sep 2020 16:44:17

US3032249

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 14:53:49

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:43:07
User entered '24 Sep 2020 11:59'	System	21 Sep 2020 16:44:17

US3032249

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 14:53:49

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:43:07
Data entry locked.	System	21 Sep 2020 16:44:17
User entered 'Day 4'	System	21 Sep 2020 16:44:17

US3032249

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 14:53:49

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:43:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5a55dca4933e096f)', Time: '2020-09-25T00:03:48', User OID: 'PatientReportedOutcome (US3032249)', ODM File OID: 'd4861249-e6fb-4744-87e5-7fa18defe8d3'	System	25 Sep 2020 05:04:40
User entered 'None (0)'	System	25 Sep 2020 05:04:40

US3032249

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 14:53:49

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:43:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5a55dca4933e096f)', Time: '2020-09-25T00:03:53', User OID: 'PatientReportedOutcome (US3032249)', ODM File OID: 'd4861249-e6fb-4744-87e5-7fa18defe8d3'	System	25 Sep 2020 05:04:40
User entered 'None (0)'	System	25 Sep 2020 05:04:40

US3032249

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 14:53:49

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:43:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5a55dca4933e096f)', Time: '2020-09-25T00:03:58', User OID: 'PatientReportedOutcome (US3032249)', ODM File OID: 'd4861249-e6fb-4744-87e5-7fa18defe8d3'	System	25 Sep 2020 05:04:40
User entered 'None (0)'	System	25 Sep 2020 05:04:40

US3032249

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 14:53:49

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:43:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5a55dca4933e096f)', Time: '2020-09-25T00:04:03', User OID: 'PatientReportedOutcome (US3032249)', ODM File OID: 'd4861249-e6fb-4744-87e5-7fa18defe8d3'	System	25 Sep 2020 05:04:40
User entered 'None (0)'	System	25 Sep 2020 05:04:40

US3032249

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 14:53:49

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:43:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5a55dca4933e096f)', Time: '2020-09-25T00:04:09', User OID: 'PatientReportedOutcome (US3032249)', ODM File OID: 'd4861249-e6fb-4744-87e5-7fa18defe8d3'	System	25 Sep 2020 05:04:40
User entered 'None (0)'	System	25 Sep 2020 05:04:40

US3032249

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 14:53:49

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:43:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5a55dca4933e096f)', Time: '2020-09-25T00:04:14', User OID: 'PatientReportedOutcome (US3032249)', ODM File OID: 'd4861249-e6fb-4744-87e5-7fa18defe8d3'	System	25 Sep 2020 05:04:40
User entered 'None (0)'	System	25 Sep 2020 05:04:40

US3032249

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 14:53:49

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)	27 Mar 2021 20:43:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5a55dca4933e096f)', Time: '2020-09-25T00:04:23', User OID: 'PatientReportedOutcome (US3032249)', ODM File OID: 'd4861249-e6fb-4744-87e5-7fa18defe8d3'	System	25 Sep 2020 05:04:40
User entered 'No (N)'	System	25 Sep 2020 05:04:40

US3032249

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 14:53:49

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:43:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5a55dca4933e096f)', Time: '2020-09-25T00:04:36', User OID: 'PatientReportedOutcome (US3032249)', ODM File OID: 'd4861249-e6fb-4744-87e5-7fa18defe8d3'	System	25 Sep 2020 05:04:40
User entered '25 Sep 2020 00:04'	System	25 Sep 2020 05:04:40

US3032249

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 14:53:49

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:43:07
User entered '24 Sep 2020 12:00'	System	21 Sep 2020 16:44:17

US3032249

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 14:53:49

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:43:07
User entered '25 Sep 2020 11:59'	System	21 Sep 2020 16:44:17

US3032249

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 14:53:49

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:43:07
Data entry locked.	System	21 Sep 2020 16:44:17
User entered 'Day 5'	System	21 Sep 2020 16:44:17

US3032249

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 14:53:49

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:43:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5a55dca4933e096f)', Time: '2020-09-25T12:03:53', User OID: 'PatientReportedOutcome (US3032249)', ODM File OID: 'e756405b-4bc8-4069-a42b-c3aa70cf9622'	System	25 Sep 2020 17:05:23
User entered 'None (0)'	System	25 Sep 2020 17:05:23

US3032249

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 14:53:49

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:43:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5a55dca4933e096f)', Time: '2020-09-25T12:03:57', User OID: 'PatientReportedOutcome (US3032249)', ODM File OID: 'e756405b-4bc8-4069-a42b-c3aa70cf9622'	System	25 Sep 2020 17:05:23
User entered 'None (0)'	System	25 Sep 2020 17:05:23

US3032249

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 14:53:49

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:43:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5a55dca4933e096f)', Time: '2020-09-25T12:04:01', User OID: 'PatientReportedOutcome (US3032249)', ODM File OID: 'e756405b-4bc8-4069-a42b-c3aa70cf9622'	System	25 Sep 2020 17:05:23
User entered 'None (0)'	System	25 Sep 2020 17:05:23

US3032249

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 14:53:49

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:43:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5a55dca4933e096f)', Time: '2020-09-25T12:04:09', User OID: 'PatientReportedOutcome (US3032249)', ODM File OID: 'e756405b-4bc8-4069-a42b-c3aa70cf9622'	System	25 Sep 2020 17:05:23
User entered 'None (0)'	System	25 Sep 2020 17:05:23

US3032249

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 14:53:49

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:43:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5a55dca4933e096f)', Time: '2020-09-25T12:04:12', User OID: 'PatientReportedOutcome (US3032249)', ODM File OID: 'e756405b-4bc8-4069-a42b-c3aa70cf9622'	System	25 Sep 2020 17:05:23
User entered 'None (0)'	System	25 Sep 2020 17:05:23

US3032249

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 14:53:49

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:43:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5a55dca4933e096f)', Time: '2020-09-25T12:04:16', User OID: 'PatientReportedOutcome (US3032249)', ODM File OID: 'e756405b-4bc8-4069-a42b-c3aa70cf9622'	System	25 Sep 2020 17:05:23
User entered 'None (0)'	System	25 Sep 2020 17:05:23

US3032249

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 14:53:49

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)	27 Mar 2021 20:43:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5a55dca4933e096f)', Time: '2020-09-25T12:04:22', User OID: 'PatientReportedOutcome (US3032249)', ODM File OID: 'e756405b-4bc8-4069-a42b-c3aa70cf9622'	System	25 Sep 2020 17:05:23
User entered 'No (N)'	System	25 Sep 2020 17:05:23

US3032249

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 14:53:49

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:43:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5a55dca4933e096f)', Time: '2020-09-25T12:04:35', User OID: 'PatientReportedOutcome (US3032249)', ODM File OID: 'e756405b-4bc8-4069-a42b-c3aa70cf9622'	System	25 Sep 2020 17:05:23
User entered '25 Sep 2020 12:04'	System	25 Sep 2020 17:05:23

US3032249

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 14:53:49

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:43:07
User entered '25 Sep 2020 12:00'	System	21 Sep 2020 16:44:17

US3032249

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 14:53:49

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:43:07
User entered '26 Sep 2020 11:59'	System	21 Sep 2020 16:44:17

US3032249

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 14:53:49

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:43:07
Data entry locked.	System	21 Sep 2020 16:44:17
User entered 'Day 6'	System	21 Sep 2020 16:44:17

US3032249

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 14:53:49

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:43:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5a55dca4933e096f)', Time: '2020-09-26T12:01:48', User OID: 'PatientReportedOutcome (US3032249)', ODM File OID: '3a4eb473-1b10-4886-ae19-5e2517fd48dc'	System	26 Sep 2020 17:02:50
User entered 'None (0)'	System	26 Sep 2020 17:02:50

US3032249

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 14:53:49

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:43:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5a55dca4933e096f)', Time: '2020-09-26T12:01:54', User OID: 'PatientReportedOutcome (US3032249)', ODM File OID: '3a4eb473-1b10-4886-ae19-5e2517fd48dc'	System	26 Sep 2020 17:02:50
User entered 'None (0)'	System	26 Sep 2020 17:02:50

US3032249

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 14:53:49

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:43:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5a55dca4933e096f)', Time: '2020-09-26T12:02:00', User OID: 'PatientReportedOutcome (US3032249)', ODM File OID: '3a4eb473-1b10-4886-ae19-5e2517fd48dc'	System	26 Sep 2020 17:02:50
User entered 'None (0)'	System	26 Sep 2020 17:02:50

US3032249

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 14:53:49

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:43:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5a55dca4933e096f)', Time: '2020-09-26T12:02:05', User OID: 'PatientReportedOutcome (US3032249)', ODM File OID: '3a4eb473-1b10-4886-ae19-5e2517fd48dc'	System	26 Sep 2020 17:02:50
User entered 'None (0)'	System	26 Sep 2020 17:02:50

US3032249

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 14:53:49

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:43:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5a55dca4933e096f)', Time: '2020-09-26T12:02:08', User OID: 'PatientReportedOutcome (US3032249)', ODM File OID: '3a4eb473-1b10-4886-ae19-5e2517fd48dc'	System	26 Sep 2020 17:02:50
User entered 'None (0)'	System	26 Sep 2020 17:02:50

US3032249

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 14:53:49

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:43:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5a55dca4933e096f)', Time: '2020-09-26T12:02:13', User OID: 'PatientReportedOutcome (US3032249)', ODM File OID: '3a4eb473-1b10-4886-ae19-5e2517fd48dc'	System	26 Sep 2020 17:02:50
User entered 'None (0)'	System	26 Sep 2020 17:02:50

US3032249

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 14:53:49

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)	27 Mar 2021 20:43:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5a55dca4933e096f)', Time: '2020-09-26T12:02:25', User OID: 'PatientReportedOutcome (US3032249)', ODM File OID: '3a4eb473-1b10-4886-ae19-5e2517fd48dc'	System	26 Sep 2020 17:02:50
User entered 'No (N)'	System	26 Sep 2020 17:02:50

US3032249

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 14:53:49

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:43:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5a55dca4933e096f)', Time: '2020-09-26T12:02:29', User OID: 'PatientReportedOutcome (US3032249)', ODM File OID: '3a4eb473-1b10-4886-ae19-5e2517fd48dc'	System	26 Sep 2020 17:02:50
User entered '26 Sep 2020 12:02'	System	26 Sep 2020 17:02:50

US3032249

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 14:53:49

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:43:07
User entered '26 Sep 2020 12:00'	System	21 Sep 2020 16:44:17

US3032249

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 14:53:49

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:43:07
User entered '27 Sep 2020 11:59'	System	21 Sep 2020 16:44:17

US3032249

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 14:53:49

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:43:07
Data entry locked.	System	21 Sep 2020 16:44:17
User entered 'Day 7'	System	21 Sep 2020 16:44:17

US3032249

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 14:53:49

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:43:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5a55dca4933e096f)', Time: '2020-09-27T12:33:43', User OID: 'PatientReportedOutcome (US3032249)', ODM File OID: '3c08346e-c46a-4bcf-9d72-5908c7d64c74'	System	27 Sep 2020 17:36:02
User entered 'None (0)'	System	27 Sep 2020 17:36:02

US3032249

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 14:53:49

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:43:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5a55dca4933e096f)', Time: '2020-09-27T12:34:06', User OID: 'PatientReportedOutcome (US3032249)', ODM File OID: '3c08346e-c46a-4bcf-9d72-5908c7d64c74'	System	27 Sep 2020 17:36:02
User entered 'None (0)'	System	27 Sep 2020 17:36:02

US3032249

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 14:53:49

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:43:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5a55dca4933e096f)', Time: '2020-09-27T12:34:09', User OID: 'PatientReportedOutcome (US3032249)', ODM File OID: '3c08346e-c46a-4bcf-9d72-5908c7d64c74'	System	27 Sep 2020 17:36:02
User entered 'None (0)'	System	27 Sep 2020 17:36:02

US3032249

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 14:53:49

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:43:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5a55dca4933e096f)', Time: '2020-09-27T12:34:19', User OID: 'PatientReportedOutcome (US3032249)', ODM File OID: '3c08346e-c46a-4bcf-9d72-5908c7d64c74'	System	27 Sep 2020 17:36:02
User entered 'None (0)'	System	27 Sep 2020 17:36:02

US3032249

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 14:53:49

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:43:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5a55dca4933e096f)', Time: '2020-09-27T12:34:31', User OID: 'PatientReportedOutcome (US3032249)', ODM File OID: '3c08346e-c46a-4bcf-9d72-5908c7d64c74'	System	27 Sep 2020 17:36:02
User entered 'None (0)'	System	27 Sep 2020 17:36:02

US3032249

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 14:53:49

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:43:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5a55dca4933e096f)', Time: '2020-09-27T12:34:51', User OID: 'PatientReportedOutcome (US3032249)', ODM File OID: '3c08346e-c46a-4bcf-9d72-5908c7d64c74'	System	27 Sep 2020 17:36:02
User entered 'None (0)'	System	27 Sep 2020 17:36:02

US3032249

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 14:53:49

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)	27 Mar 2021 20:43:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5a55dca4933e096f)', Time: '2020-09-27T12:35:31', User OID: 'PatientReportedOutcome (US3032249)', ODM File OID: '3c08346e-c46a-4bcf-9d72-5908c7d64c74'	System	27 Sep 2020 17:36:02
User entered 'No (N)'	System	27 Sep 2020 17:36:02

US3032249

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 14:53:49

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:43:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5a55dca4933e096f)', Time: '2020-09-27T12:35:58', User OID: 'PatientReportedOutcome (US3032249)', ODM File OID: '3c08346e-c46a-4bcf-9d72-5908c7d64c74'	System	27 Sep 2020 17:36:02
User entered '27 Sep 2020 12:35'	System	27 Sep 2020 17:36:02

US3032249

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 14:53:49

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:43:07
User entered '27 Sep 2020 12:00'	System	21 Sep 2020 16:44:17

US3032249

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 14:53:49

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:43:07
User entered '28 Sep 2020 11:59'	System	21 Sep 2020 16:44:17

US3032249

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 09 Jun 2021 14:53:49

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:25:26
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:50:49
User entered 'Yes (Y)'	(b) (4) Samantha Wieseler (b) (4)	28 Sep 2020 15:26:35

US3032249

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 09 Jun 2021 14:53:49

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:25:26
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:50:49
User entered '28 Sep 2020'	Samantha Wieseler (b) (4)	28 Sep 2020 15:26:35

US3032249

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 09 Jun 2021 14:53:49

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:25:26
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:50:49
User entered 'Contact Made (CONTACT MADE)'	Samantha Wieseler (b) (4)	28 Sep 2020 15:26:35

US3032249

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 09 Jun 2021 14:53:49

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:25:26
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:50:49
User entered empty.	Samantha Wieseler (b) (4)	28 Sep 2020 15:26:35

US3032249

Folder: Safety Call Day 36 (1)

Form: Continuing

Generated On: 09 Jun 2021 14:53:49

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:25:26
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:50:49
User entered 'Yes (Y)'	Samantha Wieseler (b) (4)	28 Sep 2020 15:26:54

US3032249

Folder: Safety Call Day 36 (1)

Form: Continuing

Generated On: 09 Jun 2021 14:53:49

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:25:26
User entered 'I'	System	28 Sep 2020 15:26:54

US3032249

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 09 Jun 2021 14:53:49

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:25:26
User signature succeeded.	Keith Vrbicky (b) (4)	08 Oct 2020 15:43:04
User entered 'Yes (Y)'	(b) (4) Linden DeBoer (b) (4)	05 Oct 2020 22:15:41

US3032249

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 09 Jun 2021 14:53:49

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:25:26
User signature succeeded.	Keith Vrbicky (b) (4)	08 Oct 2020 15:43:04
User entered '5 Oct 2020'	Linden DeBoer (b) (4)	05 Oct 2020 22:15:41

US3032249

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 09 Jun 2021 14:53:49

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:25:26
User signature succeeded.	Keith Vrbicky (b) (4)	08 Oct 2020 15:43:04
User entered 'Contact Made (CONTACT MADE)'	Linden DeBoer (b) (4)	05 Oct 2020 22:15:41

US3032249

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 09 Jun 2021 14:53:49

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:25:26
User signature succeeded.	Keith Vrbicky (b) (4)	08 Oct 2020 15:43:04
User entered empty.	Linden DeBoer (b) (4)	05 Oct 2020 22:15:41

US3032249

Folder: Safety Call Day 43 (1)

Form: Continuing

Generated On: 09 Jun 2021 14:53:49

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:25:26
User signature succeeded.	Keith Vrbicky (b) (4)	08 Oct 2020 15:43:04
User entered 'Yes (Y)'	Linden DeBoer (b) (4)	05 Oct 2020 22:15:45

US3032249

Folder: Safety Call Day 43 (1)

Form: Continuing

Generated On: 09 Jun 2021 14:53:49

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:25:26
User entered 'I'	System	05 Oct 2020 22:15:45

US3032249

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 09 Jun 2021 14:53:49

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:25:26
User signature succeeded.	Keith Vrbicky (b) (4)	13 Oct 2020 14:01:29
User entered 'Yes (Y)'	(b) (4) Kelsey Kelley (b) (4)	12 Oct 2020 16:07:02

US3032249

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 09 Jun 2021 14:53:49

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:25:26
User signature succeeded.	Keith Vrbicky (b) (4)	13 Oct 2020 14:01:29
User entered '12 Oct 2020'	Kelsey Kelley (b) (4)	12 Oct 2020 16:07:02

US3032249

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 09 Jun 2021 14:53:49

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:25:26
User signature succeeded.	Keith Vrbicky (b) (4)	13 Oct 2020 14:01:29
User entered 'Contact Made (CONTACT MADE)'	(b) (4) Kelsey Kelley (b) (4)	12 Oct 2020 16:07:02

US3032249

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 09 Jun 2021 14:53:49

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:25:26
User signature succeeded.	Keith Vrbicky (b) (4)	13 Oct 2020 14:01:29
User entered empty.	(b) (4) Kelsey Kelley (b) (4) (b) (4)	12 Oct 2020 16:07:02

US3032249

Folder: Safety Call Day 50 (1)

Form: Continuing

Generated On: 09 Jun 2021 14:53:49

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:25:26
User signature succeeded.	Keith Vrbicky (b) (4)	13 Oct 2020 14:01:29
User entered 'Yes (Y)'	(b) (4) Kelsey Kelley (b) (4)	12 Oct 2020 16:07:19

US3032249

Folder: Safety Call Day 50 (1)

Form: Continuing

Generated On: 09 Jun 2021 14:53:49

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:25:26
User entered 'I'	System	12 Oct 2020 16:07:19

US3032249

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 09 Jun 2021 14:53:49

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:25:32
User signature succeeded.	Keith Vrbicky (b) (4)	28 Oct 2020 16:40:09
User entered 'Yes (Y)'	(b) (4) Kelsey Kelley (b) (4)	23 Oct 2020 16:11:20

US3032249

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 09 Jun 2021 14:53:49

[Visit date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:25:32
User signature succeeded.	Keith Vrbicky (b) (4)	28 Oct 2020 16:40:09
User entered '23 Oct 2020'	(b) (4) Kelsey Kelley (b) (4)	23 Oct 2020 16:11:20
	(b) (4)	

US3032249

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 09 Jun 2021 14:53:49

[Was visit performed at the participant's home or at the clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:25:32
User signature succeeded.	Keith Vrbicky (b) (4)	28 Oct 2020 16:40:09
User entered 'Clinic (Clinic)'	(b) (4) Kelsey Kelley (b) (4)	23 Oct 2020 16:11:20

US3032249

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 09 Jun 2021 14:53:49

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:25:32
User entered 'VISIT3'	System	23 Oct 2020 16:11:20

US3032249

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 14:53:49

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:25:32
User signature succeeded.	Keith Vrbicky (b) (4)	28 Oct 2020 16:40:09
User entered 'Yes (Y)'	(b) (4) Kelsey Kelley (b) (4)	23 Oct 2020 16:12:58

US3032249

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 14:53:49

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:25:32
User signature succeeded.	Keith Vrbicky (b) (4)	28 Oct 2020 16:40:09
User entered '23 Oct 2020'	(b) (4) Kelsey Kelley (b) (4)	23 Oct 2020 16:12:58
	(b) (4)	

US3032249

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 14:53:49

[Time of assessment \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:25:32
User signature succeeded.	Keith Vrbicky (b) (4)	28 Oct 2020 16:40:09
User entered '09:00'	(b) (4) Kelsey Kelley (b) (4)	23 Oct 2020 16:12:58

US3032249

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 14:53:49

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:25:32
User entered '23 Oct 2020 09:00'	System	23 Oct 2020 16:12:58

US3032249

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 14:53:49

[Temperature \(xxx.x\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:25:32
User signature succeeded.	Keith Vrbicky (b) (4)	28 Oct 2020 16:40:09
User entered '36.9' C	(b) (4) Kelsey Kelley (b) (4)	23 Oct 2020 16:12:58

US3032249

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 14:53:49

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:25:32
User signature succeeded.	Keith Vrbicky (b) (4)	28 Oct 2020 16:40:09
User entered 'Oral (Oral)'	(b) (4) Kelsey Kelley (b) (4)	23 Oct 2020 16:12:58

US3032249

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 14:53:49

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:25:32
User signature succeeded.	Keith Vrbicky (b) (4)	28 Oct 2020 16:40:09
User entered empty.	(b) (4) Kelsey Kelley (b) (4)	23 Oct 2020 16:12:58

US3032249

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 14:53:49

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:25:32
User signature succeeded.	Keith Vrbicky (b) (4)	28 Oct 2020 16:40:09
User entered '68'	(b) (4) Kelsey Kelley (b) (4)	23 Oct 2020 16:12:58

US3032249

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 14:53:49

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:25:32
User entered 'bpm'	System	23 Oct 2020 16:12:58

US3032249

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 14:53:49

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:25:32
User signature succeeded.	Keith Vrbicky (b) (4)	28 Oct 2020 16:40:09
User entered '16'	(b) (4) Kelsey Kelley (b) (4)	23 Oct 2020 16:12:58

US3032249

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 14:53:49

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:25:32
User entered 'breaths/min'	System	23 Oct 2020 16:12:58

US3032249

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 14:53:49

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:25:32
User signature succeeded.	Keith Vrbicky (b) (4)	28 Oct 2020 16:40:09
User entered '126'	(b) (4) Kelsey Kelley (b) (4)	23 Oct 2020 16:12:58

US3032249

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 14:53:49

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:25:32
User entered 'mmHg'	System	23 Oct 2020 16:12:58

US3032249

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 14:53:49

[Diastolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:25:32
User signature succeeded.	Keith Vrbicky (b) (4)	28 Oct 2020 16:40:09
User entered '65'	(b) (4) Kelsey Kelley (b) (4)	23 Oct 2020 16:12:58

US3032249

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 14:53:49

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:25:32
User entered 'mmHg'	System	23 Oct 2020 16:12:58

US3032249

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 14:53:49

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:25:32

US3032249

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 14:53:49

[Weight \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:25:32

US3032249

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 14:53:49

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:25:32
User signature succeeded.	Keith Vrbicky (b) (4)	28 Oct 2020 16:40:09
User entered 'Yes (Y)'	(b) (4) Kelsey Kelley (b) (4)	23 Oct 2020 16:13:07

US3032249

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 14:53:49

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:25:32
User signature succeeded.	Keith Vrbicky (b) (4)	28 Oct 2020 16:40:09
User entered '23 Oct 2020'	(b) (4) Kelsey Kelley (b) (4)	23 Oct 2020 16:13:07
	(b) (4)	

US3032249

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 14:53:49

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:25:32
User signature succeeded.	Keith Vrbicky (b) (4)	28 Oct 2020 16:40:09
User entered 'Yes (Y)'	(b) (4) Kelsey Kelley (b) (4)	23 Oct 2020 16:13:32

US3032249

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 14:53:49

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:25:32
User signature succeeded.	Keith Vrbicky (b) (4)	28 Oct 2020 16:40:09
User entered '23 Oct 2020'	(b) (4) Kelsey Kelley (b) (4)	23 Oct 2020 16:13:32
	(b) (4)	

US3032249

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 14:53:49

[Collection time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:25:32
User signature succeeded.	Keith Vrbicky (b) (4)	28 Oct 2020 16:40:09
User entered '09:11'	(b) (4) Kelsey Kelley (b) (4)	23 Oct 2020 16:13:32

US3032249

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 14:53:49

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:25:32
User entered '23 Oct 2020 09:11'	System	23 Oct 2020 16:13:32

US3032249

Folder: Visit 3 Day 57 (1)

Form: Continuing

Generated On: 09 Jun 2021 14:53:49

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:25:32
User signature succeeded.	Keith Vrbicky (b) (4)	28 Oct 2020 16:40:09
User entered 'Yes (Y)'	(b) (4) Kelsey Kelley (b) (4)	23 Oct 2020 16:13:34

US3032249

Folder: Visit 3 Day 57 (1)

Form: Continuing

Generated On: 09 Jun 2021 14:53:49

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:25:32
User entered 'I'	System	23 Oct 2020 16:13:34

US3032249

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:53:49

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:43:07
Data entry locked.	System	19 Aug 2020 23:40:48
User entered 'Day 64'	System	19 Aug 2020 23:40:48

US3032249

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:53:49

[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)	27 Mar 2021 20:43:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (898ced6280f9892f)', Time: '2020-10-23T09:24:46', User OID: 'PatientReportedOutcome (US3032249)', ODM File OID: '9fbb874a-48fe-4b2e-bb51-f6019f955004'	System	23 Oct 2020 14:25:06
User entered 'No (N)'	System	23 Oct 2020 14:25:06

US3032249

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:53:49

Have you been exposed to someone with 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)	27 Mar 2021 20:43:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (898ced6280f9892f)', Time: '2020-10-23T09:24:51', User OID: 'PatientReportedOutcome (US3032249)', ODM File OID: '9fbb874a-48fe-4b2e-bb51-f6019f955004'	System	23 Oct 2020 14:25:06
User entered 'No (N)'	System	23 Oct 2020 14:25:06

US3032249

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:53:49

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:43:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (898ced6280f9892f)', Time: '2020-10-23T09:24:59', User OID: 'PatientReportedOutcome (US3032249)', ODM File OID: '9fbb874a-48fe-4b2e-bb51-f6019f955004'	System	23 Oct 2020 14:25:06
User entered '23 Oct 2020 09:24:59'	System	23 Oct 2020 14:25:06

US3032249

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:53:49

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:43:07
Data entry locked.	System	19 Aug 2020 23:40:48
User entered '19 Oct 2020 00:01'	System	19 Aug 2020 23:40:48

US3032249

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:53:49

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:43:07
Data entry locked.	System	19 Aug 2020 23:40:48
User entered '23 Oct 2020 23:59'	System	19 Aug 2020 23:40:48

US3032249

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:53:49

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:43:07
Data entry locked.	System	19 Aug 2020 23:40:48
User entered 'Day 71'	System	19 Aug 2020 23:40:48

US3032249

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:53:49

[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)	27 Mar 2021 20:43:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (898ced6280f9892f)', Time: '2020-10-26T00:03:12', User OID: 'PatientReportedOutcome (US3032249)', ODM File OID: '268828b1-0bab-43fa-9d73-8a50548b1c7f'	System	26 Oct 2020 05:03:47
User entered 'No (N)'	System	26 Oct 2020 05:03:47

US3032249

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:53:49

[Have you been exposed to someone with 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)	27 Mar 2021 20:43:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (898ced6280f9892f)', Time: '2020-10-26T00:03:35', User OID: 'PatientReportedOutcome (US3032249)', ODM File OID: '268828b1-0bab-43fa-9d73-8a50548b1c7f'	System	26 Oct 2020 05:03:47
User entered 'No (N)'	System	26 Oct 2020 05:03:47

US3032249

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:53:49

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:43:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (898ced6280f9892f)', Time: '2020-10-26T00:03:44', User OID: 'PatientReportedOutcome (US3032249)', ODM File OID: '268828b1-0bab-43fa-9d73-8a50548b1c7f' User entered '26 Oct 2020 00:03:44'	System	26 Oct 2020 05:03:47
	System	26 Oct 2020 05:03:47

US3032249

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:53:49

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:43:07
Data entry locked.	System	19 Aug 2020 23:40:48
User entered '26 Oct 2020 00:01'	System	19 Aug 2020 23:40:48

US3032249

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:53:49

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:43:07
Data entry locked.	System	19 Aug 2020 23:40:48
User entered '30 Oct 2020 23:59'	System	19 Aug 2020 23:40:48

US3032249

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:53:49

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:43:07
Data entry locked.	System	19 Aug 2020 23:40:48
User entered 'Day 78'	System	19 Aug 2020 23:40:48

US3032249

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:53:49

[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)	27 Mar 2021 20:43:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (898ced6280f9892f)', Time: '2020-11-06T11:37:12', User OID: 'PatientReportedOutcome (US3032249)', ODM File OID: 'ee8b1926-d40d-4014-bcd1-cc6b9b6a37df'	System	06 Nov 2020 17:37:35
User entered 'No (N)'	System	06 Nov 2020 17:37:35

US3032249

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:53:49

[Have you been exposed to someone with 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)	27 Mar 2021 20:43:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (898ced6280f9892f)', Time: '2020-11-06T11:37:16', User OID: 'PatientReportedOutcome (US3032249)', ODM File OID: 'ee8b1926-d40d-4014-bcd1-cc6b9b6a37df'	System	06 Nov 2020 17:37:35
User entered 'No (N)'	System	06 Nov 2020 17:37:35

US3032249

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:53:49

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:43:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (898ced6280f9892f)', Time: '2020-11-06T11:37:29', User OID: 'PatientReportedOutcome (US3032249)', ODM File OID: 'ee8b1926-d40d-4014-bcd1-cc6b9b6a37df'	System	06 Nov 2020 17:37:35
User entered '06 Nov 2020 11:37:29'	System	06 Nov 2020 17:37:35

US3032249

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:53:49

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:43:07
Data entry locked.	System	19 Aug 2020 23:40:48
User entered '02 Nov 2020 00:01'	System	19 Aug 2020 23:40:48

US3032249

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:53:49

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:43:07
Data entry locked.	System	19 Aug 2020 23:40:48
User entered '06 Nov 2020 23:59'	System	19 Aug 2020 23:40:48

US3032249

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:53:49

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:43:07
Data entry locked.	System	19 Aug 2020 23:40:48
User entered 'Day 92'	System	19 Aug 2020 23:40:48

US3032249

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:53:49

[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)	27 Mar 2021 20:43:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (898ced6280f9892f)', Time: '2020-11-16T17:18:24', User OID: 'PatientReportedOutcome (US3032249)', ODM File OID: '899be193-793a-410a-99ab-6f8fee2c8e9b'	System	16 Nov 2020 23:18:46
User entered 'No (N)'	System	16 Nov 2020 23:18:46

US3032249

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:53:49

[Have you been exposed to someone with 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)	27 Mar 2021 20:43:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (898ced6280f9892f)', Time: '2020-11-16T17:18:28', User OID: 'PatientReportedOutcome (US3032249)', ODM File OID: '899be193-793a-410a-99ab-6f8fee2c8e9b'	System	16 Nov 2020 23:18:46
User entered 'No (N)'	System	16 Nov 2020 23:18:46

US3032249

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:53:49

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:43:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (898ced6280f9892f)', Time: '2020-11-16T17:18:43', User OID: 'PatientReportedOutcome (US3032249)', ODM File OID: '899be193-793a-410a-99ab-6f8fee2c8e9b'	System	16 Nov 2020 23:18:46
User entered '16 Nov 2020 17:18:43'	System	16 Nov 2020 23:18:46

US3032249

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:53:49

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:43:07
Data entry locked.	System	19 Aug 2020 23:40:48
User entered '16 Nov 2020 00:01'	System	19 Aug 2020 23:40:48

US3032249

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:53:49

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:43:07
Data entry locked.	System	19 Aug 2020 23:40:48
User entered '20 Nov 2020 23:59'	System	19 Aug 2020 23:40:48

US3032249

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:53:49

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:25:12
Amendment Manager: User entered 'Day 96'	System	19 Nov 2020 23:25:12

US3032249

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:53:49

[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 (898ced6280f9892f)', Time: '2020-11-23T00:41:31', User OID: 'PatientReportedOutcome (US3032249)', ODM File OID: '777e3529-6b8f-4930-bf32-c5742ed25f4f'	System	23 Nov 2020 06:42:07
User entered 'No (N)'	System	23 Nov 2020 06:42:07

US3032249

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:53:49

Have you been exposed to someone with 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 (898ced6280f9892f)', Time: '2020-11-23T00:41:51', User OID: 'PatientReportedOutcome (US3032249)', ODM File OID: '777e3529-6b8f-4930-bf32-c5742ed25f4f'	System	23 Nov 2020 06:42:07
User entered 'No (N)'	System	23 Nov 2020 06:42:07

US3032249

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:53:49

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (898ced6280f9892f)', Time: '2020-11-23T00:42:03', User OID: 'PatientReportedOutcome (US3032249)', ODM File OID: '777e3529-6b8f-4930-bf32-c5742ed25f4f'	System	23 Nov 2020 06:42:07
User entered '23 Nov 2020 00:42:03'	System	23 Nov 2020 06:42:07

US3032249

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:53:49

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:25:12
Amendment Manager: User entered '20 Nov 2020 00:01'	System	19 Nov 2020 23:25:12

US3032249

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:53:49

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:25:12
Amendment Manager: User entered '24 Nov 2020 23:59'	System	19 Nov 2020 23:25:12

US3032249

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:53:49

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:25:12
Amendment Manager: User entered 'Day 103'	System	19 Nov 2020 23:25:12

US3032249

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:53:49

[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 (898ced6280f9892f)', Time: '2020-11-27T01:09:04', User OID: 'PatientReportedOutcome (US3032249)', ODM File OID: '5b17ccf2-c848-4cba-89ba-f84a80418a35'	System	27 Nov 2020 07:09:50
User entered 'No (N)'	System	27 Nov 2020 07:09:50

US3032249

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:53:49

[Have you been exposed to someone with 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 (898ced6280f9892f)', Time: '2020-11-27T01:09:14', User OID: 'PatientReportedOutcome (US3032249)', ODM File OID: '5b17ccf2-c848-4cba-89ba-f84a80418a35'	System	27 Nov 2020 07:09:50
User entered 'No (N)'	System	27 Nov 2020 07:09:50

US3032249

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:53:49

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (898ced6280f9892f)', Time: '2020-11-27T01:09:47', User OID: 'PatientReportedOutcome (US3032249)', ODM File OID: '5b17ccf2-c848-4cba-89ba-f84a80418a35'	System	27 Nov 2020 07:09:50
User entered '27 Nov 2020 01:09:47'	System	27 Nov 2020 07:09:50

US3032249

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:53:49

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:25:12
Amendment Manager: User entered '27 Nov 2020 00:01'	System	19 Nov 2020 23:25:12

US3032249

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:53:49

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:25:12
Amendment Manager: User entered '01 Dec 2020 23:59'	System	19 Nov 2020 23:25:12

US3032249

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:53:49

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:25:12
Amendment Manager: User entered 'Day 110'	System	19 Nov 2020 23:25:12

US3032249

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:53:49

[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 (898ced6280f9892f)', Time: '2020-12-04T00:01:53', User OID: 'PatientReportedOutcome (US3032249)', ODM File OID: 'fb0c8bd5-e5cd-4283-b8a7-5afd7be599d8'	System	04 Dec 2020 06:02:26
User entered 'No (N)'	System	04 Dec 2020 06:02:26

US3032249

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:53:49

Have you been exposed to someone with 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 (898ced6280f9892f)', Time: '2020-12-04T00:02:14', User OID: 'PatientReportedOutcome (US3032249)', ODM File OID: 'fb0c8bd5-e5cd-4283-b8a7-5afd7be599d8'	System	04 Dec 2020 06:02:26
User entered 'No (N)'	System	04 Dec 2020 06:02:26

US3032249

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:53:49

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (898ced6280f9892f)', Time: '2020-12-04T00:02:20', User OID: 'PatientReportedOutcome (US3032249)', ODM File OID: 'fb0c8bd5-e5cd-4283-b8a7-5afd7be599d8'	System	04 Dec 2020 06:02:26
User entered '04 Dec 2020 00:02:20'	System	04 Dec 2020 06:02:26

US3032249

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:53:49

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:25:12
Amendment Manager: User entered '04 Dec 2020 00:01'	System	19 Nov 2020 23:25:12

US3032249

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:53:49

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:25:12
Amendment Manager: User entered '08 Dec 2020 23:59'	System	19 Nov 2020 23:25:12

US3032249

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:53:49

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:25:12
Amendment Manager: User entered 'Day 117'	System	19 Nov 2020 23:25:12

US3032249

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:53:49

[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 (898ced6280f9892f)', Time: '2020-12-11T23:37:08', User OID: 'PatientReportedOutcome (US3032249)', ODM File OID: 'def35108-d1c8-45d3-8cfe-a70d1a8de782'	System	12 Dec 2020 05:43:51
User entered 'No (N)'	System	12 Dec 2020 05:43:51

US3032249

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:53:49

Have you been exposed to someone with 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 (898ced6280f9892f)', Time: '2020-12-11T23:37:13', User OID: 'PatientReportedOutcome (US3032249)', ODM File OID: 'def35108-d1c8-45d3-8cfe-a70d1a8de782'	System	12 Dec 2020 05:43:51
User entered 'No (N)'	System	12 Dec 2020 05:43:51

US3032249

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:53:49

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (898ced6280f9892f)', Time: '2020-12-11T23:37:18', User OID: 'PatientReportedOutcome (US3032249)', ODM File OID: 'def35108-d1c8-45d3-8cfe-a70d1a8de782'	System	12 Dec 2020 05:43:51
User entered '11 Dec 2020 23:37:18'	System	12 Dec 2020 05:43:51

US3032249

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:53:49

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:25:12
Amendment Manager: User entered '11 Dec 2020 00:01'	System	19 Nov 2020 23:25:12

US3032249

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:53:49

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:25:12
Amendment Manager: User entered '15 Dec 2020 23:59'	System	19 Nov 2020 23:25:12

US3032249

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:53:49

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:25:12
Amendment Manager: User entered 'Day 124'	System	19 Nov 2020 23:25:12

US3032249

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:53:49

[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 (898ced6280f9892f)', Time: '2020-12-19T08:58:11', User OID: 'PatientReportedOutcome (US3032249)', ODM File OID: '5a090058-bed0-450b-815e-23cda61f2fe6'	System	19 Dec 2020 14:58:30
User entered 'No (N)'	System	19 Dec 2020 14:58:30

US3032249

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:53:49

[Have you been exposed to someone with 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 (898ced6280f9892f)', Time: '2020-12-19T08:58:14', User OID: 'PatientReportedOutcome (US3032249)', ODM File OID: '5a090058-bed0-450b-815e-23cda61f2fe6'	System	19 Dec 2020 14:58:30
User entered 'No (N)'	System	19 Dec 2020 14:58:30

US3032249

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:53:49

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (898ced6280f9892f)', Time: '2020-12-19T08:58:25', User OID: 'PatientReportedOutcome (US3032249)', ODM File OID: '5a090058-bed0-450b-815e-23cda61f2fe6'	System	19 Dec 2020 14:58:30
User entered '19 Dec 2020 08:58:25'	System	19 Dec 2020 14:58:30

US3032249

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:53:49

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:25:12
Amendment Manager: User entered '18 Dec 2020 00:01'	System	19 Nov 2020 23:25:12

US3032249

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:53:49

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:25:12
Amendment Manager: User entered '22 Dec 2020 23:59'	System	19 Nov 2020 23:25:12

US3032249

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:53:49

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:25:12
Amendment Manager: User entered 'Day 131'	System	19 Nov 2020 23:25:12

US3032249

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:53:49

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:25:12
Amendment Manager: User entered '25 Dec 2020 00:01'	System	19 Nov 2020 23:25:12

US3032249

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:53:49

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:25:12
Amendment Manager: User entered '29 Dec 2020 23:59'	System	19 Nov 2020 23:25:12

US3032249

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:53:49

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:25:12
Amendment Manager: User entered 'Day 138'	System	19 Nov 2020 23:25:12

US3032249

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:53:49

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:25:12
Amendment Manager: User entered '01 Jan 2021 00:01'	System	19 Nov 2020 23:25:12

US3032249

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:53:49

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:25:12
Amendment Manager: User entered '05 Jan 2021 23:59'	System	19 Nov 2020 23:25:12

US3032249

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:53:49

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:25:12
Amendment Manager: User entered 'Day 145'	System	19 Nov 2020 23:25:12

US3032249

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:53:49

[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 (898ced6280f9892f)', Time: '2021-01-08T00:02:35', User OID: 'PatientReportedOutcome (US3032249)', ODM File OID: '589c5972-33e1-4a9d-96bf-bec59ba28fc4'	System	08 Jan 2021 06:02:58
User entered 'No (N)'	System	08 Jan 2021 06:02:58

US3032249

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:53:49

Have you been exposed to someone with 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 (898ced6280f9892f)', Time: '2021-01-08T00:02:41', User OID: 'PatientReportedOutcome (US3032249)', ODM File OID: '589c5972-33e1-4a9d-96bf-bec59ba28fc4'	System	08 Jan 2021 06:02:58
User entered 'No (N)'	System	08 Jan 2021 06:02:58

US3032249

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:53:49

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (898ced6280f9892f)', Time: '2021-01-08T00:02:53', User OID: 'PatientReportedOutcome (US3032249)', ODM File OID: '589c5972-33e1-4a9d-96bf-bec59ba28fc4' User entered '08 Jan 2021 00:02:53'	System	08 Jan 2021 06:02:58
	System	08 Jan 2021 06:02:58

US3032249

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:53:49

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:25:12
Amendment Manager: User entered '08 Jan 2021 00:01'	System	19 Nov 2020 23:25:12

US3032249

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:53:49

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:25:12
Amendment Manager: User entered '12 Jan 2021 23:59'	System	19 Nov 2020 23:25:12

US3032249

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:53:49

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:25:12
Amendment Manager: User entered 'Day 152'	System	19 Nov 2020 23:25:12

US3032249

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:53:49

[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 (898ced6280f9892f)', Time: '2021-01-15T02:43:04', User OID: 'PatientReportedOutcome (US3032249)', ODM File OID: 'a73d5843-aaa8-4d15-b33f-a1a893060aa2'	System	15 Jan 2021 08:43:17
User entered 'No (N)'	System	15 Jan 2021 08:43:17

US3032249

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:53:49

[Have you been exposed to someone with 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 (898ced6280f9892f)', Time: '2021-01-15T02:43:09', User OID: 'PatientReportedOutcome (US3032249)', ODM File OID: 'a73d5843-aaa8-4d15-b33f-a1a893060aa2'	System	15 Jan 2021 08:43:17
User entered 'No (N)'	System	15 Jan 2021 08:43:17

US3032249

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:53:49

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (898ced6280f9892f)', Time: '2021-01-15T02:43:14', User OID: 'PatientReportedOutcome (US3032249)', ODM File OID: 'a73d5843-aaa8-4d15-b33f-a1a893060aa2'	System	15 Jan 2021 08:43:17
User entered '15 Jan 2021 02:43:14'	System	15 Jan 2021 08:43:17

US3032249

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:53:49

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:25:12
Amendment Manager: User entered '15 Jan 2021 00:01'	System	19 Nov 2020 23:25:12

US3032249

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:53:49

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:25:12
Amendment Manager: User entered '19 Jan 2021 23:59'	System	19 Nov 2020 23:25:12

US3032249

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:53:49

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:25:12
Amendment Manager: User entered 'Day 159'	System	19 Nov 2020 23:25:12

US3032249

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:53:49

[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 (898ced6280f9892f)', Time: '2021-01-23T14:23:20', User OID: 'PatientReportedOutcome (US3032249)', ODM File OID: 'f7f14126-693b-4636-b39b-4cd55e50cc4e'	System	23 Jan 2021 20:23:38
User entered 'No (N)'	System	23 Jan 2021 20:23:38

US3032249

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:53:49

Have you been exposed to someone with 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 (898ced6280f9892f)', Time: '2021-01-23T14:23:25', User OID: 'PatientReportedOutcome (US3032249)', ODM File OID: 'f7f14126-693b-4636-b39b-4cd55e50cc4e'	System	23 Jan 2021 20:23:38
User entered 'No (N)'	System	23 Jan 2021 20:23:38

US3032249

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:53:49

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (898ced6280f9892f)', Time: '2021-01-23T14:23:35', User OID: 'PatientReportedOutcome (US3032249)', ODM File OID: 'f7f14126-693b-4636-b39b-4cd55e50cc4e'	System	23 Jan 2021 20:23:38
User entered '23 Jan 2021 14:23:35'	System	23 Jan 2021 20:23:38

US3032249

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:53:49

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:25:12
Amendment Manager: User entered '22 Jan 2021 00:01'	System	19 Nov 2020 23:25:12

US3032249

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:53:49

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:25:12
Amendment Manager: User entered '26 Jan 2021 23:59'	System	19 Nov 2020 23:25:12

US3032249

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:53:49

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:25:12
Amendment Manager: User entered 'Day 166'	System	19 Nov 2020 23:25:12

US3032249

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:53:49

[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 (898ced6280f9892f)', Time: '2021-01-29T00:25:57', User OID: 'PatientReportedOutcome (US3032249)', ODM File OID: 'd903006b-4c6a-4c33-87e2-1ecb792574d2'	System	29 Jan 2021 06:26:15
User entered 'No (N)'	System	29 Jan 2021 06:26:15

US3032249

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:53:49

Have you been exposed to someone with 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 (898ced6280f9892f)', Time: '2021-01-29T00:26:02', User OID: 'PatientReportedOutcome (US3032249)', ODM File OID: 'd903006b-4c6a-4c33-87e2-1ecb792574d2'	System	29 Jan 2021 06:26:15
User entered 'No (N)'	System	29 Jan 2021 06:26:15

US3032249

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:53:49

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (898ced6280f9892f)', Time: '2021-01-29T00:26:10', User OID: 'PatientReportedOutcome (US3032249)', ODM File OID: 'd903006b-4c6a-4c33-87e2-1ecb792574d2'	System	29 Jan 2021 06:26:15
User entered '29 Jan 2021 00:26:10'	System	29 Jan 2021 06:26:15

US3032249

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:53:49

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:25:12
Amendment Manager: User entered '29 Jan 2021 00:01'	System	19 Nov 2020 23:25:12

US3032249

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:53:49

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:25:12
Amendment Manager: User entered '02 Feb 2021 23:59'	System	19 Nov 2020 23:25:12

US3032249

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:53:49

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:25:12
Amendment Manager: User entered 'Day 173'	System	19 Nov 2020 23:25:12

US3032249

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:53:49

[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 (898ced6280f9892f)', Time: '2021-02-05T21:56:28', User OID: 'PatientReportedOutcome (US3032249)', ODM File OID: 'a300ae7e-c596-4f83-ab48-48f34b6b2928'	System	06 Feb 2021 04:02:11
User entered 'Yes (Y)'	System	06 Feb 2021 04:02:11

US3032249

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:53:49

Have you been exposed to someone with 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 (898ced6280f9892f)', Time: '2021-02-05T21:56:51', User OID: 'PatientReportedOutcome (US3032249)', ODM File OID: 'a300ae7e-c596-4f83-ab48-48f34b6b2928'	System	06 Feb 2021 04:02:11
User entered 'Yes (Y)'	System	06 Feb 2021 04:02:11

US3032249

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:53:49

Please 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 (898ced6280f9892f)', Time: '2021-02-05T21:57:11', User OID: 'PatientReportedOutcome (US3032249)', ODM File OID: 'a300ae7e-c596-4f83-ab48-48f34b6b2928'	System	06 Feb 2021 04:02:11
User entered 'I confirm I have read this message and will call the study clinic immediately (9)'	System	06 Feb 2021 04:02:11

US3032249

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:53:49

[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 (898ced6280f9892f)', Time: '2021-02-05T21:57:25', User OID: 'PatientReportedOutcome (US3032249)', ODM File OID: 'a300ae7e-c596-4f83-ab48-48f34b6b2928'	System	06 Feb 2021 04:02:11
User entered 'Yes (Y)'	System	06 Feb 2021 04:02:11

US3032249

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:53:49

[Fever \(Temperature \$\geq\$ 100.4°F/38°C\)](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (898ced6280f9892f)', Time: '2021-02-05T21:58:49', User OID: 'PatientReportedOutcome (US3032249)', ODM File OID: 'a300ae7e-c596-4f83-ab48-48f34b6b2928'	System	06 Feb 2021 04:02:11
User entered '1'	System	06 Feb 2021 04:02:11

US3032249

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:53:49

[Chills](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (898ced6280f9892f)', Time: '2021-02-05T21:58:49', User OID: 'PatientReportedOutcome (US3032249)', ODM File OID: 'a300ae7e-c596-4f83-ab48-48f34b6b2928'	System	06 Feb 2021 04:02:11
User entered '1'	System	06 Feb 2021 04:02:11

US3032249

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:53:49

[Cough](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (898ced6280f9892f)', Time: '2021-02-05T21:58:49', User OID: 'PatientReportedOutcome (US3032249)', ODM File OID: 'a300ae7e-c596-4f83-ab48-48f34b6b2928'	System	06 Feb 2021 04:02:11
User entered '1'	System	06 Feb 2021 04:02:11

US3032249

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:53:49

[Shortness of breath](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (898ced6280f9892f)', Time: '2021-02-05T21:58:49', User OID: 'PatientReportedOutcome (US3032249)', ODM File OID: 'a300ae7e-c596-4f83-ab48-48f34b6b2928'	System	06 Feb 2021 04:02:11
User entered '1'	System	06 Feb 2021 04:02:11

US3032249

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:53:49

[Difficulty breathing](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (898ced6280f9892f)', Time: '2021-02-05T21:58:49', User OID: 'PatientReportedOutcome (US3032249)', ODM File OID: 'a300ae7e-c596-4f83-ab48-48f34b6b2928'	System	06 Feb 2021 04:02:11
User entered '0'	System	06 Feb 2021 04:02:11

US3032249

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:53:49

[Fatigue](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (898ced6280f9892f)', Time: '2021-02-05T21:58:49', User OID: 'PatientReportedOutcome (US3032249)', ODM File OID: 'a300ae7e-c596-4f83-ab48-48f34b6b2928'	System	06 Feb 2021 04:02:11
User entered '1'	System	06 Feb 2021 04:02:11

US3032249

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:53:49

[Muscle aches](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (898ced6280f9892f)', Time: '2021-02-05T21:58:49', User OID: 'PatientReportedOutcome (US3032249)', ODM File OID: 'a300ae7e-c596-4f83-ab48-48f34b6b2928'	System	06 Feb 2021 04:02:11
User entered '0'	System	06 Feb 2021 04:02:11

US3032249

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:53:49

[Body aches](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (898ced6280f9892f)', Time: '2021-02-05T21:58:49', User OID: 'PatientReportedOutcome (US3032249)', ODM File OID: 'a300ae7e-c596-4f83-ab48-48f34b6b2928'	System	06 Feb 2021 04:02:11
User entered '0'	System	06 Feb 2021 04:02:11

US3032249

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:53:49

[Headache](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (898ced6280f9892f)', Time: '2021-02-05T21:58:49', User OID: 'PatientReportedOutcome (US3032249)', ODM File OID: 'a300ae7e-c596-4f83-ab48-48f34b6b2928'	System	06 Feb 2021 04:02:11
User entered '0'	System	06 Feb 2021 04:02:11

US3032249

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:53:49

[New loss of taste](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (898ced6280f9892f)', Time: '2021-02-05T21:58:49', User OID: 'PatientReportedOutcome (US3032249)', ODM File OID: 'a300ae7e-c596-4f83-ab48-48f34b6b2928'	System	06 Feb 2021 04:02:11
User entered '0'	System	06 Feb 2021 04:02:11

US3032249

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:53:49

[New loss of smell](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (898ced6280f9892f)', Time: '2021-02-05T21:58:49', User OID: 'PatientReportedOutcome (US3032249)', ODM File OID: 'a300ae7e-c596-4f83-ab48-48f34b6b2928'	System	06 Feb 2021 04:02:11
User entered '0'	System	06 Feb 2021 04:02:11

US3032249

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:53:49

[Sore throat](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (898ced6280f9892f)', Time: '2021-02-05T21:58:49', User OID: 'PatientReportedOutcome (US3032249)', ODM File OID: 'a300ae7e-c596-4f83-ab48-48f34b6b2928'	System	06 Feb 2021 04:02:11
User entered '1'	System	06 Feb 2021 04:02:11

US3032249

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:53:49

[Congestion](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (898ced6280f9892f)', Time: '2021-02-05T21:58:49', User OID: 'PatientReportedOutcome (US3032249)', ODM File OID: 'a300ae7e-c596-4f83-ab48-48f34b6b2928'	System	06 Feb 2021 04:02:11
User entered '1'	System	06 Feb 2021 04:02:11

US3032249

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:53:49

[Runny nose](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (898ced6280f9892f)', Time: '2021-02-05T21:58:49', User OID: 'PatientReportedOutcome (US3032249)', ODM File OID: 'a300ae7e-c596-4f83-ab48-48f34b6b2928'	System	06 Feb 2021 04:02:11
User entered '0'	System	06 Feb 2021 04:02:11

US3032249

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:53:49

[Nausea](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (898ced6280f9892f)', Time: '2021-02-05T21:58:49', User OID: 'PatientReportedOutcome (US3032249)', ODM File OID: 'a300ae7e-c596-4f83-ab48-48f34b6b2928'	System	06 Feb 2021 04:02:11
User entered '0'	System	06 Feb 2021 04:02:11

US3032249

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:53:49

[Vomiting](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (898ced6280f9892f)', Time: '2021-02-05T21:58:49', User OID: 'PatientReportedOutcome (US3032249)', ODM File OID: 'a300ae7e-c596-4f83-ab48-48f34b6b2928'	System	06 Feb 2021 04:02:11
User entered '0'	System	06 Feb 2021 04:02:11

US3032249

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:53:49

[Diarrhea](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (898ced6280f9892f)', Time: '2021-02-05T21:58:49', User OID: 'PatientReportedOutcome (US3032249)', ODM File OID: 'a300ae7e-c596-4f83-ab48-48f34b6b2928'	System	06 Feb 2021 04:02:11
User entered '0'	System	06 Feb 2021 04:02:11

US3032249

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:53:49

[Please 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 (898ced6280f9892f)', Time: '2021-02-05T21:59:05', User OID: 'PatientReportedOutcome (US3032249)', ODM File OID: 'a300ae7e-c596-4f83-ab48-48f34b6b2928'	System	06 Feb 2021 04:02:11
User entered 'I confirm I have read this message and will call the study clinic immediately (9)'	System	06 Feb 2021 04:02:11

US3032249

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:53:49

[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 (898ced6280f9892f)', Time: '2021-02-05T21:59:28', User OID: 'PatientReportedOutcome (US3032249)', ODM File OID: 'a300ae7e-c596-4f83-ab48-48f34b6b2928'	System	06 Feb 2021 04:02:11
User entered 'Yes (Y)'	System	06 Feb 2021 04:02:11

US3032249

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:53:49

Please 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 (898ced6280f9892f)', Time: '2021-02-05T21:59:45', User OID: 'PatientReportedOutcome (US3032249)', ODM File OID: 'a300ae7e-c596-4f83-ab48-48f34b6b2928'	System	06 Feb 2021 04:02:11
User entered 'I confirm I have read this message and will call the study clinic immediately (9)'	System	06 Feb 2021 04:02:11

US3032249

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:53:49

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (898ced6280f9892f)', Time: '2021-02-05T22:01:59', User OID: 'PatientReportedOutcome (US3032249)', ODM File OID: 'a300ae7e-c596-4f83-ab48-48f34b6b2928'	System	06 Feb 2021 04:02:11
User entered '05 Feb 2021 22:01:59'	System	06 Feb 2021 04:02:11

US3032249

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:53:49

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:25:12
Amendment Manager: User entered '05 Feb 2021 00:01'	System	19 Nov 2020 23:25:12

US3032249

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:53:49

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:25:12
Amendment Manager: User entered '09 Feb 2021 23:59'	System	19 Nov 2020 23:25:12

US3032249

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:53:49

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:25:12
Amendment Manager: User entered 'Day 180'	System	19 Nov 2020 23:25:12

US3032249

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:53:49

[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 (898ced6280f9892f)', Time: '2021-02-12T19:21:49', User OID: 'PatientReportedOutcome (US3032249)', ODM File OID: '126898c2-6519-4f76-a0ab-72a172559763'	System	13 Feb 2021 01:26:49
User entered 'Yes (Y)'	System	13 Feb 2021 01:26:49

US3032249

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:53:49

Have you been exposed to someone with 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 (898ced6280f9892f)', Time: '2021-02-12T19:23:06', User OID: 'PatientReportedOutcome (US3032249)', ODM File OID: '126898c2-6519-4f76-a0ab-72a172559763'	System	13 Feb 2021 01:26:49
User entered 'Yes (Y)'	System	13 Feb 2021 01:26:49

US3032249

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:53:49

Please 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 (898ced6280f9892f)', Time: '2021-02-12T19:22:51', User OID: 'PatientReportedOutcome (US3032249)', ODM File OID: '126898c2-6519-4f76-a0ab-72a172559763'	System	13 Feb 2021 01:26:49
User entered 'I confirm I have read this message and will call the study clinic immediately (9)'	System	13 Feb 2021 01:26:49

US3032249

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:53:49

[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 (898ced6280f9892f)', Time: '2021-02-12T19:22:50', User OID: 'PatientReportedOutcome (US3032249)', ODM File OID: '126898c2-6519-4f76-a0ab-72a172559763'	System	13 Feb 2021 01:26:49
User entered 'Yes (Y)'	System	13 Feb 2021 01:26:49

US3032249

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:53:49

[Fever \(Temperature \$\geq\$ 100.4°F/38°C\)](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (898ced6280f9892f)', Time: '2021-02-12T19:23:48', User OID: 'PatientReportedOutcome (US3032249)', ODM File OID: '126898c2-6519-4f76-a0ab-72a172559763'	System	13 Feb 2021 01:26:49
User entered '1'	System	13 Feb 2021 01:26:49

US3032249

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:53:49

[Chills](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (898ced6280f9892f)', Time: '2021-02-12T19:23:48', User OID: 'PatientReportedOutcome (US3032249)', ODM File OID: '126898c2-6519-4f76-a0ab-72a172559763'	System	13 Feb 2021 01:26:49
User entered '1'	System	13 Feb 2021 01:26:49

US3032249

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:53:49

[Cough](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (898ced6280f9892f)', Time: '2021-02-12T19:23:48', User OID: 'PatientReportedOutcome (US3032249)', ODM File OID: '126898c2-6519-4f76-a0ab-72a172559763'	System	13 Feb 2021 01:26:49
User entered '1'	System	13 Feb 2021 01:26:49

US3032249

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:53:49

[Shortness of breath](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (898ced6280f9892f)', Time: '2021-02-12T19:23:48', User OID: 'PatientReportedOutcome (US3032249)', ODM File OID: '126898c2-6519-4f76-a0ab-72a172559763'	System	13 Feb 2021 01:26:49
User entered '1'	System	13 Feb 2021 01:26:49

US3032249

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:53:49

[Difficulty breathing](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (898ced6280f9892f)', Time: '2021-02-12T19:23:48', User OID: 'PatientReportedOutcome (US3032249)', ODM File OID: '126898c2-6519-4f76-a0ab-72a172559763'	System	13 Feb 2021 01:26:49
User entered '1'	System	13 Feb 2021 01:26:49

US3032249

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:53:49

[Fatigue](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (898ced6280f9892f)', Time: '2021-02-12T19:23:48', User OID: 'PatientReportedOutcome (US3032249)', ODM File OID: '126898c2-6519-4f76-a0ab-72a172559763'	System	13 Feb 2021 01:26:49
User entered '1'	System	13 Feb 2021 01:26:49

US3032249

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:53:49

[Muscle aches](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (898ced6280f9892f)', Time: '2021-02-12T19:23:48', User OID: 'PatientReportedOutcome (US3032249)', ODM File OID: '126898c2-6519-4f76-a0ab-72a172559763'	System	13 Feb 2021 01:26:49
User entered '0'	System	13 Feb 2021 01:26:49

US3032249

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:53:49

[Body aches](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (898ced6280f9892f)', Time: '2021-02-12T19:23:48', User OID: 'PatientReportedOutcome (US3032249)', ODM File OID: '126898c2-6519-4f76-a0ab-72a172559763'	System	13 Feb 2021 01:26:49
User entered '1'	System	13 Feb 2021 01:26:49

US3032249

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:53:49

[Headache](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (898ced6280f9892f)', Time: '2021-02-12T19:23:48', User OID: 'PatientReportedOutcome (US3032249)', ODM File OID: '126898c2-6519-4f76-a0ab-72a172559763'	System	13 Feb 2021 01:26:49
User entered '1'	System	13 Feb 2021 01:26:49

US3032249

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:53:49

[New loss of taste](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (898ced6280f9892f)', Time: '2021-02-12T19:23:48', User OID: 'PatientReportedOutcome (US3032249)', ODM File OID: '126898c2-6519-4f76-a0ab-72a172559763'	System	13 Feb 2021 01:26:49
User entered '1'	System	13 Feb 2021 01:26:49

US3032249

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:53:49

[New loss of smell](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (898ced6280f9892f)', Time: '2021-02-12T19:23:48', User OID: 'PatientReportedOutcome (US3032249)', ODM File OID: '126898c2-6519-4f76-a0ab-72a172559763'	System	13 Feb 2021 01:26:49
User entered '1'	System	13 Feb 2021 01:26:49

US3032249

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:53:49

[Sore throat](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (898ced6280f9892f)', Time: '2021-02-12T19:23:48', User OID: 'PatientReportedOutcome (US3032249)', ODM File OID: '126898c2-6519-4f76-a0ab-72a172559763'	System	13 Feb 2021 01:26:49
User entered '1'	System	13 Feb 2021 01:26:49

US3032249

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:53:49

[Congestion](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (898ced6280f9892f)', Time: '2021-02-12T19:23:48', User OID: 'PatientReportedOutcome (US3032249)', ODM File OID: '126898c2-6519-4f76-a0ab-72a172559763'	System	13 Feb 2021 01:26:49
User entered '1'	System	13 Feb 2021 01:26:49

US3032249

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:53:49

[Runny nose](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (898ced6280f9892f)', Time: '2021-02-12T19:23:48', User OID: 'PatientReportedOutcome (US3032249)', ODM File OID: '126898c2-6519-4f76-a0ab-72a172559763'	System	13 Feb 2021 01:26:49
User entered '1'	System	13 Feb 2021 01:26:49

US3032249

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:53:49

[Nausea](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (898ced6280f9892f)', Time: '2021-02-12T19:23:48', User OID: 'PatientReportedOutcome (US3032249)', ODM File OID: '126898c2-6519-4f76-a0ab-72a172559763'	System	13 Feb 2021 01:26:49
User entered '1'	System	13 Feb 2021 01:26:49

US3032249

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:53:49

[Vomiting](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (898ced6280f9892f)', Time: '2021-02-12T19:23:48', User OID: 'PatientReportedOutcome (US3032249)', ODM File OID: '126898c2-6519-4f76-a0ab-72a172559763'	System	13 Feb 2021 01:26:49
User entered '0'	System	13 Feb 2021 01:26:49

US3032249

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:53:49

[Diarrhea](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (898ced6280f9892f)', Time: '2021-02-12T19:23:48', User OID: 'PatientReportedOutcome (US3032249)', ODM File OID: '126898c2-6519-4f76-a0ab-72a172559763'	System	13 Feb 2021 01:26:49
User entered '1'	System	13 Feb 2021 01:26:49

US3032249

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:53:49

[Please 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 (898ced6280f9892f)', Time: '2021-02-12T19:24:19', User OID: 'PatientReportedOutcome (US3032249)', ODM File OID: '126898c2-6519-4f76-a0ab-72a172559763'	System	13 Feb 2021 01:26:49
User entered 'I confirm I have read this message and will call the study clinic immediately (9)'	System	13 Feb 2021 01:26:49

US3032249

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:53:49

[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 (898ced6280f9892f)', Time: '2021-02-12T19:24:32', User OID: 'PatientReportedOutcome (US3032249)', ODM File OID: '126898c2-6519-4f76-a0ab-72a172559763'	System	13 Feb 2021 01:26:49
User entered 'Yes (Y)'	System	13 Feb 2021 01:26:49

US3032249

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:53:49

Please 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 (898ced6280f9892f)', Time: '2021-02-12T19:24:52', User OID: 'PatientReportedOutcome (US3032249)', ODM File OID: '126898c2-6519-4f76-a0ab-72a172559763'	System	13 Feb 2021 01:26:49
User entered 'I confirm I have read this message and will call the study clinic immediately (9)'	System	13 Feb 2021 01:26:49

US3032249

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:53:49

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (898ced6280f9892f)', Time: '2021-02-12T19:26:33', User OID: 'PatientReportedOutcome (US3032249)', ODM File OID: '126898c2-6519-4f76-a0ab-72a172559763'	System	13 Feb 2021 01:26:49
User entered '12 Feb 2021 19:26:33'	System	13 Feb 2021 01:26:49

US3032249

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:53:49

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:25:12
Amendment Manager: User entered '12 Feb 2021 00:01'	System	19 Nov 2020 23:25:12

US3032249

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:53:49

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:25:12
Amendment Manager: User entered '16 Feb 2021 23:59'	System	19 Nov 2020 23:25:12

US3032249

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:53:49

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:25:12
Amendment Manager: User entered 'Day 187'	System	19 Nov 2020 23:25:12

US3032249

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:53:49

[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 (898ced6280f9892f)', Time: '2021-02-19T12:02:52', User OID: 'PatientReportedOutcome (US3032249)', ODM File OID: 'e37ff258-3037-4efb-becf-679a29159d08'	System	19 Feb 2021 18:06:46
User entered 'No (N)'	System	19 Feb 2021 18:06:46

US3032249

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:53:49

Have you been exposed to someone with 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 (898ced6280f9892f)', Time: '2021-02-19T12:03:14', User OID: 'PatientReportedOutcome (US3032249)', ODM File OID: 'e37ff258-3037-4efb-becf-679a29159d08'	System	19 Feb 2021 18:06:46
User entered 'No (N)'	System	19 Feb 2021 18:06:46

US3032249

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:53:49

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (898ced6280f9892f)', Time: '2021-02-19T12:03:25', User OID: 'PatientReportedOutcome (US3032249)', ODM File OID: 'e37ff258-3037-4efb-becf-679a29159d08'	System	19 Feb 2021 18:06:46
User entered '19 Feb 2021 12:03:25'	System	19 Feb 2021 18:06:46

US3032249

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:53:49

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:25:12
Amendment Manager: User entered '19 Feb 2021 00:01'	System	19 Nov 2020 23:25:12

US3032249

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:53:49

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:25:12
Amendment Manager: User entered '23 Feb 2021 23:59'	System	19 Nov 2020 23:25:12

US3032249

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:53:49

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:25:12
Amendment Manager: User entered 'Day 194'	System	19 Nov 2020 23:25:12

US3032249

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:53:49

[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 (898ced6280f9892f)', Time: '2021-02-27T02:33:35', User OID: 'PatientReportedOutcome (US3032249)', ODM File OID: 'b605b075-d9f0-4c19-bc58-002535a42409'	System	27 Feb 2021 08:33:57
User entered 'No (N)'	System	27 Feb 2021 08:33:57

US3032249

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:53:49

Have you been exposed to someone with 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 (898ced6280f9892f)', Time: '2021-02-27T02:33:48', User OID: 'PatientReportedOutcome (US3032249)', ODM File OID: 'b605b075-d9f0-4c19-bc58-002535a42409'	System	27 Feb 2021 08:33:57
User entered 'No (N)'	System	27 Feb 2021 08:33:57

US3032249

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:53:49

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (898ced6280f9892f)', Time: '2021-02-27T02:33:53', User OID: 'PatientReportedOutcome (US3032249)', ODM File OID: 'b605b075-d9f0-4c19-bc58-002535a42409'	System	27 Feb 2021 08:33:57
User entered '27 Feb 2021 02:33:53'	System	27 Feb 2021 08:33:57

US3032249

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:53:49

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:25:12
Amendment Manager: User entered '26 Feb 2021 00:01'	System	19 Nov 2020 23:25:12

US3032249

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:53:49

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:25:12
Amendment Manager: User entered '02 Mar 2021 23:59'	System	19 Nov 2020 23:25:12

US3032249

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:53:49

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:25:12
Amendment Manager: User entered 'Day 201'	System	19 Nov 2020 23:25:12

US3032249

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:53:49

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:25:12
Amendment Manager: User entered '05 Mar 2021 00:01'	System	19 Nov 2020 23:25:12

US3032249

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:53:49

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:25:12
Amendment Manager: User entered '09 Mar 2021 23:59'	System	19 Nov 2020 23:25:12

US3032249

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:53:49

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:25:12
Amendment Manager: User entered 'Day 208'	System	19 Nov 2020 23:25:12

US3032249

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:53:49

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:25:12
Amendment Manager: User entered '12 Mar 2021 00:01'	System	19 Nov 2020 23:25:12

US3032249

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:53:49

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:25:12
Amendment Manager: User entered '16 Mar 2021 23:59'	System	19 Nov 2020 23:25:12

US3032249

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:53:49

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:25:12
Amendment Manager: User entered 'Day 215'	System	19 Nov 2020 23:25:12

US3032249

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:53:49

[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 (898ced6280f9892f)', Time: '2021-03-21T16:33:26', User OID: 'PatientReportedOutcome (US3032249)', ODM File OID: 'f68a4007-78ea-4c9c-869d-f08dfc5af2e1'	System	21 Mar 2021 21:34:38
User entered 'Yes (Y)'	System	21 Mar 2021 21:34:38

US3032249

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:53:49

Have you been exposed to someone with 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 (898ced6280f9892f)', Time: '2021-03-21T16:33:39', User OID: 'PatientReportedOutcome (US3032249)', ODM File OID: 'f68a4007-78ea-4c9c-869d-f08dfc5af2e1'	System	21 Mar 2021 21:34:38
User entered 'No (N)'	System	21 Mar 2021 21:34:38

US3032249

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:53:49

[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 (898ced6280f9892f)', Time: '2021-03-21T16:33:49', User OID: 'PatientReportedOutcome (US3032249)', ODM File OID: 'f68a4007-78ea-4c9c-869d-f08dfc5af2e1'	System	21 Mar 2021 21:34:38
User entered 'No (N)'	System	21 Mar 2021 21:34:38

US3032249

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:53:49

[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 (898ced6280f9892f)', Time: '2021-03-21T16:34:01', User OID: 'PatientReportedOutcome (US3032249)', ODM File OID: 'f68a4007-78ea-4c9c-869d-f08dfc5af2e1'	System	21 Mar 2021 21:34:38
User entered 'Yes (Y)'	System	21 Mar 2021 21:34:38

US3032249

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:53:49

[Please 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 (898ced6280f9892f)', Time: '2021-03-21T16:34:12', User OID: 'PatientReportedOutcome (US3032249)', ODM File OID: 'f68a4007-78ea-4c9c-869d-f08dfc5af2e1'	System	21 Mar 2021 21:34:38
User entered 'I confirm I have read this message and will call the study clinic immediately (9)'	System	21 Mar 2021 21:34:38

US3032249

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:53:49

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (898ced6280f9892f)', Time: '2021-03-21T16:34:26', User OID: 'PatientReportedOutcome (US3032249)', ODM File OID: 'f68a4007-78ea-4c9c-869d-f08dfc5af2e1' User entered '21 Mar 2021 16:34:26'	System	21 Mar 2021 21:34:38
	System	21 Mar 2021 21:34:38

US3032249

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:53:49

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:25:12
Amendment Manager: User entered '19 Mar 2021 00:01'	System	19 Nov 2020 23:25:12

US3032249

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:53:49

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:25:12
Amendment Manager: User entered '23 Mar 2021 23:59'	System	19 Nov 2020 23:25:12

US3032249

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:53:49

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:25:12
Amendment Manager: User entered 'Day 222'	System	19 Nov 2020 23:25:12

US3032249

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:53:49

[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 (898ced6280f9892f)', Time: '2021-03-29T15:12:49', User OID: 'PatientReportedOutcome (US3032249)', ODM File OID: '5ebe7156-8d0f-4940-a478-17314e560454'	System	29 Mar 2021 20:13:19
User entered 'No (N)'	System	29 Mar 2021 20:13:19

US3032249

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:53:49

Have you been exposed to someone with 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 (898ced6280f9892f)', Time: '2021-03-29T15:12:54', User OID: 'PatientReportedOutcome (US3032249)', ODM File OID: '5ebe7156-8d0f-4940-a478-17314e560454'	System	29 Mar 2021 20:13:19
User entered 'No (N)'	System	29 Mar 2021 20:13:19

US3032249

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:53:49

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (898ced6280f9892f)', Time: '2021-03-29T15:13:08', User OID: 'PatientReportedOutcome (US3032249)', ODM File OID: '5ebe7156-8d0f-4940-a478-17314e560454'	System	29 Mar 2021 20:13:19
User entered '29 Mar 2021 15:13:08'	System	29 Mar 2021 20:13:19

US3032249

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:53:49

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:25:12
Amendment Manager: User entered '26 Mar 2021 00:01'	System	19 Nov 2020 23:25:12

US3032249

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:53:49

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:25:12
Amendment Manager: User entered '30 Mar 2021 23:59'	System	19 Nov 2020 23:25:12

US3032249

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:53:49

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:25:12
Amendment Manager: User entered 'Day 229'	System	19 Nov 2020 23:25:12

US3032249

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:53:49

[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 (898ced6280f9892f)', Time: '2021-04-02T00:01:43', User OID: 'PatientReportedOutcome (US3032249)', ODM File OID: '7ae768ab-7069-4a1b-9bf5-bcd34b9f1b9b'	System	02 Apr 2021 05:02:13
User entered 'No (N)'	System	02 Apr 2021 05:02:13

US3032249

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:53:49

Have you been exposed to someone with 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 (898ced6280f9892f)', Time: '2021-04-02T00:01:54', User OID: 'PatientReportedOutcome (US3032249)', ODM File OID: '7ae768ab-7069-4a1b-9bf5-bcd34b9f1b9b'	System	02 Apr 2021 05:02:13
User entered 'No (N)'	System	02 Apr 2021 05:02:13

US3032249

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:53:49

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (898ced6280f9892f)', Time: '2021-04-02T00:02:08', User OID: 'PatientReportedOutcome (US3032249)', ODM File OID: '7ae768ab-7069-4a1b-9bf5-bcd34b9f1b9b'	System	02 Apr 2021 05:02:13
User entered '02 Apr 2021 00:02:08'	System	02 Apr 2021 05:02:13

US3032249

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:53:49

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:25:12
Amendment Manager: User entered '02 Apr 2021 00:01'	System	19 Nov 2020 23:25:12

US3032249

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:53:49

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:25:12
Amendment Manager: User entered '06 Apr 2021 23:59'	System	19 Nov 2020 23:25:12

US3032249

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:53:49

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:25:12
Amendment Manager: User entered 'Day 236'	System	19 Nov 2020 23:25:12

US3032249

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:53:49

[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 (898ced6280f9892f)', Time: '2021-04-09T00:01:36', User OID: 'PatientReportedOutcome (US3032249)', ODM File OID: 'c17abc74-0937-4c58-941e-79a5d1405d64'	System	09 Apr 2021 05:02:11
User entered 'No (N)'	System	09 Apr 2021 05:02:11

US3032249

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:53:49

[Have you been exposed to someone with 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 (898ced6280f9892f)', Time: '2021-04-09T00:01:56', User OID: 'PatientReportedOutcome (US3032249)', ODM File OID: 'c17abc74-0937-4c58-941e-79a5d1405d64'	System	09 Apr 2021 05:02:11
User entered 'No (N)'	System	09 Apr 2021 05:02:11

US3032249

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:53:49

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (898ced6280f9892f)', Time: '2021-04-09T00:02:06', User OID: 'PatientReportedOutcome (US3032249)', ODM File OID: 'c17abc74-0937-4c58-941e-79a5d1405d64'	System	09 Apr 2021 05:02:11
User entered '09 Apr 2021 00:02:06'	System	09 Apr 2021 05:02:11

US3032249

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:53:49

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:25:12
Amendment Manager: User entered '09 Apr 2021 00:01'	System	19 Nov 2020 23:25:12

US3032249

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:53:49

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:25:12
Amendment Manager: User entered '13 Apr 2021 23:59'	System	19 Nov 2020 23:25:12

US3032249

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:53:49

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:25:12
Amendment Manager: User entered 'Day 243'	System	19 Nov 2020 23:25:12

US3032249

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:53:49

[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 (898ced6280f9892f)', Time: '2021-04-20T11:51:00', User OID: 'PatientReportedOutcome (US3032249)', ODM File OID: '2269c5d6-ccc8-4f1b-b83d-b72968061117'	System	20 Apr 2021 16:51:32
User entered 'No (N)'	System	20 Apr 2021 16:51:32

US3032249

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:53:49

Have you been exposed to someone with 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 (898ced6280f9892f)', Time: '2021-04-20T11:51:13', User OID: 'PatientReportedOutcome (US3032249)', ODM File OID: '2269c5d6-ccc8-4f1b-b83d-b72968061117'	System	20 Apr 2021 16:51:32
User entered 'No (N)'	System	20 Apr 2021 16:51:32

US3032249

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:53:49

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (898ced6280f9892f)', Time: '2021-04-20T11:51:26', User OID: 'PatientReportedOutcome (US3032249)', ODM File OID: '2269c5d6-ccc8-4f1b-b83d-b72968061117'	System	20 Apr 2021 16:51:32
User entered '20 Apr 2021 11:51:26'	System	20 Apr 2021 16:51:32

US3032249

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:53:49

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:25:12
Amendment Manager: User entered '16 Apr 2021 00:01'	System	19 Nov 2020 23:25:12

US3032249

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:53:49

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:25:12
Amendment Manager: User entered '20 Apr 2021 23:59'	System	19 Nov 2020 23:25:12

US3032249

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:53:49

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:25:12
Amendment Manager: User entered 'Day 250'	System	19 Nov 2020 23:25:12

US3032249

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:53:49

[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 (898ced6280f9892f)', Time: '2021-04-23T00:27:26', User OID: 'PatientReportedOutcome (US3032249)', ODM File OID: '3d133b81-949e-4526-85e5-2c807655a692'	System	23 Apr 2021 05:28:40
User entered 'No (N)'	System	23 Apr 2021 05:28:40

US3032249

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:53:49

[Have you been exposed to someone with 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 (898ced6280f9892f)', Time: '2021-04-23T00:28:12', User OID: 'PatientReportedOutcome (US3032249)', ODM File OID: '3d133b81-949e-4526-85e5-2c807655a692'	System	23 Apr 2021 05:28:40
User entered 'No (N)'	System	23 Apr 2021 05:28:40

US3032249

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:53:49

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (898ced6280f9892f)', Time: '2021-04-23T00:28:35', User OID: 'PatientReportedOutcome (US3032249)', ODM File OID: '3d133b81-949e-4526-85e5-2c807655a692'	System	23 Apr 2021 05:28:40
User entered '23 Apr 2021 00:28:35'	System	23 Apr 2021 05:28:40

US3032249

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:53:49

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:25:12
Amendment Manager: User entered '23 Apr 2021 00:01'	System	19 Nov 2020 23:25:12

US3032249

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:53:49

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:25:12
Amendment Manager: User entered '27 Apr 2021 23:59'	System	19 Nov 2020 23:25:12

US3032249

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:53:49

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:25:12
Amendment Manager: User entered 'Day 257'	System	19 Nov 2020 23:25:12

US3032249

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:53:49

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:25:12
Amendment Manager: User entered '30 Apr 2021 00:01'	System	19 Nov 2020 23:25:12

US3032249

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:53:49

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:25:12
Amendment Manager: User entered '04 May 2021 23:59'	System	19 Nov 2020 23:25:12

US3032249

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:53:49

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:25:12
Amendment Manager: User entered 'Day 264'	System	19 Nov 2020 23:25:12

US3032249

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:53:49

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:25:12
Amendment Manager: User entered '07 May 2021 00:01'	System	19 Nov 2020 23:25:12

US3032249

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:53:49

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:25:12
Amendment Manager: User entered '11 May 2021 23:59'	System	19 Nov 2020 23:25:12

US3032249

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:53:49

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:25:12
Amendment Manager: User entered 'Day 271'	System	19 Nov 2020 23:25:12

US3032249

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:53:49

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:25:12
Amendment Manager: User entered '14 May 2021 00:01'	System	19 Nov 2020 23:25:12

US3032249

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:53:49

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:25:12
Amendment Manager: User entered '18 May 2021 23:59'	System	19 Nov 2020 23:25:12

US3032249

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:53:49

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:25:12
Amendment Manager: User entered 'Day 278'	System	19 Nov 2020 23:25:12

US3032249

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:53:49

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:25:12
Amendment Manager: User entered '21 May 2021 00:01'	System	19 Nov 2020 23:25:12

US3032249

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:53:49

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:25:12
Amendment Manager: User entered '25 May 2021 23:59'	System	19 Nov 2020 23:25:12

US3032249

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:53:49

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:25:12
Amendment Manager: User entered 'Day 285'	System	19 Nov 2020 23:25:12

US3032249

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:53:49

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:25:12
Amendment Manager: User entered '28 May 2021 00:01'	System	19 Nov 2020 23:25:12

US3032249

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:53:49

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:25:12
Amendment Manager: User entered '01 Jun 2021 23:59'	System	19 Nov 2020 23:25:12

US3032249

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:53:49

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:25:12
Amendment Manager: User entered 'Day 292'	System	19 Nov 2020 23:25:12

US3032249

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:53:49

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:25:12
Amendment Manager: User entered '04 Jun 2021 00:01'	System	19 Nov 2020 23:25:12

US3032249

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:53:49

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:25:12
Amendment Manager: User entered '08 Jun 2021 23:59'	System	19 Nov 2020 23:25:12

US3032249

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:53:49

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:25:12
Amendment Manager: User entered 'Day 299'	System	19 Nov 2020 23:25:12

US3032249

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:53:49

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:25:12
Amendment Manager: User entered '11 Jun 2021 00:01'	System	19 Nov 2020 23:25:12

US3032249

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:53:49

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:25:12
Amendment Manager: User entered '15 Jun 2021 23:59'	System	19 Nov 2020 23:25:12

US3032249

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:53:49

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:25:12
Amendment Manager: User entered 'Day 306'	System	19 Nov 2020 23:25:12

US3032249

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:53:49

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:25:12
Amendment Manager: User entered '18 Jun 2021 00:01'	System	19 Nov 2020 23:25:12

US3032249

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:53:49

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:25:12
Amendment Manager: User entered '22 Jun 2021 23:59'	System	19 Nov 2020 23:25:12

US3032249

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:53:49

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:25:12
Amendment Manager: User entered 'Day 313'	System	19 Nov 2020 23:25:12

US3032249

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:53:49

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:25:12
Amendment Manager: User entered '25 Jun 2021 00:01'	System	19 Nov 2020 23:25:12

US3032249

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:53:49

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:25:12
Amendment Manager: User entered '29 Jun 2021 23:59'	System	19 Nov 2020 23:25:12

US3032249

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:53:49

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:25:12
Amendment Manager: User entered 'Day 320'	System	19 Nov 2020 23:25:12

US3032249

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:53:49

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:25:12
Amendment Manager: User entered '02 Jul 2021 00:01'	System	19 Nov 2020 23:25:12

US3032249

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:53:49

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:25:12
Amendment Manager: User entered '06 Jul 2021 23:59'	System	19 Nov 2020 23:25:12

US3032249

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:53:49

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:25:12
Amendment Manager: User entered 'Day 327'	System	19 Nov 2020 23:25:12

US3032249

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:53:49

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:25:12
Amendment Manager: User entered '09 Jul 2021 00:01'	System	19 Nov 2020 23:25:12

US3032249

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:53:49

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:25:12
Amendment Manager: User entered '13 Jul 2021 23:59'	System	19 Nov 2020 23:25:12

US3032249

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:53:49

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:25:12
Amendment Manager: User entered 'Day 334'	System	19 Nov 2020 23:25:12

US3032249

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:53:49

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:25:12
Amendment Manager: User entered '16 Jul 2021 00:01'	System	19 Nov 2020 23:25:12

US3032249

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:53:49

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:25:12
Amendment Manager: User entered '20 Jul 2021 23:59'	System	19 Nov 2020 23:25:12

US3032249

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:53:49

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:25:12
Amendment Manager: User entered 'Day 341'	System	19 Nov 2020 23:25:12

US3032249

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:53:49

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:25:12
Amendment Manager: User entered '23 Jul 2021 00:01'	System	19 Nov 2020 23:25:12

US3032249

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:53:49

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:25:12
Amendment Manager: User entered '27 Jul 2021 23:59'	System	19 Nov 2020 23:25:12

US3032249

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:53:49

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:25:12
Amendment Manager: User entered 'Day 348'	System	19 Nov 2020 23:25:12

US3032249

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:53:49

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:25:12
Amendment Manager: User entered '30 Jul 2021 00:01'	System	19 Nov 2020 23:25:12

US3032249

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:53:49

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:25:12
Amendment Manager: User entered '03 Aug 2021 23:59'	System	19 Nov 2020 23:25:12

US3032249

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:53:49

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:25:12
Amendment Manager: User entered 'Day 355'	System	19 Nov 2020 23:25:12

US3032249

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:53:49

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:25:12
Amendment Manager: User entered '06 Aug 2021 00:01'	System	19 Nov 2020 23:25:12

US3032249

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:53:49

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:25:12
Amendment Manager: User entered '10 Aug 2021 23:59'	System	19 Nov 2020 23:25:12

US3032249

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:53:49

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:25:12
Amendment Manager: User entered 'Day 362'	System	19 Nov 2020 23:25:12

US3032249

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:53:49

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:25:12
Amendment Manager: User entered '13 Aug 2021 00:01'	System	19 Nov 2020 23:25:12

US3032249

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:53:49

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:25:12
Amendment Manager: User entered '17 Aug 2021 23:59'	System	19 Nov 2020 23:25:12

US3032249

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:53:49

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:25:12
Amendment Manager: User entered 'Day 369'	System	19 Nov 2020 23:25:12

US3032249

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:53:49

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:25:12
Amendment Manager: User entered '20 Aug 2021 00:01'	System	19 Nov 2020 23:25:12

US3032249

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:53:49

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:25:12
Amendment Manager: User entered '24 Aug 2021 23:59'	System	19 Nov 2020 23:25:12

US3032249

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:53:49

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:25:12
Amendment Manager: User entered 'Day 376'	System	19 Nov 2020 23:25:12

US3032249

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:53:49

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:25:12
Amendment Manager: User entered '27 Aug 2021 00:01'	System	19 Nov 2020 23:25:12

US3032249

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:53:49

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:25:12
Amendment Manager: User entered '31 Aug 2021 23:59'	System	19 Nov 2020 23:25:12

US3032249

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:53:49

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:25:12
Amendment Manager: User entered 'Day 383'	System	19 Nov 2020 23:25:12

US3032249

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:53:49

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:25:12
Amendment Manager: User entered '03 Sep 2021 00:01'	System	19 Nov 2020 23:25:12

US3032249

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:53:49

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:25:12
Amendment Manager: User entered '07 Sep 2021 23:59'	System	19 Nov 2020 23:25:12

US3032249

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:53:49

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:25:12
Amendment Manager: User entered 'Day 390'	System	19 Nov 2020 23:25:12

US3032249

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:53:49

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:25:12
Amendment Manager: User entered '10 Sep 2021 00:01'	System	19 Nov 2020 23:25:12

US3032249

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:53:49

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:25:12
Amendment Manager: User entered '14 Sep 2021 23:59'	System	19 Nov 2020 23:25:12

US3032249

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:53:49

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:25:12
Amendment Manager: User entered 'Day 397'	System	19 Nov 2020 23:25:12

US3032249

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:53:49

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:25:12
Amendment Manager: User entered '17 Sep 2021 00:01'	System	19 Nov 2020 23:25:12

US3032249

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:53:49

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:25:12
Amendment Manager: User entered '21 Sep 2021 23:59'	System	19 Nov 2020 23:25:12

US3032249

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:53:49

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:25:12
Amendment Manager: User entered 'Day 404'	System	19 Nov 2020 23:25:12

US3032249

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:53:49

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:25:12
Amendment Manager: User entered '24 Sep 2021 00:01'	System	19 Nov 2020 23:25:12

US3032249

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:53:49

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:25:12
Amendment Manager: User entered '28 Sep 2021 23:59'	System	19 Nov 2020 23:25:12

US3032249

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:53:49

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:25:12
Amendment Manager: User entered 'Day 411'	System	19 Nov 2020 23:25:12

US3032249

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:53:49

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:25:12
Amendment Manager: User entered '01 Oct 2021 00:01'	System	19 Nov 2020 23:25:12

US3032249

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:53:49

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:25:12
Amendment Manager: User entered '05 Oct 2021 23:59'	System	19 Nov 2020 23:25:12

US3032249

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:53:49

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:25:12
Amendment Manager: User entered 'Day 418'	System	19 Nov 2020 23:25:12

US3032249

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:53:49

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:25:12
Amendment Manager: User entered '08 Oct 2021 00:01'	System	19 Nov 2020 23:25:12

US3032249

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:53:49

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:25:12
Amendment Manager: User entered '12 Oct 2021 23:59'	System	19 Nov 2020 23:25:12

US3032249

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:53:49

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:25:12
Amendment Manager: User entered 'Day 425'	System	19 Nov 2020 23:25:12

US3032249

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:53:49

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:25:12
Amendment Manager: User entered '15 Oct 2021 00:01'	System	19 Nov 2020 23:25:12

US3032249

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:53:49

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:25:12
Amendment Manager: User entered '19 Oct 2021 23:59'	System	19 Nov 2020 23:25:12

US3032249

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:53:49

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:25:12
Amendment Manager: User entered 'Day 432'	System	19 Nov 2020 23:25:12

US3032249

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:53:49

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:25:12
Amendment Manager: User entered '22 Oct 2021 00:01'	System	19 Nov 2020 23:25:12

US3032249

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:53:49

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:25:12
Amendment Manager: User entered '26 Oct 2021 23:59'	System	19 Nov 2020 23:25:12

US3032249

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:53:49

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:25:12
Amendment Manager: User entered 'Day 439'	System	19 Nov 2020 23:25:12

US3032249

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:53:49

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:25:12
Amendment Manager: User entered '29 Oct 2021 00:01'	System	19 Nov 2020 23:25:12

US3032249

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:53:49

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:25:12
Amendment Manager: User entered '02 Nov 2021 23:59'	System	19 Nov 2020 23:25:12

US3032249

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:53:49

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:25:12
Amendment Manager: User entered 'Day 446'	System	19 Nov 2020 23:25:12

US3032249

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:53:49

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:25:12
Amendment Manager: User entered '05 Nov 2021 00:01'	System	19 Nov 2020 23:25:12

US3032249

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:53:49

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:25:12
Amendment Manager: User entered '09 Nov 2021 23:59'	System	19 Nov 2020 23:25:12

US3032249

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:53:49

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:25:12
Amendment Manager: User entered 'Day 453'	System	19 Nov 2020 23:25:12

US3032249

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:53:49

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:25:12
Amendment Manager: User entered '12 Nov 2021 00:01'	System	19 Nov 2020 23:25:12

US3032249

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:53:49

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:25:12
Amendment Manager: User entered '16 Nov 2021 23:59'	System	19 Nov 2020 23:25:12

US3032249

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:53:49

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:25:12
Amendment Manager: User entered 'Day 460'	System	19 Nov 2020 23:25:12

US3032249

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:53:49

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:25:12
Amendment Manager: User entered '19 Nov 2021 00:01'	System	19 Nov 2020 23:25:12

US3032249

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:53:49

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:25:12
Amendment Manager: User entered '23 Nov 2021 23:59'	System	19 Nov 2020 23:25:12

US3032249

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:53:49

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:25:12
Amendment Manager: User entered 'Day 467'	System	19 Nov 2020 23:25:12

US3032249

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:53:49

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:25:12
Amendment Manager: User entered '26 Nov 2021 00:01'	System	19 Nov 2020 23:25:12

US3032249

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:53:49

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:25:12
Amendment Manager: User entered '30 Nov 2021 23:59'	System	19 Nov 2020 23:25:12

US3032249

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:53:49

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:25:12
Amendment Manager: User entered 'Day 474'	System	19 Nov 2020 23:25:12

US3032249

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:53:49

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:25:12
Amendment Manager: User entered '03 Dec 2021 00:01'	System	19 Nov 2020 23:25:12

US3032249

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:53:49

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:25:12
Amendment Manager: User entered '07 Dec 2021 23:59'	System	19 Nov 2020 23:25:12

US3032249

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:53:49

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:25:12
Amendment Manager: User entered 'Day 481'	System	19 Nov 2020 23:25:12

US3032249

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:53:49

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:25:12
Amendment Manager: User entered '10 Dec 2021 00:01'	System	19 Nov 2020 23:25:12

US3032249

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:53:49

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:25:12
Amendment Manager: User entered '14 Dec 2021 23:59'	System	19 Nov 2020 23:25:12

US3032249

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:53:49

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:25:12
Amendment Manager: User entered 'Day 488'	System	19 Nov 2020 23:25:12

US3032249

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:53:49

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:25:12
Amendment Manager: User entered '17 Dec 2021 00:01'	System	19 Nov 2020 23:25:12

US3032249

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:53:49

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:25:12
Amendment Manager: User entered '21 Dec 2021 23:59'	System	19 Nov 2020 23:25:12

US3032249

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:53:49

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:25:12
Amendment Manager: User entered 'Day 495'	System	19 Nov 2020 23:25:12

US3032249

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:53:49

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:25:12
Amendment Manager: User entered '24 Dec 2021 00:01'	System	19 Nov 2020 23:25:12

US3032249

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:53:49

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:25:12
Amendment Manager: User entered '28 Dec 2021 23:59'	System	19 Nov 2020 23:25:12

US3032249

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:53:49

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:25:12
Amendment Manager: User entered 'Day 502'	System	19 Nov 2020 23:25:12

US3032249

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:53:49

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:25:12
Amendment Manager: User entered '31 Dec 2021 00:01'	System	19 Nov 2020 23:25:12

US3032249

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:53:49

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:25:12
Amendment Manager: User entered '04 Jan 2022 23:59'	System	19 Nov 2020 23:25:12

US3032249

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:53:49

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:25:12
Amendment Manager: User entered 'Day 509'	System	19 Nov 2020 23:25:12

US3032249

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:53:49

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:25:12
Amendment Manager: User entered '07 Jan 2022 00:01'	System	19 Nov 2020 23:25:12

US3032249

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:53:49

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:25:12
Amendment Manager: User entered '11 Jan 2022 23:59'	System	19 Nov 2020 23:25:12

US3032249

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:53:49

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:25:12
Amendment Manager: User entered 'Day 516'	System	19 Nov 2020 23:25:12

US3032249

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:53:49

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:25:12
Amendment Manager: User entered '14 Jan 2022 00:01'	System	19 Nov 2020 23:25:12

US3032249

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:53:49

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:25:12
Amendment Manager: User entered '18 Jan 2022 23:59'	System	19 Nov 2020 23:25:12

US3032249

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:53:49

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:25:12
Amendment Manager: User entered 'Day 523'	System	19 Nov 2020 23:25:12

US3032249

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:53:49

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:25:12
Amendment Manager: User entered '21 Jan 2022 00:01'	System	19 Nov 2020 23:25:12

US3032249

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:53:49

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:25:12
Amendment Manager: User entered '25 Jan 2022 23:59'	System	19 Nov 2020 23:25:12

US3032249

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:53:49

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:25:12
Amendment Manager: User entered 'Day 530'	System	19 Nov 2020 23:25:12

US3032249

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:53:49

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:25:12
Amendment Manager: User entered '28 Jan 2022 00:01'	System	19 Nov 2020 23:25:12

US3032249

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:53:49

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:25:12
Amendment Manager: User entered '01 Feb 2022 23:59'	System	19 Nov 2020 23:25:12

US3032249

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:53:49

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:25:12
Amendment Manager: User entered 'Day 537'	System	19 Nov 2020 23:25:12

US3032249

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:53:49

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:25:12
Amendment Manager: User entered '04 Feb 2022 00:01'	System	19 Nov 2020 23:25:12

US3032249

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:53:49

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:25:12
Amendment Manager: User entered '08 Feb 2022 23:59'	System	19 Nov 2020 23:25:12

US3032249

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:53:49

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:25:12
Amendment Manager: User entered 'Day 544'	System	19 Nov 2020 23:25:12

US3032249

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:53:49

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:25:12
Amendment Manager: User entered '11 Feb 2022 00:01'	System	19 Nov 2020 23:25:12

US3032249

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:53:49

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:25:12
Amendment Manager: User entered '15 Feb 2022 23:59'	System	19 Nov 2020 23:25:12

US3032249

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:53:49

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:25:12
Amendment Manager: User entered 'Day 551'	System	19 Nov 2020 23:25:12

US3032249

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:53:49

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:25:12
Amendment Manager: User entered '18 Feb 2022 00:01'	System	19 Nov 2020 23:25:12

US3032249

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:53:49

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:25:12
Amendment Manager: User entered '22 Feb 2022 23:59'	System	19 Nov 2020 23:25:12

US3032249

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:53:49

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:25:12
Amendment Manager: User entered 'Day 558'	System	19 Nov 2020 23:25:12

US3032249

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:53:49

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:25:12
Amendment Manager: User entered '25 Feb 2022 00:01'	System	19 Nov 2020 23:25:12

US3032249

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:53:49

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:25:12
Amendment Manager: User entered '01 Mar 2022 23:59'	System	19 Nov 2020 23:25:12

US3032249

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:53:49

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:25:12
Amendment Manager: User entered 'Day 565'	System	19 Nov 2020 23:25:12

US3032249

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:53:49

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:25:12
Amendment Manager: User entered '04 Mar 2022 00:01'	System	19 Nov 2020 23:25:12

US3032249

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:53:49

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:25:12
Amendment Manager: User entered '08 Mar 2022 23:59'	System	19 Nov 2020 23:25:12

US3032249

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:53:49

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:25:12
Amendment Manager: User entered 'Day 572'	System	19 Nov 2020 23:25:12

US3032249

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:53:49

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:25:12
Amendment Manager: User entered '11 Mar 2022 00:01'	System	19 Nov 2020 23:25:12

US3032249

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:53:49

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:25:12
Amendment Manager: User entered '15 Mar 2022 23:59'	System	19 Nov 2020 23:25:12

US3032249

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:53:49

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:25:12
Amendment Manager: User entered 'Day 579'	System	19 Nov 2020 23:25:12

US3032249

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:53:49

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:25:12
Amendment Manager: User entered '18 Mar 2022 00:01'	System	19 Nov 2020 23:25:12

US3032249

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:53:49

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:25:12
Amendment Manager: User entered '22 Mar 2022 23:59'	System	19 Nov 2020 23:25:12

US3032249

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:53:49

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:25:12
Amendment Manager: User entered 'Day 586'	System	19 Nov 2020 23:25:12

US3032249

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:53:49

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:25:12
Amendment Manager: User entered '25 Mar 2022 00:01'	System	19 Nov 2020 23:25:12

US3032249

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:53:49

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:25:12
Amendment Manager: User entered '29 Mar 2022 23:59'	System	19 Nov 2020 23:25:12

US3032249

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:53:49

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:25:12
Amendment Manager: User entered 'Day 593'	System	19 Nov 2020 23:25:12

US3032249

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:53:49

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:25:12
Amendment Manager: User entered '01 Apr 2022 00:01'	System	19 Nov 2020 23:25:12

US3032249

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:53:49

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:25:12
Amendment Manager: User entered '05 Apr 2022 23:59'	System	19 Nov 2020 23:25:12

US3032249

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:53:49

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:25:12
Amendment Manager: User entered 'Day 600'	System	19 Nov 2020 23:25:12

US3032249

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:53:49

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:25:12
Amendment Manager: User entered '08 Apr 2022 00:01'	System	19 Nov 2020 23:25:12

US3032249

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:53:49

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:25:12
Amendment Manager: User entered '12 Apr 2022 23:59'	System	19 Nov 2020 23:25:12

US3032249

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:53:49

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:25:12
Amendment Manager: User entered 'Day 607'	System	19 Nov 2020 23:25:12

US3032249

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:53:49

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:25:12
Amendment Manager: User entered '15 Apr 2022 00:01'	System	19 Nov 2020 23:25:12

US3032249

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:53:49

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:25:12
Amendment Manager: User entered '19 Apr 2022 23:59'	System	19 Nov 2020 23:25:12

US3032249

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:53:49

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:25:12
Amendment Manager: User entered 'Day 614'	System	19 Nov 2020 23:25:12

US3032249

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:53:49

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:25:12
Amendment Manager: User entered '22 Apr 2022 00:01'	System	19 Nov 2020 23:25:12

US3032249

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:53:49

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:25:12
Amendment Manager: User entered '26 Apr 2022 23:59'	System	19 Nov 2020 23:25:12

US3032249

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:53:49

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:25:12
Amendment Manager: User entered 'Day 621'	System	19 Nov 2020 23:25:12

US3032249

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:53:49

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:25:12
Amendment Manager: User entered '29 Apr 2022 00:01'	System	19 Nov 2020 23:25:12

US3032249

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:53:49

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:25:12
Amendment Manager: User entered '03 May 2022 23:59'	System	19 Nov 2020 23:25:12

US3032249

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:53:49

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:25:12
Amendment Manager: User entered 'Day 628'	System	19 Nov 2020 23:25:12

US3032249

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:53:49

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:25:12
Amendment Manager: User entered '06 May 2022 00:01'	System	19 Nov 2020 23:25:12

US3032249

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:53:49

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:25:12
Amendment Manager: User entered '10 May 2022 23:59'	System	19 Nov 2020 23:25:12

US3032249

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:53:49

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:25:12
Amendment Manager: User entered 'Day 635'	System	19 Nov 2020 23:25:12

US3032249

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:53:49

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:25:12
Amendment Manager: User entered '13 May 2022 00:01'	System	19 Nov 2020 23:25:12

US3032249

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:53:49

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:25:12
Amendment Manager: User entered '17 May 2022 23:59'	System	19 Nov 2020 23:25:12

US3032249

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:53:49

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:25:12
Amendment Manager: User entered 'Day 642'	System	19 Nov 2020 23:25:12

US3032249

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:53:49

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:25:12
Amendment Manager: User entered '20 May 2022 00:01'	System	19 Nov 2020 23:25:12

US3032249

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:53:49

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:25:12
Amendment Manager: User entered '24 May 2022 23:59'	System	19 Nov 2020 23:25:12

US3032249

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:53:49

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:25:12
Amendment Manager: User entered 'Day 649'	System	19 Nov 2020 23:25:12

US3032249

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:53:49

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:25:12
Amendment Manager: User entered '27 May 2022 00:01'	System	19 Nov 2020 23:25:12

US3032249

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:53:49

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:25:12
Amendment Manager: User entered '31 May 2022 23:59'	System	19 Nov 2020 23:25:12

US3032249

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:53:49

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:25:12
Amendment Manager: User entered 'Day 656'	System	19 Nov 2020 23:25:12

US3032249

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:53:49

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:25:12
Amendment Manager: User entered '03 Jun 2022 00:01'	System	19 Nov 2020 23:25:12

US3032249

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:53:49

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:25:12
Amendment Manager: User entered '07 Jun 2022 23:59'	System	19 Nov 2020 23:25:12

US3032249

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:53:49

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:25:12
Amendment Manager: User entered 'Day 663'	System	19 Nov 2020 23:25:12

US3032249

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:53:49

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:25:12
Amendment Manager: User entered '10 Jun 2022 00:01'	System	19 Nov 2020 23:25:12

US3032249

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:53:49

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:25:12
Amendment Manager: User entered '14 Jun 2022 23:59'	System	19 Nov 2020 23:25:12

US3032249

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:53:49

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:25:12
Amendment Manager: User entered 'Day 670'	System	19 Nov 2020 23:25:12

US3032249

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:53:49

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:25:12
Amendment Manager: User entered '17 Jun 2022 00:01'	System	19 Nov 2020 23:25:12

US3032249

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:53:49

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:25:12
Amendment Manager: User entered '21 Jun 2022 23:59'	System	19 Nov 2020 23:25:12

US3032249

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:53:49

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:25:12
Amendment Manager: User entered 'Day 677'	System	19 Nov 2020 23:25:12

US3032249

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:53:49

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:25:12
Amendment Manager: User entered '24 Jun 2022 00:01'	System	19 Nov 2020 23:25:12

US3032249

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:53:49

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:25:12
Amendment Manager: User entered '28 Jun 2022 23:59'	System	19 Nov 2020 23:25:12

US3032249

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:53:49

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:25:12
Amendment Manager: User entered 'Day 684'	System	19 Nov 2020 23:25:12

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Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:53:49

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:25:12
Amendment Manager: User entered '01 Jul 2022 00:01'	System	19 Nov 2020 23:25:12

US3032249

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:53:49

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:25:12
Amendment Manager: User entered '05 Jul 2022 23:59'	System	19 Nov 2020 23:25:12

US3032249

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:53:49

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:25:12
Amendment Manager: User entered 'Day 691'	System	19 Nov 2020 23:25:12

US3032249

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:53:49

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:25:12
Amendment Manager: User entered '08 Jul 2022 00:01'	System	19 Nov 2020 23:25:12

US3032249

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:53:49

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:25:12
Amendment Manager: User entered '12 Jul 2022 23:59'	System	19 Nov 2020 23:25:12

US3032249

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:53:49

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:25:12
Amendment Manager: User entered 'Day 698'	System	19 Nov 2020 23:25:12

US3032249

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:53:49

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:25:12
Amendment Manager: User entered '15 Jul 2022 00:01'	System	19 Nov 2020 23:25:12

US3032249

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:53:49

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:25:12
Amendment Manager: User entered '19 Jul 2022 23:59'	System	19 Nov 2020 23:25:12

US3032249

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:53:49

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:25:12
Amendment Manager: User entered 'Day 705'	System	19 Nov 2020 23:25:12

US3032249

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:53:49

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:25:12
Amendment Manager: User entered '22 Jul 2022 00:01'	System	19 Nov 2020 23:25:12

US3032249

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:53:49

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:25:12
Amendment Manager: User entered '26 Jul 2022 23:59'	System	19 Nov 2020 23:25:12

US3032249

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:53:49

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:25:12
Amendment Manager: User entered 'Day 712'	System	19 Nov 2020 23:25:12

US3032249

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:53:49

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:25:12
Amendment Manager: User entered '29 Jul 2022 00:01'	System	19 Nov 2020 23:25:12

US3032249

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:53:49

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:25:12
Amendment Manager: User entered '02 Aug 2022 23:59'	System	19 Nov 2020 23:25:12

US3032249

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:53:49

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:25:12
Amendment Manager: User entered 'Day 719'	System	19 Nov 2020 23:25:12

US3032249

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:53:49

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:25:12
Amendment Manager: User entered '05 Aug 2022 00:01'	System	19 Nov 2020 23:25:12

US3032249

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:53:49

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:25:12
Amendment Manager: User entered '09 Aug 2022 23:59'	System	19 Nov 2020 23:25:12

US3032249

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:53:49

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:25:12
Amendment Manager: User entered 'Day 726'	System	19 Nov 2020 23:25:12

US3032249

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:53:49

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:25:12
Amendment Manager: User entered '12 Aug 2022 00:01'	System	19 Nov 2020 23:25:12

US3032249

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:53:49

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:25:12
Amendment Manager: User entered '16 Aug 2022 23:59'	System	19 Nov 2020 23:25:12

US3032249

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:53:49

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:25:12
Amendment Manager: User entered 'Day 733'	System	19 Nov 2020 23:25:12

US3032249

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:53:49

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:25:12
Amendment Manager: User entered '19 Aug 2022 00:01'	System	19 Nov 2020 23:25:12

US3032249

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:53:49

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:25:12
Amendment Manager: User entered '23 Aug 2022 23:59'	System	19 Nov 2020 23:25:12

US3032249

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:53:49

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:25:12
Amendment Manager: User entered 'Day 740'	System	19 Nov 2020 23:25:12

US3032249

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:53:49

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:25:12
Amendment Manager: User entered '26 Aug 2022 00:01'	System	19 Nov 2020 23:25:12

US3032249

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:53:49

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:25:12
Amendment Manager: User entered '30 Aug 2022 23:59'	System	19 Nov 2020 23:25:12

US3032249

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:53:49

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:25:12
Amendment Manager: User entered 'Day 747'	System	19 Nov 2020 23:25:12

US3032249

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:53:49

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:25:12
Amendment Manager: User entered '02 Sep 2022 00:01'	System	19 Nov 2020 23:25:12

US3032249

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:53:49

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:25:12
Amendment Manager: User entered '06 Sep 2022 23:59'	System	19 Nov 2020 23:25:12

US3032249

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:53:49

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:25:12
Amendment Manager: User entered 'Day 754'	System	19 Nov 2020 23:25:12

US3032249

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:53:49

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:25:12
Amendment Manager: User entered '09 Sep 2022 00:01'	System	19 Nov 2020 23:25:12

US3032249

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:53:49

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:25:12
Amendment Manager: User entered '13 Sep 2022 23:59'	System	19 Nov 2020 23:25:12

US3032249

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:53:49

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:25:12
Amendment Manager: User entered 'Day 761'	System	19 Nov 2020 23:25:12

US3032249

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:53:49

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:25:12
Amendment Manager: User entered '16 Sep 2022 00:01'	System	19 Nov 2020 23:25:12

US3032249

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:53:49

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:25:12
Amendment Manager: User entered '20 Sep 2022 23:59'	System	19 Nov 2020 23:25:12

US3032249

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:53:49

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:25:12
Amendment Manager: User entered 'Day 768'	System	19 Nov 2020 23:25:12

US3032249

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:53:49

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:25:12
Amendment Manager: User entered '23 Sep 2022 00:01'	System	19 Nov 2020 23:25:12

US3032249

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:53:49

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:25:12
Amendment Manager: User entered '27 Sep 2022 23:59'	System	19 Nov 2020 23:25:12

US3032249

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:53:49

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:25:12
Amendment Manager: User entered 'Day 775'	System	19 Nov 2020 23:25:12

US3032249

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:53:49

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:25:12
Amendment Manager: User entered '30 Sep 2022 00:01'	System	19 Nov 2020 23:25:12

US3032249

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:53:49

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:25:12
Amendment Manager: User entered '04 Oct 2022 23:59'	System	19 Nov 2020 23:25:12

US3032249

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:53:49

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:25:12
Amendment Manager: User entered 'Day 782'	System	19 Nov 2020 23:25:12

US3032249

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:53:49

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:25:12
Amendment Manager: User entered '07 Oct 2022 00:01'	System	19 Nov 2020 23:25:12

US3032249

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:53:49

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:25:12
Amendment Manager: User entered '11 Oct 2022 23:59'	System	19 Nov 2020 23:25:12

US3032249

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:53:49

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:25:12
Amendment Manager: User entered 'Day 789'	System	19 Nov 2020 23:25:12

US3032249

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:53:49

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:25:12
Amendment Manager: User entered '14 Oct 2022 00:01'	System	19 Nov 2020 23:25:12

US3032249

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:53:49

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:25:12
Amendment Manager: User entered '18 Oct 2022 23:59'	System	19 Nov 2020 23:25:12

US3032249

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:53:49

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:25:12
Amendment Manager: User entered 'Day 796'	System	19 Nov 2020 23:25:12

US3032249

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:53:49

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:25:12
Amendment Manager: User entered '21 Oct 2022 00:01'	System	19 Nov 2020 23:25:12

US3032249

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:53:49

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:25:12
Amendment Manager: User entered '25 Oct 2022 23:59'	System	19 Nov 2020 23:25:12

US3032249

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection_ Dermal Filler eDiary (1)

Generated On: 09 Jun 2021 14:53:49

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 12:21:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (898ced6280f9892f)', Time: '2021-03-21T18:26:54', User OID: 'PatientReportedOutcome (US3032249)', ODM File OID: '8927747b-bc5e-4965-bc31-b30cff06a66'	System	21 Mar 2021 23:27:11
User entered 'No (N)'	System	21 Mar 2021 23:27:11

US3032249

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection_ Dermal Filler eDiary (1)

Generated On: 09 Jun 2021 14:53:49

[Date & Time of Submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 12:21:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (898ced6280f9892f)', Time: '2021-03-21T18:27:05', User OID: 'PatientReportedOutcome (US3032249)', ODM File OID: '8927747b-bc5e-4965-bc31-b30cff06a66'	System	21 Mar 2021 23:27:11
User entered '21 Mar 2021 18:27:05'	System	21 Mar 2021 23:27:11

US3032249

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 09 Jun 2021 14:53:49

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:25:26
User signature succeeded.	Keith Vrbicky (b) (4)	08 Dec 2020 19:48:23
User entered 'Yes (Y)'	(b) (4) Linden DeBoer (b) (4)	01 Dec 2020 19:12:59

US3032249

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 09 Jun 2021 14:53:49

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:25:26
User signature succeeded.	Keith Vrbicky (b) (4)	08 Dec 2020 19:48:23
User entered '13 Nov 2020'	Linden DeBoer (b) (4)	01 Dec 2020 19:12:59

US3032249

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 09 Jun 2021 14:53:49

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:25:26
User signature succeeded.	Keith Vrbicky (b) (4)	08 Dec 2020 19:48:23
User entered 'Contact Made (CONTACT MADE)'	Linden DeBoer (b) (4)	01 Dec 2020 19:12:59

US3032249

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 09 Jun 2021 14:53:49

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:25:26
User signature succeeded.	Keith Vrbicky (b) (4)	08 Dec 2020 19:48:23
User entered empty.	Linden DeBoer (b) (4)	01 Dec 2020 19:12:59

US3032249

Folder: Safety Call Day 85 (1)

Form: Continuing

Generated On: 09 Jun 2021 14:53:49

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:25:26
User signature succeeded.	Keith Vrbicky (b) (4)	08 Dec 2020 19:48:23
User entered 'Yes (Y)'	Linden DeBoer (b) (4)	01 Dec 2020 19:13:07

US3032249

Folder: Safety Call Day 85 (1)

Form: Continuing

Generated On: 09 Jun 2021 14:53:49

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:25:26
User entered 'I'	System	01 Dec 2020 19:13:07

US3032249

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 09 Jun 2021 14:53:49

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 15:10:18
User signature succeeded.	Keith Vrbicky (b) (4)	23 Dec 2020 15:55:06
User entered 'Yes (Y)'	(b) (4) Kelsey Kelley (b) (4)	17 Dec 2020 14:36:13

US3032249

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 09 Jun 2021 14:53:49

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 15:10:18
User signature succeeded.	Keith Vrbicky (b) (4)	23 Dec 2020 15:55:06
User entered '16 Dec 2020'	Kelsey Kelley (b) (4)	17 Dec 2020 14:36:13

US3032249

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 09 Jun 2021 14:53:49

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 15:10:18
User signature succeeded.	Keith Vrbicky (b) (4)	23 Dec 2020 15:55:06
User entered 'Contact Made (CONTACT MADE)'	(b) (4) Kelsey Kelley (b) (4)	17 Dec 2020 14:36:13

US3032249

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 09 Jun 2021 14:53:49

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 15:10:18
User signature succeeded.	Keith Vrbicky (b) (4)	23 Dec 2020 15:55:06
User entered empty.	(b) (4) Kelsey Kelley (b) (4) (b) (4)	17 Dec 2020 14:36:13

US3032249

Folder: Safety Call Day 119 (1)

Form: Continuing

Generated On: 09 Jun 2021 14:53:49

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 15:10:16
User signature succeeded.	Keith Vrbicky (b) (4)	23 Dec 2020 15:55:06
User entered 'Yes (Y)'	(b) (4) Kelsey Kelley (b) (4)	17 Dec 2020 14:36:24

US3032249

Folder: Safety Call Day 119 (1)

Form: Continuing

Generated On: 09 Jun 2021 14:53:49

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 15:10:16
User entered 'I'	System	17 Dec 2020 14:36:24

US3032249

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 09 Jun 2021 14:53:49

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 15:10:18
User signature succeeded.	Keith Vrbicky (b) (4)	10 Mar 2021 15:38:13
User entered 'Yes (Y)'	(b) (4) Chelsie Nutsch (b) (4)	04 Mar 2021 21:45:35

US3032249

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 09 Jun 2021 14:53:49

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 15:10:18
User signature succeeded.	Keith Vrbicky (b) (4)	10 Mar 2021 15:38:13
User entered '18 Jan 2021'	(b) (4) Chelsie Nutsch (b) (4)	04 Mar 2021 21:45:35

US3032249

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 09 Jun 2021 14:53:49

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 15:10:18
User signature succeeded.	Keith Vrbicky (b) (4)	10 Mar 2021 15:38:13
User entered 'Contact Made (CONTACT MADE)'	Chelsie Nutsch (b) (4)	04 Mar 2021 21:45:35

US3032249

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 09 Jun 2021 14:53:49

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 15:10:18
User signature succeeded.	Keith Vrbicky (b) (4)	10 Mar 2021 15:38:13
User entered empty.	(b) (4) Chelsie Nutsch (b) (4)	04 Mar 2021 21:45:35

US3032249

Folder: Safety Call Day 149 (1)

Form: Continuing

Generated On: 09 Jun 2021 14:53:49

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 15:10:18
User signature succeeded.	Keith Vrbicky (b) (4)	10 Mar 2021 15:38:13
User entered 'Yes (Y)'	(b) (4) Chelsie Nutsch (b) (4)	04 Mar 2021 21:45:43

US3032249

Folder: Safety Call Day 149 (1)

Form: Continuing

Generated On: 09 Jun 2021 14:53:49

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 15:10:18
User entered 'I'	System	04 Mar 2021 21:45:43

US3032249

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 09 Jun 2021 14:53:49

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 15:10:18
User signature succeeded.	Keith Vrbicky (b) (4)	10 Mar 2021 15:38:13
User entered 'Yes (Y)'	(b) (4) Chelsie Nutsch (b) (4)	04 Mar 2021 22:13:29

US3032249

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 09 Jun 2021 14:53:49

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 15:10:18
User signature succeeded.	Keith Vrbicky (b) (4)	10 Mar 2021 15:38:13
User entered '15 Feb 2021'	Chelsie Nutsch (b) (4)	04 Mar 2021 22:13:29

US3032249

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 09 Jun 2021 14:53:49

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 15:10:18
User signature succeeded.	Keith Vrbicky (b) (4)	10 Mar 2021 15:38:13
User entered 'Contact Made (CONTACT MADE)'	Chelsie Nutsch (b) (4)	04 Mar 2021 22:13:29

US3032249

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 09 Jun 2021 14:53:49

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 15:10:18
User signature succeeded.	Keith Vrbicky (b) (4)	10 Mar 2021 15:38:13
User entered empty.	Chelsie Nutsch (b) (4)	04 Mar 2021 22:13:29

US3032249

Folder: Safety Call Day 179 (1)

Form: Continuing

Generated On: 09 Jun 2021 14:53:49

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 15:10:18
User signature succeeded.	Keith Vrbicky (b) (4)	10 Mar 2021 15:38:13
User entered 'Yes (Y)'	(b) (4) Chelsie Nutsch (b) (4)	04 Mar 2021 22:13:36

US3032249

Folder: Safety Call Day 179 (1)

Form: Continuing

Generated On: 09 Jun 2021 14:53:49

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 15:10:18
User entered 'I'	System	04 Mar 2021 22:13:36

US3032249

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 09 Jun 2021 14:53:49

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 15:10:18
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:41:55
User entered 'Yes (Y)'	(b) (4) Kelsey Kelley (b) (4)	23 Mar 2021 15:27:11

US3032249

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 09 Jun 2021 14:53:49

[Visit date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 15:10:18
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:41:55
User entered '22 Mar 2021'	(b) (4) Kelsey Kelley (b) (4)	23 Mar 2021 15:27:11

US3032249

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 09 Jun 2021 14:53:49

[Was visit performed at the participant's home or at the clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 15:10:18
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:41:55
User entered 'Clinic (Clinic)'	Kelsey Kelley (b) (4)	23 Mar 2021 15:27:11

US3032249

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 09 Jun 2021 14:53:49

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 15:10:18
User entered 'VISIT4'	System	23 Mar 2021 15:27:11

US3032249

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 14:53:49

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:42:38
User closed query 'Per CDM, re-query: Thank you for your response, however, if a visit from Part A overlaps with a Visit from Part B and the visits occur on the same day, the data in assessments occurring in both visits must be identical. Please reconcile. ' (Site from DM).		28 Apr 2021 06:24:36
Query 'Per CDM, re-query: Thank you for your response, however, if a visit from Part A overlaps with a Visit from Part B and the visits occur on the same day, the data in assessments occurring in both visits must be identical. Please reconcile. ' answered with 'if vitals are charted in visit 4 in EDC they will not match source due to protocol not wanting vitals for Visit 4, therefore vitals will not be input for visit 4' (Site from DM).	Samantha Wieseler (b) (4) (b) (4)	20 Apr 2021 13:04:47
User opened query 'Per CDM, re-query: Thank you for your response, however, if a visit from Part A overlaps with a Visit from Part B and the visits occur on the same day, the data in assessments occurring in both visits must be identical. Please reconcile. ' (Site from DM).	(b) (4), (b) (6)	20 Apr 2021 09:29:39
User closed query ' Per Sponsor review (RQ): Please note Visit 4 D209 and Convalescent visit is done on the same date, Part A and Part B data needs to be consistent as both the visits are done on same date. Kindly reconcile and update. thanks' (Site from DM).		20 Apr 2021 09:29:39
Query ' Per Sponsor review (RQ): Please note Visit 4 D209 and Convalescent visit is done on the same date, Part A and Part B data needs to be consistent as both the visits are done on same date. Kindly reconcile and update. thanks' answered with 'per protocol Visit 4 vitals not collected' (Site from DM).	Samantha Wieseler (b) (4) (b) (4)	09 Apr 2021 19:53:54
User opened query ' Per Sponsor review (RQ): Please note Visit 4 D209 and Convalescent visit is done on the same date, Part A and Part B data needs to be consistent as both the visits are done on same date. Kindly reconcile and update. thanks' (Site from DM).	(b) (4), (b) (6)	09 Apr 2021 11:18:01

US3032249

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 14:53:49

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
User closed query 'Per Sponsor Review : Please note Visit 4 D209 and Convalescent visit (1) is done on the same date, Data should be same in Part A and Part B for Vital signs/Physical examination pages and all the respective pages to be completed, if done on the same day the data should be present in both the pages and should be same. Kindly reconcile and update appropriately. Thank you. ' (Site from DM).	(b) (4), (b) (6)	09 Apr 2021 11:18:01
Query 'Per Sponsor Review : Please note Visit 4 D209 and Convalescent visit (1) is done on the same date, Data should be same in Part A and Part B for Vital signs/Physical examination pages and all the respective pages to be completed, if done on the same day the data should be present in both the pages and should be same. Kindly reconcile and update appropriately. Thank you. ' answered with 'Per protocol, vital signs are not collected as a part of visit 4.' (Site from DM).	Kelsey Kelley (b) (4) (b) (4)	07 Apr 2021 19:48:29
User opened query 'Per Sponsor Review : Please note Visit 4 D209 and Convalescent visit (1) is done on the same date, Data should be same in Part A and Part B for Vital signs/Physical examination pages and all the respective pages to be completed, if done on the same day the data should be present in both the pages and should be same. Kindly reconcile and update appropriately. Thank you. ' (Site from DM).	(b) (4), (b) (6)	07 Apr 2021 07:15:29
User signature succeeded.	Keith Vrbicky (b) (4) (b) (4)	06 Apr 2021 15:41:55
User entered 'No (N)'	Samantha Wieseler (b) (4) (b) (4)	30 Mar 2021 21:38:05

US3032249

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 14:53:49

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:42:38
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:41:55
User entered empty.	(b) (4) Samantha Wieseler (b) (4)	30 Mar 2021 21:38:05

US3032249

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 14:53:49

Time of assessment (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:42:38
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:41:55
User entered empty.	(b) (4) Samantha Wieseler (b) (4)	30 Mar 2021 21:38:05

US3032249

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 14:53:49

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:42:38
User entered empty.	System	30 Mar 2021 21:38:05

US3032249

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 14:53:49

[Temperature \(xxx.x\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:42:38
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:41:55
User entered empty.	(b) (4) Samantha Wieseler (b) (4)	30 Mar 2021 21:38:05

US3032249

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 14:53:49

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:42:38
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:41:55
User entered empty.	(b) (4) Samantha Wieseler (b) (4)	30 Mar 2021 21:38:05

US3032249

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 14:53:49

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:42:38
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:41:55
User entered empty.	(b) (4) Samantha Wieseler (b) (4)	30 Mar 2021 21:38:05

US3032249

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 14:53:49

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:42:38
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:41:55
User entered empty.	(b) (4) Samantha Wieseler (b) (4)	30 Mar 2021 21:38:05

US3032249

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 14:53:49

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:42:38
User entered empty.	System	30 Mar 2021 21:38:05

US3032249

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 14:53:49

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:42:38
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:41:55
User entered empty.	(b) (4) Samantha Wieseler (b) (4)	30 Mar 2021 21:38:05

US3032249

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 14:53:49

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:42:38
User entered empty.	System	30 Mar 2021 21:38:05

US3032249

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 14:53:49

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:42:38
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:41:55
User entered empty.	(b) (4) Samantha Wieseler (b) (4)	30 Mar 2021 21:38:05
	(b) (4)	

US3032249

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 14:53:49

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:42:38
User entered empty.	System	30 Mar 2021 21:38:05

US3032249

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 14:53:49

[Diastolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:42:38
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:41:55
User entered empty.	(b) (4) Samantha Wieseler (b) (4)	30 Mar 2021 21:38:05

US3032249

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 14:53:49

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:42:38
User entered empty.	System	30 Mar 2021 21:38:05

US3032249

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 14:53:49

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:42:38

US3032249

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 14:53:49

[Weight \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:42:38

US3032249

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 14:53:49

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 15:10:18
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:41:55
User entered 'No (N)'	(b) (4) Kelsey Kelley (b) (4)	23 Mar 2021 15:27:15

US3032249

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 14:53:49

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 15:10:18
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:41:55
User entered empty.	Kelsey Kelley (b) (4)	23 Mar 2021 15:27:15

US3032249

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 14:53:49

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 15:10:18
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:41:55
User entered 'Yes (Y)'	(b) (4) Kelsey Kelley (b) (4)	23 Mar 2021 15:27:27

US3032249

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 14:53:49

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 15:10:18
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:41:55
User entered '22 Mar 2021'	Kelsey Kelley (b) (4)	23 Mar 2021 15:27:27

US3032249

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 14:53:49

[Collection time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 15:10:18
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:41:55
User entered '17:09'	(b) (4) Kelsey Kelley (b) (4)	23 Mar 2021 15:27:27

US3032249

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 14:53:49

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 15:10:18
User entered '22 Mar 2021 17:09'	System	23 Mar 2021 15:27:27

US3032249

Folder: Visit 4 Day 209 (1)

Form: Continuing

Generated On: 09 Jun 2021 14:53:49

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 15:10:18
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:41:55
User entered 'Yes (Y)'	Kelsey Kelley (b) (4)	23 Mar 2021 15:27:30

US3032249

Folder: Visit 4 Day 209 (1)

Form: Continuing

Generated On: 09 Jun 2021 14:53:49

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 15:10:18
User entered 'I'	System	23 Mar 2021 15:27:30

US3032249

Folder: Covid-19 Assessment 08 Feb 2021

Form: COVID-19 Contact

Generated On: 09 Jun 2021 14:53:49

[Date of Contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:51:36
User signature succeeded.	Keith Vrbicky (b) (4)	04 Mar 2021 16:04:32
User entered '08 Feb 2021'	(b) (4) Kelsey Kelley (b) (4)	03 Mar 2021 19:48:26

US3032249

Folder: Covid-19 Assessment 08 Feb 2021

Form: COVID-19 Contact

Generated On: 09 Jun 2021 14:53:49

[Time of Contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:51:36
User signature succeeded.	Keith Vrbicky (b) (4)	04 Mar 2021 16:04:32
User entered '19:12'	(b) (4) Kelsey Kelley (b) (4)	03 Mar 2021 19:48:26

US3032249

Folder: Covid-19 Assessment 08 Feb 2021

Form: COVID-19 Contact

Generated On: 09 Jun 2021 14:53:49

[Date and Time of Contact \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:51:36
User entered '08 Feb 2021 19:12'	System	03 Mar 2021 19:48:26

US3032249

Folder: Covid-19 Assessment 08 Feb 2021

Form: COVID-19 Contact

Generated On: 09 Jun 2021 14:53:49

[Type of Contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:51:36
User signature succeeded.	Keith Vrbicky (b) (4)	04 Mar 2021 16:04:32
User entered 'Convalescent Tele-visit (Convalescent Tele-visit)'	(b) (4) Kelsey Kelley (b) (4)	03 Mar 2021 19:48:26

US3032249

Folder: Covid-19 Assessment 08 Feb 2021

Form: COVID-19 Contact

Generated On: 09 Jun 2021 14:53:49

[Has the subject reported symptoms of SARS-COV-2?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:51:36
User signature succeeded.	Keith Vrbicky (b) (4)	04 Mar 2021 16:04:32
User entered 'Yes (Y)'	Kelsey Kelley (b) (4)	03 Mar 2021 19:48:26

US3032249

Folder: Covid-19 Assessment 08 Feb 2021

Form: Symptom Log (1)

Generated On: 09 Jun 2021 14:53:49

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:51:43
User signature succeeded.	Keith Vrbicky (b) (4)	04 Mar 2021 16:04:32
User entered 'Day 1 (Day 1)'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	03 Mar 2021 19:49:27

US3032249

Folder: Covid-19 Assessment 08 Feb 2021

Form: Symptom Log (1)

Generated On: 09 Jun 2021 14:53:49

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:51:43
User signature succeeded.	Keith Vrbicky (b) (4)	04 Mar 2021 16:04:32
User entered '2 Feb 2021'	(b) (4) Kelsey Kelley (b) (4)	03 Mar 2021 19:49:27
	(b) (4)	

US3032249

Folder: Covid-19 Assessment 08 Feb 2021

Form: Symptom Log (1)

Generated On: 09 Jun 2021 14:53:49

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:51:43
User signature succeeded.	Keith Vrbicky (b) (4)	04 Mar 2021 16:04:32
User entered 'I'	Kelsey Kelley (b) (4)	03 Mar 2021 19:49:27

US3032249

Folder: Covid-19 Assessment 08 Feb 2021

Form: Symptom Log (1)

Generated On: 09 Jun 2021 14:53:49

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:51:43
User signature succeeded.	Keith Vrbicky (b) (4)	04 Mar 2021 16:04:32
User entered empty.	(b) (4) Kelsey Kelley (b) (4)	03 Mar 2021 19:49:27

US3032249

Folder: Covid-19 Assessment 08 Feb 2021

Form: Symptom Log (1)

Generated On: 09 Jun 2021 14:53:49

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:51:43
User entered empty.	System	03 Mar 2021 19:49:27

US3032249

Folder: Covid-19 Assessment 08 Feb 2021

Form: Symptom Log (1)

Generated On: 09 Jun 2021 14:53:49

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:51:43
User signature succeeded.	Keith Vrbicky (b) (4)	04 Mar 2021 16:04:32
User entered empty.	(b) (4) Kelsey Kelley (b) (4)	03 Mar 2021 19:49:27

US3032249

Folder: Covid-19 Assessment 08 Feb 2021

Form: Symptom Log (1)

Generated On: 09 Jun 2021 14:53:49

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:51:43
User signature succeeded.	Keith Vrbicky (b) (4)	04 Mar 2021 16:04:32
User entered empty.	(b) (4) Kelsey Kelley (b) (4)	03 Mar 2021 19:49:27

US3032249

Folder: Covid-19 Assessment 08 Feb 2021

Form: Symptom Log (1)

Generated On: 09 Jun 2021 14:53:49

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:51:43
User signature succeeded.	Keith Vrbicky (b) (4)	04 Mar 2021 16:04:32
User entered empty.	(b) (4) Kelsey Kelley (b) (4)	03 Mar 2021 19:49:27

US3032249

Folder: Covid-19 Assessment 08 Feb 2021

Form: Symptom Log (1)

Generated On: 09 Jun 2021 14:53:49

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:51:43
User signature succeeded.	Keith Vrbicky (b) (4)	04 Mar 2021 16:04:32
User entered empty.	(b) (4) Kelsey Kelley (b) (4)	03 Mar 2021 19:49:27

US3032249

Folder: Covid-19 Assessment 08 Feb 2021

Form: Symptom Log (1)

Generated On: 09 Jun 2021 14:53:49

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:51:43
User signature succeeded.	Keith Vrbicky (b) (4)	04 Mar 2021 16:04:32
User entered empty.	(b) (4) Kelsey Kelley (b) (4)	03 Mar 2021 19:49:27

US3032249

Folder: Covid-19 Assessment 08 Feb 2021

Form: Symptom Log (1)

Generated On: 09 Jun 2021 14:53:49

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:51:43
User signature succeeded.	Keith Vrbicky (b) (4)	04 Mar 2021 16:04:32
User entered empty.	(b) (4) Kelsey Kelley (b) (4)	03 Mar 2021 19:49:27

US3032249

Folder: Covid-19 Assessment 08 Feb 2021

Form: Symptom Log (1)

Generated On: 09 Jun 2021 14:53:49

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:51:43
User signature succeeded.	Keith Vrbicky (b) (4)	04 Mar 2021 16:04:32
User entered empty.	(b) (4) Kelsey Kelley (b) (4)	03 Mar 2021 19:49:27

US3032249

Folder: Covid-19 Assessment 08 Feb 2021

Form: Symptom Log (1)

Generated On: 09 Jun 2021 14:53:49

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:51:43
User signature succeeded.	Keith Vrbicky (b) (4)	04 Mar 2021 16:04:32
User entered empty.	(b) (4) Kelsey Kelley (b) (4)	03 Mar 2021 19:49:27

US3032249

Folder: Covid-19 Assessment 08 Feb 2021

Form: Symptom Log (1)

Generated On: 09 Jun 2021 14:53:49

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:51:43
User signature succeeded.	Keith Vrbicky (b) (4)	04 Mar 2021 16:04:32
User entered empty.	(b) (4) Kelsey Kelley (b) (4)	03 Mar 2021 19:49:27

US3032249

Folder: Covid-19 Assessment 08 Feb 2021

Form: Symptom Log (1)

Generated On: 09 Jun 2021 14:53:49

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:51:43
User signature succeeded.	Keith Vrbicky (b) (4)	04 Mar 2021 16:04:32
User entered empty.	(b) (4) Kelsey Kelley (b) (4)	03 Mar 2021 19:49:27

US3032249

Folder: Covid-19 Assessment 08 Feb 2021

Form: Symptom Log (1)

Generated On: 09 Jun 2021 14:53:49

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:51:43
User signature succeeded.	Keith Vrbicky (b) (4)	04 Mar 2021 16:04:32
User entered empty.	(b) (4) Kelsey Kelley (b) (4)	03 Mar 2021 19:49:27

US3032249

Folder: Covid-19 Assessment 08 Feb 2021

Form: Symptom Log (1)

Generated On: 09 Jun 2021 14:53:49

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:51:43
User signature succeeded.	Keith Vrbicky (b) (4)	04 Mar 2021 16:04:32
User entered empty.	(b) (4) Kelsey Kelley (b) (4)	03 Mar 2021 19:49:27

US3032249

Folder: Covid-19 Assessment 08 Feb 2021

Form: Symptom Log (1)

Generated On: 09 Jun 2021 14:53:49

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:51:43
User signature succeeded.	Keith Vrbicky (b) (4)	04 Mar 2021 16:04:32
User entered empty.	Kelsey Kelley (b) (4)	03 Mar 2021 19:49:27

US3032249

Folder: Covid-19 Assessment 08 Feb 2021

Form: Symptom Log (1)

Generated On: 09 Jun 2021 14:53:49

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:51:43
User signature succeeded.	Keith Vrbicky (b) (4)	04 Mar 2021 16:04:32
User entered empty.	(b) (4) Kelsey Kelley (b) (4)	03 Mar 2021 19:49:27

US3032249

Folder: Covid-19 Assessment 08 Feb 2021

Form: Symptom Log (1)

Generated On: 09 Jun 2021 14:53:49

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:51:43
User signature succeeded.	Keith Vrbicky (b) (4)	04 Mar 2021 16:04:32
User entered empty.	(b) (4) Kelsey Kelley (b) (4)	03 Mar 2021 19:49:27

US3032249

Folder: Covid-19 Assessment 08 Feb 2021

Form: Symptom Log (1)

Generated On: 09 Jun 2021 14:53:49

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:51:43
User signature succeeded.	Keith Vrbicky (b) (4)	04 Mar 2021 16:04:32
User entered empty.	(b) (4) Kelsey Kelley (b) (4)	03 Mar 2021 19:49:27

US3032249

Folder: Covid-19 Assessment 08 Feb 2021

Form: Symptom Log (1)

Generated On: 09 Jun 2021 14:53:49

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:51:43
User signature succeeded.	Keith Vrbicky (b) (4)	04 Mar 2021 16:04:32
User entered empty.	(b) (4) Kelsey Kelley (b) (4)	03 Mar 2021 19:49:27

US3032249

Folder: Covid-19 Assessment 08 Feb 2021

Form: Symptom Log (2)

Generated On: 09 Jun 2021 14:53:49

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:51:43
User signature succeeded.	Keith Vrbicky (b) (4)	04 Mar 2021 16:04:32
User entered 'Day 2 (Day 2)'	(b) (4) Kelsey Kelley (b) (4)	03 Mar 2021 19:49:33

US3032249

Folder: Covid-19 Assessment 08 Feb 2021

Form: Symptom Log (2)

Generated On: 09 Jun 2021 14:53:49

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:51:43
User signature succeeded.	Keith Vrbicky (b) (4)	04 Mar 2021 16:04:32
User entered '3 Feb 2021'	(b) (4) Kelsey Kelley (b) (4)	03 Mar 2021 19:49:33
	(b) (4)	

US3032249

Folder: Covid-19 Assessment 08 Feb 2021

Form: Symptom Log (2)

Generated On: 09 Jun 2021 14:53:49

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:51:43
User signature succeeded.	Keith Vrbicky (b) (4)	04 Mar 2021 16:04:32
User entered '1' reason for change: Data Entry Error	(b) (4)	
	Kelsey Kelley (b) (4)	03 Mar 2021 19:49:37
User entered '0'	(b) (4)	
	Kelsey Kelley (b) (4)	03 Mar 2021 19:49:33
	(b) (4)	

US3032249

Folder: Covid-19 Assessment 08 Feb 2021

Form: Symptom Log (2)

Generated On: 09 Jun 2021 14:53:49

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:51:43
User signature succeeded.	Keith Vrbicky (b) (4)	04 Mar 2021 16:04:32
User entered empty.	(b) (4) Kelsey Kelley (b) (4)	03 Mar 2021 19:49:33
	(b) (4)	

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Folder: Covid-19 Assessment 08 Feb 2021

Form: Symptom Log (2)

Generated On: 09 Jun 2021 14:53:49

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:51:43
User entered empty.	System	03 Mar 2021 19:49:33

US3032249

Folder: Covid-19 Assessment 08 Feb 2021

Form: Symptom Log (2)

Generated On: 09 Jun 2021 14:53:49

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:51:43
User signature succeeded.	Keith Vrbicky (b) (4)	04 Mar 2021 16:04:32
User entered empty.	(b) (4) Kelsey Kelley (b) (4)	03 Mar 2021 19:49:33

US3032249

Folder: Covid-19 Assessment 08 Feb 2021

Form: Symptom Log (2)

Generated On: 09 Jun 2021 14:53:49

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:51:43
User signature succeeded.	Keith Vrbicky (b) (4)	04 Mar 2021 16:04:32
User entered empty.	(b) (4) Kelsey Kelley (b) (4)	03 Mar 2021 19:49:33

US3032249

Folder: Covid-19 Assessment 08 Feb 2021

Form: Symptom Log (2)

Generated On: 09 Jun 2021 14:53:49

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:51:43
User signature succeeded.	Keith Vrbicky (b) (4)	04 Mar 2021 16:04:32
User entered empty.	Kelsey Kelley (b) (4)	03 Mar 2021 19:49:33

US3032249

Folder: Covid-19 Assessment 08 Feb 2021

Form: Symptom Log (2)

Generated On: 09 Jun 2021 14:53:49

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:51:43
User signature succeeded.	Keith Vrbicky (b) (4)	04 Mar 2021 16:04:32
User entered empty.	(b) (4) Kelsey Kelley (b) (4)	03 Mar 2021 19:49:33

US3032249

Folder: Covid-19 Assessment 08 Feb 2021

Form: Symptom Log (2)

Generated On: 09 Jun 2021 14:53:49

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:51:43
User signature succeeded.	Keith Vrbicky (b) (4)	04 Mar 2021 16:04:32
User entered empty.	(b) (4) Kelsey Kelley (b) (4)	03 Mar 2021 19:49:33

US3032249

Folder: Covid-19 Assessment 08 Feb 2021

Form: Symptom Log (2)

Generated On: 09 Jun 2021 14:53:49

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:51:43
User signature succeeded.	Keith Vrbicky (b) (4)	04 Mar 2021 16:04:32
User entered empty.	(b) (4) Kelsey Kelley (b) (4)	03 Mar 2021 19:49:33
	(b) (4)	

US3032249

Folder: Covid-19 Assessment 08 Feb 2021

Form: Symptom Log (2)

Generated On: 09 Jun 2021 14:53:49

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:51:43
User signature succeeded.	Keith Vrbicky (b) (4)	04 Mar 2021 16:04:32
User entered empty.	(b) (4) Kelsey Kelley (b) (4)	03 Mar 2021 19:49:33
	(b) (4)	

US3032249

Folder: Covid-19 Assessment 08 Feb 2021

Form: Symptom Log (2)

Generated On: 09 Jun 2021 14:53:49

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:51:43
User signature succeeded.	Keith Vrbicky (b) (4)	04 Mar 2021 16:04:32
User entered empty.	(b) (4) Kelsey Kelley (b) (4)	03 Mar 2021 19:49:33
	(b) (4)	

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Folder: Covid-19 Assessment 08 Feb 2021

Form: Symptom Log (2)

Generated On: 09 Jun 2021 14:53:49

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:51:43
User signature succeeded.	Keith Vrbicky (b) (4)	04 Mar 2021 16:04:32
User entered empty.	(b) (4) Kelsey Kelley (b) (4)	03 Mar 2021 19:49:33
	(b) (4)	

US3032249

Folder: Covid-19 Assessment 08 Feb 2021

Form: Symptom Log (2)

Generated On: 09 Jun 2021 14:53:49

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:51:43
User signature succeeded.	Keith Vrbicky (b) (4)	04 Mar 2021 16:04:32
User entered empty.	(b) (4) Kelsey Kelley (b) (4)	03 Mar 2021 19:49:33

US3032249

Folder: Covid-19 Assessment 08 Feb 2021

Form: Symptom Log (2)

Generated On: 09 Jun 2021 14:53:49

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:51:43
User signature succeeded.	Keith Vrbicky (b) (4)	04 Mar 2021 16:04:32
User entered empty.	(b) (4) Kelsey Kelley (b) (4)	03 Mar 2021 19:49:33

US3032249

Folder: Covid-19 Assessment 08 Feb 2021

Form: Symptom Log (2)

Generated On: 09 Jun 2021 14:53:49

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:51:43
User signature succeeded.	Keith Vrbicky (b) (4)	04 Mar 2021 16:04:32
User entered empty.	(b) (4) Kelsey Kelley (b) (4)	03 Mar 2021 19:49:33
	(b) (4)	

US3032249

Folder: Covid-19 Assessment 08 Feb 2021

Form: Symptom Log (2)

Generated On: 09 Jun 2021 14:53:49

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:51:43
User signature succeeded.	Keith Vrbicky (b) (4)	04 Mar 2021 16:04:32
User entered empty.	Kelsey Kelley (b) (4)	03 Mar 2021 19:49:33

US3032249

Folder: Covid-19 Assessment 08 Feb 2021

Form: Symptom Log (2)

Generated On: 09 Jun 2021 14:53:49

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:51:43
User signature succeeded.	Keith Vrbicky (b) (4)	04 Mar 2021 16:04:32
User entered empty.	(b) (4) Kelsey Kelley (b) (4)	03 Mar 2021 19:49:33
	(b) (4)	

US3032249

Folder: Covid-19 Assessment 08 Feb 2021

Form: Symptom Log (2)

Generated On: 09 Jun 2021 14:53:49

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:51:43
User signature succeeded.	Keith Vrbicky (b) (4)	04 Mar 2021 16:04:32
User entered empty.	(b) (4) Kelsey Kelley (b) (4)	03 Mar 2021 19:49:33
	(b) (4)	

US3032249

Folder: Covid-19 Assessment 08 Feb 2021

Form: Symptom Log (2)

Generated On: 09 Jun 2021 14:53:49

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:51:43
User signature succeeded.	Keith Vrbicky (b) (4)	04 Mar 2021 16:04:32
User entered empty.	(b) (4) Kelsey Kelley (b) (4)	03 Mar 2021 19:49:33
	(b) (4)	

US3032249

Folder: Covid-19 Assessment 08 Feb 2021

Form: Symptom Log (2)

Generated On: 09 Jun 2021 14:53:49

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:51:43
User signature succeeded.	Keith Vrbicky (b) (4)	04 Mar 2021 16:04:32
User entered empty.	Kelsey Kelley (b) (4)	03 Mar 2021 19:49:33

US3032249

Folder: Covid-19 Assessment 08 Feb 2021

Form: Symptom Log (3)

Generated On: 09 Jun 2021 14:53:49

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:51:43
User signature succeeded.	Keith Vrbicky (b) (4)	04 Mar 2021 16:04:32
User entered 'Day 3 (Day 3)'	(b) (4) Kelsey Kelley (b) (4)	03 Mar 2021 19:50:02

US3032249

Folder: Covid-19 Assessment 08 Feb 2021

Form: Symptom Log (3)

Generated On: 09 Jun 2021 14:53:49

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:51:43
User signature succeeded.	Keith Vrbicky (b) (4)	04 Mar 2021 16:04:32
User entered '4 Feb 2021'	(b) (4) Kelsey Kelley (b) (4)	03 Mar 2021 19:50:02
	(b) (4)	

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Folder: Covid-19 Assessment 08 Feb 2021

Form: Symptom Log (3)

Generated On: 09 Jun 2021 14:53:49

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:51:43
User signature succeeded.	Keith Vrbicky (b) (4)	04 Mar 2021 16:04:32
User entered 'I'	Kelsey Kelley (b) (4)	03 Mar 2021 19:50:02

US3032249

Folder: Covid-19 Assessment 08 Feb 2021

Form: Symptom Log (3)

Generated On: 09 Jun 2021 14:53:49

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:51:43
User signature succeeded.	Keith Vrbicky (b) (4)	04 Mar 2021 16:04:32
User entered empty.	(b) (4) Kelsey Kelley (b) (4)	03 Mar 2021 19:50:02

US3032249

Folder: Covid-19 Assessment 08 Feb 2021

Form: Symptom Log (3)

Generated On: 09 Jun 2021 14:53:49

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:51:43
User entered empty.	System	03 Mar 2021 19:50:02

US3032249

Folder: Covid-19 Assessment 08 Feb 2021

Form: Symptom Log (3)

Generated On: 09 Jun 2021 14:53:49

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:51:43
User signature succeeded.	Keith Vrbicky (b) (4)	04 Mar 2021 16:04:32
User entered empty.	(b) (4) Kelsey Kelley (b) (4)	03 Mar 2021 19:50:02

US3032249

Folder: Covid-19 Assessment 08 Feb 2021

Form: Symptom Log (3)

Generated On: 09 Jun 2021 14:53:49

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:51:43
User signature succeeded.	Keith Vrbicky (b) (4)	04 Mar 2021 16:04:32
User entered empty.	(b) (4) Kelsey Kelley (b) (4)	03 Mar 2021 19:50:02

US3032249

Folder: Covid-19 Assessment 08 Feb 2021

Form: Symptom Log (3)

Generated On: 09 Jun 2021 14:53:49

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:51:43
User signature succeeded.	Keith Vrbicky (b) (4)	04 Mar 2021 16:04:32
User entered empty.	(b) (4) Kelsey Kelley (b) (4)	03 Mar 2021 19:50:02

US3032249

Folder: Covid-19 Assessment 08 Feb 2021

Form: Symptom Log (3)

Generated On: 09 Jun 2021 14:53:49

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:51:43
User signature succeeded.	Keith Vrbicky (b) (4)	04 Mar 2021 16:04:32
User entered empty.	(b) (4) Kelsey Kelley (b) (4)	03 Mar 2021 19:50:02

US3032249

Folder: Covid-19 Assessment 08 Feb 2021

Form: Symptom Log (3)

Generated On: 09 Jun 2021 14:53:49

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:51:43
User signature succeeded.	Keith Vrbicky (b) (4)	04 Mar 2021 16:04:32
User entered empty.	(b) (4) Kelsey Kelley (b) (4)	03 Mar 2021 19:50:02

US3032249

Folder: Covid-19 Assessment 08 Feb 2021

Form: Symptom Log (3)

Generated On: 09 Jun 2021 14:53:49

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:51:43
User signature succeeded.	Keith Vrbicky (b) (4)	04 Mar 2021 16:04:32
User entered empty.	(b) (4) Kelsey Kelley (b) (4)	03 Mar 2021 19:50:02

US3032249

Folder: Covid-19 Assessment 08 Feb 2021

Form: Symptom Log (3)

Generated On: 09 Jun 2021 14:53:49

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:51:43
User signature succeeded.	Keith Vrbicky (b) (4)	04 Mar 2021 16:04:32
User entered empty.	(b) (4) Kelsey Kelley (b) (4)	03 Mar 2021 19:50:02

US3032249

Folder: Covid-19 Assessment 08 Feb 2021

Form: Symptom Log (3)

Generated On: 09 Jun 2021 14:53:49

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:51:43
User signature succeeded.	Keith Vrbicky (b) (4)	04 Mar 2021 16:04:32
User entered empty.	(b) (4) Kelsey Kelley (b) (4)	03 Mar 2021 19:50:02

US3032249

Folder: Covid-19 Assessment 08 Feb 2021

Form: Symptom Log (3)

Generated On: 09 Jun 2021 14:53:49

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:51:43
User signature succeeded.	Keith Vrbicky (b) (4)	04 Mar 2021 16:04:32
User entered empty.	(b) (4) Kelsey Kelley (b) (4)	03 Mar 2021 19:50:02

US3032249

Folder: Covid-19 Assessment 08 Feb 2021

Form: Symptom Log (3)

Generated On: 09 Jun 2021 14:53:49

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:51:43
User signature succeeded.	Keith Vrbicky (b) (4)	04 Mar 2021 16:04:32
User entered empty.	(b) (4) Kelsey Kelley (b) (4)	03 Mar 2021 19:50:02

US3032249

Folder: Covid-19 Assessment 08 Feb 2021

Form: Symptom Log (3)

Generated On: 09 Jun 2021 14:53:49

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:51:43
User signature succeeded.	Keith Vrbicky (b) (4)	04 Mar 2021 16:04:32
User entered empty.	(b) (4) Kelsey Kelley (b) (4)	03 Mar 2021 19:50:02

US3032249

Folder: Covid-19 Assessment 08 Feb 2021

Form: Symptom Log (3)

Generated On: 09 Jun 2021 14:53:49

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:51:43
User signature succeeded.	Keith Vrbicky (b) (4)	04 Mar 2021 16:04:32
User entered empty.	(b) (4) Kelsey Kelley (b) (4)	03 Mar 2021 19:50:02

US3032249

Folder: Covid-19 Assessment 08 Feb 2021

Form: Symptom Log (3)

Generated On: 09 Jun 2021 14:53:49

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:51:43
User signature succeeded.	Keith Vrbicky (b) (4)	04 Mar 2021 16:04:32
User entered empty.	Kelsey Kelley (b) (4)	03 Mar 2021 19:50:02

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Folder: Covid-19 Assessment 08 Feb 2021

Form: Symptom Log (3)

Generated On: 09 Jun 2021 14:53:49

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:51:43
User signature succeeded.	Keith Vrbicky (b) (4)	04 Mar 2021 16:04:32
User entered empty.	(b) (4) Kelsey Kelley (b) (4)	03 Mar 2021 19:50:02
	(b) (4)	

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Folder: Covid-19 Assessment 08 Feb 2021

Form: Symptom Log (3)

Generated On: 09 Jun 2021 14:53:49

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:51:43
User signature succeeded.	Keith Vrbicky (b) (4)	04 Mar 2021 16:04:32
User entered empty.	(b) (4) Kelsey Kelley (b) (4)	03 Mar 2021 19:50:02

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Folder: Covid-19 Assessment 08 Feb 2021

Form: Symptom Log (3)

Generated On: 09 Jun 2021 14:53:49

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:51:43
User signature succeeded.	Keith Vrbicky (b) (4)	04 Mar 2021 16:04:32
User entered empty.	(b) (4) Kelsey Kelley (b) (4)	03 Mar 2021 19:50:02

US3032249

Folder: Covid-19 Assessment 08 Feb 2021

Form: Symptom Log (3)

Generated On: 09 Jun 2021 14:53:49

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:51:43
User signature succeeded.	Keith Vrbicky (b) (4)	04 Mar 2021 16:04:32
User entered empty.	(b) (4) Kelsey Kelley (b) (4)	03 Mar 2021 19:50:02

US3032249

Folder: Covid-19 Assessment 08 Feb 2021

Form: Symptom Log (4)

Generated On: 09 Jun 2021 14:53:49

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:51:43
User signature succeeded.	Keith Vrbicky (b) (4)	04 Mar 2021 16:04:32
User entered 'Day 4 (Day 4)'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	03 Mar 2021 19:50:27

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Folder: Covid-19 Assessment 08 Feb 2021

Form: Symptom Log (4)

Generated On: 09 Jun 2021 14:53:49

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:51:43
User signature succeeded.	Keith Vrbicky (b) (4)	04 Mar 2021 16:04:32
User entered '5 Feb 2021'	(b) (4) Kelsey Kelley (b) (4)	03 Mar 2021 19:50:27
	(b) (4)	

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Folder: Covid-19 Assessment 08 Feb 2021

Form: Symptom Log (4)

Generated On: 09 Jun 2021 14:53:49

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:51:43
User signature succeeded.	Keith Vrbicky (b) (4)	04 Mar 2021 16:04:32
User entered 'I'	(b) (4) Kelsey Kelley (b) (4)	03 Mar 2021 19:50:27

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Folder: Covid-19 Assessment 08 Feb 2021

Form: Symptom Log (4)

Generated On: 09 Jun 2021 14:53:49

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:51:43
User signature succeeded.	Keith Vrbicky (b) (4)	04 Mar 2021 16:04:32
User entered empty.	(b) (4) Kelsey Kelley (b) (4)	03 Mar 2021 19:50:27

US3032249

Folder: Covid-19 Assessment 08 Feb 2021

Form: Symptom Log (4)

Generated On: 09 Jun 2021 14:53:49

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:51:43
User entered empty.	System	03 Mar 2021 19:50:27

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Folder: Covid-19 Assessment 08 Feb 2021

Form: Symptom Log (4)

Generated On: 09 Jun 2021 14:53:49

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:51:43
User signature succeeded.	Keith Vrbicky (b) (4)	04 Mar 2021 16:04:32
User entered empty.	(b) (4) Kelsey Kelley (b) (4)	03 Mar 2021 19:50:27

US3032249

Folder: Covid-19 Assessment 08 Feb 2021

Form: Symptom Log (4)

Generated On: 09 Jun 2021 14:53:49

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:51:43
User signature succeeded.	Keith Vrbicky (b) (4)	04 Mar 2021 16:04:32
User entered empty.	(b) (4) Kelsey Kelley (b) (4)	03 Mar 2021 19:50:27

US3032249

Folder: Covid-19 Assessment 08 Feb 2021

Form: Symptom Log (4)

Generated On: 09 Jun 2021 14:53:49

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:51:43
User signature succeeded.	Keith Vrbicky (b) (4)	04 Mar 2021 16:04:32
User entered empty.	(b) (4) Kelsey Kelley (b) (4)	03 Mar 2021 19:50:27

US3032249

Folder: Covid-19 Assessment 08 Feb 2021

Form: Symptom Log (4)

Generated On: 09 Jun 2021 14:53:49

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:51:43
User signature succeeded.	Keith Vrbicky (b) (4)	04 Mar 2021 16:04:32
User entered empty.	(b) (4) Kelsey Kelley (b) (4)	03 Mar 2021 19:50:27

US3032249

Folder: Covid-19 Assessment 08 Feb 2021

Form: Symptom Log (4)

Generated On: 09 Jun 2021 14:53:49

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:51:43
User signature succeeded.	Keith Vrbicky (b) (4)	04 Mar 2021 16:04:32
User entered empty.	(b) (4) Kelsey Kelley (b) (4)	03 Mar 2021 19:50:27
	(b) (4)	

US3032249

Folder: Covid-19 Assessment 08 Feb 2021

Form: Symptom Log (4)

Generated On: 09 Jun 2021 14:53:49

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:51:43
User signature succeeded.	Keith Vrbicky (b) (4)	04 Mar 2021 16:04:32
User entered empty.	(b) (4) Kelsey Kelley (b) (4)	03 Mar 2021 19:50:27

US3032249

Folder: Covid-19 Assessment 08 Feb 2021

Form: Symptom Log (4)

Generated On: 09 Jun 2021 14:53:49

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:51:43
User signature succeeded.	Keith Vrbicky (b) (4)	04 Mar 2021 16:04:32
User entered empty.	(b) (4) Kelsey Kelley (b) (4)	03 Mar 2021 19:50:27

US3032249

Folder: Covid-19 Assessment 08 Feb 2021

Form: Symptom Log (4)

Generated On: 09 Jun 2021 14:53:49

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:51:43
User signature succeeded.	Keith Vrbicky (b) (4)	04 Mar 2021 16:04:32
User entered empty.	(b) (4) Kelsey Kelley (b) (4)	03 Mar 2021 19:50:27

US3032249

Folder: Covid-19 Assessment 08 Feb 2021

Form: Symptom Log (4)

Generated On: 09 Jun 2021 14:53:49

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:51:43
User signature succeeded.	Keith Vrbicky (b) (4)	04 Mar 2021 16:04:32
User entered empty.	(b) (4) Kelsey Kelley (b) (4)	03 Mar 2021 19:50:27

US3032249

Folder: Covid-19 Assessment 08 Feb 2021

Form: Symptom Log (4)

Generated On: 09 Jun 2021 14:53:49

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:51:43
User signature succeeded.	Keith Vrbicky (b) (4)	04 Mar 2021 16:04:32
User entered empty.	(b) (4) Kelsey Kelley (b) (4)	03 Mar 2021 19:50:27
	(b) (4)	

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Folder: Covid-19 Assessment 08 Feb 2021

Form: Symptom Log (4)

Generated On: 09 Jun 2021 14:53:49

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:51:43
User signature succeeded.	Keith Vrbicky (b) (4)	04 Mar 2021 16:04:32
User entered empty.	(b) (4) Kelsey Kelley (b) (4)	03 Mar 2021 19:50:27

US3032249

Folder: Covid-19 Assessment 08 Feb 2021

Form: Symptom Log (4)

Generated On: 09 Jun 2021 14:53:49

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:51:43
User signature succeeded.	Keith Vrbicky (b) (4)	04 Mar 2021 16:04:32
User entered empty.	(b) (4) Kelsey Kelley (b) (4)	03 Mar 2021 19:50:27
	(b) (4)	

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Folder: Covid-19 Assessment 08 Feb 2021

Form: Symptom Log (4)

Generated On: 09 Jun 2021 14:53:49

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:51:43
User signature succeeded.	Keith Vrbicky (b) (4)	04 Mar 2021 16:04:32
User entered empty.	Kelsey Kelley (b) (4)	03 Mar 2021 19:50:27

US3032249

Folder: Covid-19 Assessment 08 Feb 2021

Form: Symptom Log (4)

Generated On: 09 Jun 2021 14:53:49

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:51:43
User signature succeeded.	Keith Vrbicky (b) (4)	04 Mar 2021 16:04:32
User entered empty.	(b) (4) Kelsey Kelley (b) (4)	03 Mar 2021 19:50:27
	(b) (4)	

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Folder: Covid-19 Assessment 08 Feb 2021

Form: Symptom Log (4)

Generated On: 09 Jun 2021 14:53:49

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:51:43
User signature succeeded.	Keith Vrbicky (b) (4)	04 Mar 2021 16:04:32
User entered empty.	(b) (4) Kelsey Kelley (b) (4)	03 Mar 2021 19:50:27
	(b) (4)	

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Folder: Covid-19 Assessment 08 Feb 2021

Form: Symptom Log (4)

Generated On: 09 Jun 2021 14:53:49

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:51:43
User signature succeeded.	Keith Vrbicky (b) (4)	04 Mar 2021 16:04:32
User entered empty.	(b) (4) Kelsey Kelley (b) (4)	03 Mar 2021 19:50:27

US3032249

Folder: Covid-19 Assessment 08 Feb 2021

Form: Symptom Log (4)

Generated On: 09 Jun 2021 14:53:49

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:51:43
User signature succeeded.	Keith Vrbicky (b) (4)	04 Mar 2021 16:04:32
User entered empty.	(b) (4) Kelsey Kelley (b) (4)	03 Mar 2021 19:50:27

US3032249

Folder: Covid-19 Assessment 08 Feb 2021

Form: Symptom Log (5)

Generated On: 09 Jun 2021 14:53:49

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:51:43
User signature succeeded.	Keith Vrbicky (b) (4)	04 Mar 2021 16:04:32
User entered 'Day 5 (Day 5)'	(b) (4) Kelsey Kelley (b) (4)	03 Mar 2021 19:50:37

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Folder: Covid-19 Assessment 08 Feb 2021

Form: Symptom Log (5)

Generated On: 09 Jun 2021 14:53:49

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:51:43
User signature succeeded.	Keith Vrbicky (b) (4)	04 Mar 2021 16:04:32
User entered '6 Feb 2021'	(b) (4) Kelsey Kelley (b) (4)	03 Mar 2021 19:50:37
	(b) (4)	

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Folder: Covid-19 Assessment 08 Feb 2021

Form: Symptom Log (5)

Generated On: 09 Jun 2021 14:53:49

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:51:43
User signature succeeded.	Keith Vrbicky (b) (4)	04 Mar 2021 16:04:32
User entered 'I'	Kelsey Kelley (b) (4)	03 Mar 2021 19:50:37

US3032249

Folder: Covid-19 Assessment 08 Feb 2021

Form: Symptom Log (5)

Generated On: 09 Jun 2021 14:53:49

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:51:43
User signature succeeded.	Keith Vrbicky (b) (4)	04 Mar 2021 16:04:32
User entered empty.	(b) (4) Kelsey Kelley (b) (4)	03 Mar 2021 19:50:37

US3032249

Folder: Covid-19 Assessment 08 Feb 2021

Form: Symptom Log (5)

Generated On: 09 Jun 2021 14:53:49

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:51:43
User entered empty.	System	03 Mar 2021 19:50:37

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Folder: Covid-19 Assessment 08 Feb 2021

Form: Symptom Log (5)

Generated On: 09 Jun 2021 14:53:49

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:51:43
User signature succeeded.	Keith Vrbicky (b) (4)	04 Mar 2021 16:04:32
User entered empty.	(b) (4) Kelsey Kelley (b) (4)	03 Mar 2021 19:50:37

US3032249

Folder: Covid-19 Assessment 08 Feb 2021

Form: Symptom Log (5)

Generated On: 09 Jun 2021 14:53:49

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:51:43
User signature succeeded.	Keith Vrbicky (b) (4)	04 Mar 2021 16:04:32
User entered empty.	(b) (4) Kelsey Kelley (b) (4)	03 Mar 2021 19:50:37

US3032249

Folder: Covid-19 Assessment 08 Feb 2021

Form: Symptom Log (5)

Generated On: 09 Jun 2021 14:53:49

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:51:43
User signature succeeded.	Keith Vrbicky (b) (4)	04 Mar 2021 16:04:32
User entered empty.	(b) (4) Kelsey Kelley (b) (4)	03 Mar 2021 19:50:37
	(b) (4)	

US3032249

Folder: Covid-19 Assessment 08 Feb 2021

Form: Symptom Log (5)

Generated On: 09 Jun 2021 14:53:49

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:51:43
User signature succeeded.	Keith Vrbicky (b) (4)	04 Mar 2021 16:04:32
User entered empty.	(b) (4) Kelsey Kelley (b) (4)	03 Mar 2021 19:50:37

US3032249

Folder: Covid-19 Assessment 08 Feb 2021

Form: Symptom Log (5)

Generated On: 09 Jun 2021 14:53:49

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:51:43
User signature succeeded.	Keith Vrbicky (b) (4)	04 Mar 2021 16:04:32
User entered empty.	(b) (4) Kelsey Kelley (b) (4)	03 Mar 2021 19:50:37

US3032249

Folder: Covid-19 Assessment 08 Feb 2021

Form: Symptom Log (5)

Generated On: 09 Jun 2021 14:53:49

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:51:43
User signature succeeded.	Keith Vrbicky (b) (4)	04 Mar 2021 16:04:32
User entered empty.	(b) (4) Kelsey Kelley (b) (4)	03 Mar 2021 19:50:37

US3032249

Folder: Covid-19 Assessment 08 Feb 2021

Form: Symptom Log (5)

Generated On: 09 Jun 2021 14:53:49

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:51:43
User signature succeeded.	Keith Vrbicky (b) (4)	04 Mar 2021 16:04:32
User entered empty.	(b) (4) Kelsey Kelley (b) (4)	03 Mar 2021 19:50:37

US3032249

Folder: Covid-19 Assessment 08 Feb 2021

Form: Symptom Log (5)

Generated On: 09 Jun 2021 14:53:49

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:51:43
User signature succeeded.	Keith Vrbicky (b) (4)	04 Mar 2021 16:04:32
User entered empty.	(b) (4) Kelsey Kelley (b) (4)	03 Mar 2021 19:50:37
	(b) (4)	

US3032249

Folder: Covid-19 Assessment 08 Feb 2021

Form: Symptom Log (5)

Generated On: 09 Jun 2021 14:53:49

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:51:43
User signature succeeded.	Keith Vrbicky (b) (4)	04 Mar 2021 16:04:32
User entered empty.	(b) (4) Kelsey Kelley (b) (4)	03 Mar 2021 19:50:37

US3032249

Folder: Covid-19 Assessment 08 Feb 2021

Form: Symptom Log (5)

Generated On: 09 Jun 2021 14:53:49

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:51:43
User signature succeeded.	Keith Vrbicky (b) (4)	04 Mar 2021 16:04:32
User entered empty.	(b) (4) Kelsey Kelley (b) (4)	03 Mar 2021 19:50:37
	(b) (4)	

US3032249

Folder: Covid-19 Assessment 08 Feb 2021

Form: Symptom Log (5)

Generated On: 09 Jun 2021 14:53:49

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:51:43
User signature succeeded.	Keith Vrbicky (b) (4)	04 Mar 2021 16:04:32
User entered empty.	(b) (4) Kelsey Kelley (b) (4)	03 Mar 2021 19:50:37

US3032249

Folder: Covid-19 Assessment 08 Feb 2021

Form: Symptom Log (5)

Generated On: 09 Jun 2021 14:53:49

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:51:43
User signature succeeded.	Keith Vrbicky (b) (4)	04 Mar 2021 16:04:32
User entered empty.	(b) (4) Kelsey Kelley (b) (4)	03 Mar 2021 19:50:37

US3032249

Folder: Covid-19 Assessment 08 Feb 2021

Form: Symptom Log (5)

Generated On: 09 Jun 2021 14:53:49

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:51:43
User signature succeeded.	Keith Vrbicky (b) (4)	04 Mar 2021 16:04:32
User entered empty.	(b) (4) Kelsey Kelley (b) (4)	03 Mar 2021 19:50:37

US3032249

Folder: Covid-19 Assessment 08 Feb 2021

Form: Symptom Log (5)

Generated On: 09 Jun 2021 14:53:49

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:51:43
User signature succeeded.	Keith Vrbicky (b) (4)	04 Mar 2021 16:04:32
User entered empty.	(b) (4) Kelsey Kelley (b) (4)	03 Mar 2021 19:50:37

US3032249

Folder: Covid-19 Assessment 08 Feb 2021

Form: Symptom Log (5)

Generated On: 09 Jun 2021 14:53:49

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:51:43
User signature succeeded.	Keith Vrbicky (b) (4)	04 Mar 2021 16:04:32
User entered empty.	(b) (4) Kelsey Kelley (b) (4)	03 Mar 2021 19:50:37
	(b) (4)	

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Folder: Covid-19 Assessment 08 Feb 2021

Form: Symptom Log (5)

Generated On: 09 Jun 2021 14:53:49

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:51:43
User signature succeeded.	Keith Vrbicky (b) (4)	04 Mar 2021 16:04:32
User entered empty.	Kelsey Kelley (b) (4)	03 Mar 2021 19:50:37

US3032249

Folder: Covid-19 Assessment 08 Feb 2021

Form: Symptom Log (5)

Generated On: 09 Jun 2021 14:53:49

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:51:43
User signature succeeded.	Keith Vrbicky (b) (4)	04 Mar 2021 16:04:32
User entered empty.	Kelsey Kelley (b) (4)	03 Mar 2021 19:50:37

US3032249

Folder: Covid-19 Assessment 08 Feb 2021

Form: Symptom Log (6)

Generated On: 09 Jun 2021 14:53:49

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:51:43
User signature succeeded.	Keith Vrbicky (b) (4)	04 Mar 2021 16:04:32
User entered 'Day 6 (Day 6)'	(b) (4) Kelsey Kelley (b) (4)	03 Mar 2021 19:50:45

US3032249

Folder: Covid-19 Assessment 08 Feb 2021

Form: Symptom Log (6)

Generated On: 09 Jun 2021 14:53:49

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:51:43
User signature succeeded.	Keith Vrbicky (b) (4)	04 Mar 2021 16:04:32
User entered '7 Feb 2021'	(b) (4) Kelsey Kelley (b) (4)	03 Mar 2021 19:50:45
	(b) (4)	

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Folder: Covid-19 Assessment 08 Feb 2021

Form: Symptom Log (6)

Generated On: 09 Jun 2021 14:53:49

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:51:43
User signature succeeded.	Keith Vrbicky (b) (4)	04 Mar 2021 16:04:32
User entered 'I'	Kelsey Kelley (b) (4)	03 Mar 2021 19:50:45

US3032249

Folder: Covid-19 Assessment 08 Feb 2021

Form: Symptom Log (6)

Generated On: 09 Jun 2021 14:53:49

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:51:43
User signature succeeded.	Keith Vrbicky (b) (4)	04 Mar 2021 16:04:32
User entered empty.	(b) (4) Kelsey Kelley (b) (4)	03 Mar 2021 19:50:45

US3032249

Folder: Covid-19 Assessment 08 Feb 2021

Form: Symptom Log (6)

Generated On: 09 Jun 2021 14:53:49

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:51:43
User entered empty.	System	03 Mar 2021 19:50:45

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Folder: Covid-19 Assessment 08 Feb 2021

Form: Symptom Log (6)

Generated On: 09 Jun 2021 14:53:49

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:51:43
User signature succeeded.	Keith Vrbicky (b) (4)	04 Mar 2021 16:04:32
User entered empty.	(b) (4) Kelsey Kelley (b) (4)	03 Mar 2021 19:50:45

US3032249

Folder: Covid-19 Assessment 08 Feb 2021

Form: Symptom Log (6)

Generated On: 09 Jun 2021 14:53:49

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:51:43
User signature succeeded.	Keith Vrbicky (b) (4)	04 Mar 2021 16:04:32
User entered empty.	(b) (4) Kelsey Kelley (b) (4)	03 Mar 2021 19:50:45

US3032249

Folder: Covid-19 Assessment 08 Feb 2021

Form: Symptom Log (6)

Generated On: 09 Jun 2021 14:53:49

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:51:43
User signature succeeded.	Keith Vrbicky (b) (4)	04 Mar 2021 16:04:32
User entered empty.	(b) (4) Kelsey Kelley (b) (4)	03 Mar 2021 19:50:45
	(b) (4)	

US3032249

Folder: Covid-19 Assessment 08 Feb 2021

Form: Symptom Log (6)

Generated On: 09 Jun 2021 14:53:49

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:51:43
User signature succeeded.	Keith Vrbicky (b) (4)	04 Mar 2021 16:04:32
User entered empty.	(b) (4) Kelsey Kelley (b) (4)	03 Mar 2021 19:50:45
	(b) (4)	

US3032249

Folder: Covid-19 Assessment 08 Feb 2021

Form: Symptom Log (6)

Generated On: 09 Jun 2021 14:53:49

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:51:43
User signature succeeded.	Keith Vrbicky (b) (4)	04 Mar 2021 16:04:32
User entered empty.	(b) (4) Kelsey Kelley (b) (4)	03 Mar 2021 19:50:45

US3032249

Folder: Covid-19 Assessment 08 Feb 2021

Form: Symptom Log (6)

Generated On: 09 Jun 2021 14:53:49

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:51:43
User signature succeeded.	Keith Vrbicky (b) (4)	04 Mar 2021 16:04:32
User entered empty.	(b) (4) Kelsey Kelley (b) (4)	03 Mar 2021 19:50:45

US3032249

Folder: Covid-19 Assessment 08 Feb 2021

Form: Symptom Log (6)

Generated On: 09 Jun 2021 14:53:49

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:51:43
User signature succeeded.	Keith Vrbicky (b) (4)	04 Mar 2021 16:04:32
User entered empty.	(b) (4) Kelsey Kelley (b) (4)	03 Mar 2021 19:50:45

US3032249

Folder: Covid-19 Assessment 08 Feb 2021

Form: Symptom Log (6)

Generated On: 09 Jun 2021 14:53:49

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:51:43
User signature succeeded.	Keith Vrbicky (b) (4)	04 Mar 2021 16:04:32
User entered empty.	(b) (4) Kelsey Kelley (b) (4)	03 Mar 2021 19:50:45
	(b) (4)	

US3032249

Folder: Covid-19 Assessment 08 Feb 2021

Form: Symptom Log (6)

Generated On: 09 Jun 2021 14:53:49

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:51:43
User signature succeeded.	Keith Vrbicky (b) (4)	04 Mar 2021 16:04:32
User entered empty.	(b) (4) Kelsey Kelley (b) (4)	03 Mar 2021 19:50:45

US3032249

Folder: Covid-19 Assessment 08 Feb 2021

Form: Symptom Log (6)

Generated On: 09 Jun 2021 14:53:49

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:51:43
User signature succeeded.	Keith Vrbicky (b) (4)	04 Mar 2021 16:04:32
User entered empty.	(b) (4) Kelsey Kelley (b) (4)	03 Mar 2021 19:50:45

US3032249

Folder: Covid-19 Assessment 08 Feb 2021

Form: Symptom Log (6)

Generated On: 09 Jun 2021 14:53:49

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:51:43
User signature succeeded.	Keith Vrbicky (b) (4)	04 Mar 2021 16:04:32
User entered empty.	(b) (4) Kelsey Kelley (b) (4)	03 Mar 2021 19:50:45
	(b) (4)	

US3032249

Folder: Covid-19 Assessment 08 Feb 2021

Form: Symptom Log (6)

Generated On: 09 Jun 2021 14:53:49

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:51:43
User signature succeeded.	Keith Vrbicky (b) (4)	04 Mar 2021 16:04:32
User entered empty.	(b) (4) Kelsey Kelley (b) (4)	03 Mar 2021 19:50:45

US3032249

Folder: Covid-19 Assessment 08 Feb 2021

Form: Symptom Log (6)

Generated On: 09 Jun 2021 14:53:49

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:51:43
User signature succeeded.	Keith Vrbicky (b) (4)	04 Mar 2021 16:04:32
User entered empty.	Kelsey Kelley (b) (4)	03 Mar 2021 19:50:45

US3032249

Folder: Covid-19 Assessment 08 Feb 2021

Form: Symptom Log (6)

Generated On: 09 Jun 2021 14:53:49

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:51:43
User signature succeeded.	Keith Vrbicky (b) (4)	04 Mar 2021 16:04:32
User entered empty.	(b) (4) Kelsey Kelley (b) (4)	03 Mar 2021 19:50:45

US3032249

Folder: Covid-19 Assessment 08 Feb 2021

Form: Symptom Log (6)

Generated On: 09 Jun 2021 14:53:49

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:51:43
User signature succeeded.	Keith Vrbicky (b) (4)	04 Mar 2021 16:04:32
User entered empty.	(b) (4) Kelsey Kelley (b) (4)	03 Mar 2021 19:50:45
	(b) (4)	

US3032249

Folder: Covid-19 Assessment 08 Feb 2021

Form: Symptom Log (6)

Generated On: 09 Jun 2021 14:53:49

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:51:43
User signature succeeded.	Keith Vrbicky (b) (4)	04 Mar 2021 16:04:32
User entered empty.	(b) (4) Kelsey Kelley (b) (4)	03 Mar 2021 19:50:45

US3032249

Folder: Covid-19 Assessment 08 Feb 2021

Form: Symptom Log (6)

Generated On: 09 Jun 2021 14:53:49

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:51:43
User signature succeeded.	Keith Vrbicky (b) (4)	04 Mar 2021 16:04:32
User entered empty.	(b) (4) Kelsey Kelley (b) (4)	03 Mar 2021 19:50:45

US3032249

Folder: Covid-19 Assessment 08 Feb 2021

Form: Symptom Log (7)

Generated On: 09 Jun 2021 14:53:49

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:51:43
User signature succeeded.	Keith Vrbicky (b) (4)	04 Mar 2021 16:04:32
User entered 'Day 7 (Day 7)'	(b) (4) Kelsey Kelley (b) (4)	03 Mar 2021 19:53:44

US3032249

Folder: Covid-19 Assessment 08 Feb 2021

Form: Symptom Log (7)

Generated On: 09 Jun 2021 14:53:49

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:51:43
User signature succeeded.	Keith Vrbicky (b) (4)	04 Mar 2021 16:04:32
User entered '8 Feb 2021'	(b) (4) Kelsey Kelley (b) (4)	03 Mar 2021 19:53:44
	(b) (4)	

US3032249

Folder: Covid-19 Assessment 08 Feb 2021

Form: Symptom Log (7)

Generated On: 09 Jun 2021 14:53:49

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:51:43
User signature succeeded.	Keith Vrbicky (b) (4)	04 Mar 2021 16:04:32
User entered '0'	Kelsey Kelley (b) (4)	03 Mar 2021 19:53:44

US3032249

Folder: Covid-19 Assessment 08 Feb 2021

Form: Symptom Log (7)

Generated On: 09 Jun 2021 14:53:49

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:51:43
User signature succeeded.	Keith Vrbicky (b) (4)	04 Mar 2021 16:04:32
User entered missing code ND - Not Done.	(b) (4) Kelsey Kelley (b) (4)	03 Mar 2021 19:53:44

US3032249

Folder: Covid-19 Assessment 08 Feb 2021

Form: Symptom Log (7)

Generated On: 09 Jun 2021 14:53:49

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:51:43
User entered '%'	System	03 Mar 2021 19:53:44

US3032249

Folder: Covid-19 Assessment 08 Feb 2021

Form: Symptom Log (7)

Generated On: 09 Jun 2021 14:53:49

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:51:43
User signature succeeded.	Keith Vrbicky (b) (4)	04 Mar 2021 16:04:32
User entered missing code ND - Not Done.	(b) (4) Kelsey Kelley (b) (4)	03 Mar 2021 19:53:44

US3032249

Folder: Covid-19 Assessment 08 Feb 2021

Form: Symptom Log (7)

Generated On: 09 Jun 2021 14:53:49

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:51:43
User signature succeeded.	Keith Vrbicky (b) (4)	04 Mar 2021 16:04:32
User entered 'Moderate (Moderate)'	Kelsey Kelley (b) (4)	03 Mar 2021 19:53:44

US3032249

Folder: Covid-19 Assessment 08 Feb 2021

Form: Symptom Log (7)

Generated On: 09 Jun 2021 14:53:49

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:51:43
User signature succeeded.	Keith Vrbicky (b) (4)	04 Mar 2021 16:04:32
User entered 'Moderate (Moderate)'	Kelsey Kelley (b) (4)	03 Mar 2021 19:53:44

US3032249

Folder: Covid-19 Assessment 08 Feb 2021

Form: Symptom Log (7)

Generated On: 09 Jun 2021 14:53:49

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:51:43
User signature succeeded.	Keith Vrbicky (b) (4)	04 Mar 2021 16:04:32
User entered 'Moderate (Moderate)'	(b) (4) Kelsey Kelley (b) (4)	03 Mar 2021 19:53:44
	(b) (4)	

US3032249

Folder: Covid-19 Assessment 08 Feb 2021

Form: Symptom Log (7)

Generated On: 09 Jun 2021 14:53:49

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:51:43
User signature succeeded.	Keith Vrbicky (b) (4)	04 Mar 2021 16:04:32
User entered 'Mild (Mild)'	(b) (4) Kelsey Kelley (b) (4)	03 Mar 2021 19:53:44
	(b) (4)	

US3032249

Folder: Covid-19 Assessment 08 Feb 2021

Form: Symptom Log (7)

Generated On: 09 Jun 2021 14:53:49

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:51:43
User signature succeeded.	Keith Vrbicky (b) (4)	04 Mar 2021 16:04:32
User entered 'Moderate (Moderate)'	(b) (4) Kelsey Kelley (b) (4)	03 Mar 2021 19:53:44

US3032249

Folder: Covid-19 Assessment 08 Feb 2021

Form: Symptom Log (7)

Generated On: 09 Jun 2021 14:53:49

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:51:43
User signature succeeded.	Keith Vrbicky (b) (4)	04 Mar 2021 16:04:32
User entered 'Moderate (Moderate)'	(b) (4) Kelsey Kelley (b) (4)	03 Mar 2021 19:53:44

US3032249

Folder: Covid-19 Assessment 08 Feb 2021

Form: Symptom Log (7)

Generated On: 09 Jun 2021 14:53:49

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:51:43
User signature succeeded.	Keith Vrbicky (b) (4)	04 Mar 2021 16:04:32
User entered 'Moderate (Moderate)'	Kelsey Kelley (b) (4)	03 Mar 2021 19:53:44

US3032249

Folder: Covid-19 Assessment 08 Feb 2021

Form: Symptom Log (7)

Generated On: 09 Jun 2021 14:53:49

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:51:43
User signature succeeded.	Keith Vrbicky (b) (4)	04 Mar 2021 16:04:32
User entered 'Mild (Mild)'	(b) (4) Kelsey Kelley (b) (4)	03 Mar 2021 19:53:44
	(b) (4)	

US3032249

Folder: Covid-19 Assessment 08 Feb 2021

Form: Symptom Log (7)

Generated On: 09 Jun 2021 14:53:49

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:51:43
User signature succeeded.	Keith Vrbicky (b) (4)	04 Mar 2021 16:04:32
User entered 'Moderate (Moderate)'	Kelsey Kelley (b) (4)	03 Mar 2021 19:53:44

US3032249

Folder: Covid-19 Assessment 08 Feb 2021

Form: Symptom Log (7)

Generated On: 09 Jun 2021 14:53:49

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:51:43
User signature succeeded.	Keith Vrbicky (b) (4)	04 Mar 2021 16:04:32
User entered empty.	Kelsey Kelley (b) (4)	03 Mar 2021 19:53:44

US3032249

Folder: Covid-19 Assessment 08 Feb 2021

Form: Symptom Log (7)

Generated On: 09 Jun 2021 14:53:49

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:51:43
User signature succeeded.	Keith Vrbicky (b) (4)	04 Mar 2021 16:04:32
User entered 'Severe (Severe)'	(b) (4) Kelsey Kelley (b) (4)	03 Mar 2021 19:53:44

US3032249

Folder: Covid-19 Assessment 08 Feb 2021

Form: Symptom Log (7)

Generated On: 09 Jun 2021 14:53:49

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:51:43
User signature succeeded.	Keith Vrbicky (b) (4)	04 Mar 2021 16:04:32
User entered 'Moderate (Moderate)' reason for change: Data Entry Error	(b) (4)	
User entered empty.	Kelsey Kelley (b) (4)	03 Mar 2021 19:55:01
	(b) (4)	
	Kelsey Kelley (b) (4)	03 Mar 2021 19:53:44
	(b) (4)	

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Folder: Covid-19 Assessment 08 Feb 2021

Form: Symptom Log (7)

Generated On: 09 Jun 2021 14:53:49

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:51:43
User signature succeeded.	Keith Vrbicky (b) (4)	04 Mar 2021 16:04:32
User entered 'None (None)'	(b) (4) Kelsey Kelley (b) (4)	03 Mar 2021 19:53:44

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Folder: Covid-19 Assessment 08 Feb 2021

Form: Symptom Log (7)

Generated On: 09 Jun 2021 14:53:49

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:51:43
User signature succeeded.	Keith Vrbicky (b) (4)	04 Mar 2021 16:04:32
User entered 'Not Done (Not Done)'	Kelsey Kelley (b) (4)	03 Mar 2021 19:53:44

US3032249

Folder: Covid-19 Assessment 08 Feb 2021

Form: Symptom Log (7)

Generated On: 09 Jun 2021 14:53:49

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:51:43
User signature succeeded.	Keith Vrbicky (b) (4)	04 Mar 2021 16:04:32
User entered 'Not Done (Not Done)'	(b) (4) Kelsey Kelley (b) (4)	03 Mar 2021 19:53:44

US3032249

Folder: Covid-19 Assessment 08 Feb 2021

Form: Symptom Log (7)

Generated On: 09 Jun 2021 14:53:49

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:51:43
User signature succeeded.	Keith Vrbicky (b) (4)	04 Mar 2021 16:04:32
User entered 'Moderate (Moderate)'	Kelsey Kelley (b) (4)	03 Mar 2021 19:53:44

US3032249

Folder: Covid-19 Assessment 08 Feb 2021

Form: Symptom Log (8)

Generated On: 09 Jun 2021 14:53:49

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:51:43
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:41:55
User entered 'Day 8 (Day 8)'	Kelsey Kelley (b) (4)	26 Mar 2021 16:12:13

US3032249

Folder: Covid-19 Assessment 08 Feb 2021

Form: Symptom Log (8)

Generated On: 09 Jun 2021 14:53:49

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:51:43
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:41:55
User entered '9 Feb 2021'	Kelsey Kelley (b) (4)	26 Mar 2021 16:12:13

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Folder: Covid-19 Assessment 08 Feb 2021

Form: Symptom Log (8)

Generated On: 09 Jun 2021 14:53:49

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:51:43
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:41:55
User entered 'I'	Kelsey Kelley (b) (4)	26 Mar 2021 16:12:13

US3032249

Folder: Covid-19 Assessment 08 Feb 2021

Form: Symptom Log (8)

Generated On: 09 Jun 2021 14:53:49

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:51:43
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:41:55
User entered empty.	Kelsey Kelley (b) (4)	26 Mar 2021 16:12:13

US3032249

Folder: Covid-19 Assessment 08 Feb 2021

Form: Symptom Log (8)

Generated On: 09 Jun 2021 14:53:49

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:51:43
User entered empty.	System	26 Mar 2021 16:12:13

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Folder: Covid-19 Assessment 08 Feb 2021

Form: Symptom Log (8)

Generated On: 09 Jun 2021 14:53:49

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:51:43
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:41:55
User entered empty.	Kelsey Kelley (b) (4)	26 Mar 2021 16:12:13

US3032249

Folder: Covid-19 Assessment 08 Feb 2021

Form: Symptom Log (8)

Generated On: 09 Jun 2021 14:53:49

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:51:43
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:41:55
User entered empty.	Kelsey Kelley (b) (4)	26 Mar 2021 16:12:13

US3032249

Folder: Covid-19 Assessment 08 Feb 2021

Form: Symptom Log (8)

Generated On: 09 Jun 2021 14:53:49

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:51:43
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:41:55
User entered empty.	Kelsey Kelley (b) (4)	26 Mar 2021 16:12:13

US3032249

Folder: Covid-19 Assessment 08 Feb 2021

Form: Symptom Log (8)

Generated On: 09 Jun 2021 14:53:49

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:51:43
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:41:55
User entered empty.	Kelsey Kelley (b) (4)	26 Mar 2021 16:12:13

US3032249

Folder: Covid-19 Assessment 08 Feb 2021

Form: Symptom Log (8)

Generated On: 09 Jun 2021 14:53:49

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:51:43
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:41:55
User entered empty.	Kelsey Kelley (b) (4)	26 Mar 2021 16:12:13

US3032249

Folder: Covid-19 Assessment 08 Feb 2021

Form: Symptom Log (8)

Generated On: 09 Jun 2021 14:53:49

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:51:43
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:41:55
User entered empty.	Kelsey Kelley (b) (4)	26 Mar 2021 16:12:13

US3032249

Folder: Covid-19 Assessment 08 Feb 2021

Form: Symptom Log (8)

Generated On: 09 Jun 2021 14:53:49

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:51:43
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:41:55
User entered empty.	Kelsey Kelley (b) (4)	26 Mar 2021 16:12:13

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Folder: Covid-19 Assessment 08 Feb 2021

Form: Symptom Log (8)

Generated On: 09 Jun 2021 14:53:49

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:51:43
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:41:55
User entered empty.	Kelsey Kelley (b) (4)	26 Mar 2021 16:12:13

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Folder: Covid-19 Assessment 08 Feb 2021

Form: Symptom Log (8)

Generated On: 09 Jun 2021 14:53:49

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:51:43
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:41:55
User entered empty.	Kelsey Kelley (b) (4)	26 Mar 2021 16:12:13

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Folder: Covid-19 Assessment 08 Feb 2021

Form: Symptom Log (8)

Generated On: 09 Jun 2021 14:53:49

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:51:43
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:41:55
User entered empty.	Kelsey Kelley (b) (4)	26 Mar 2021 16:12:13

US3032249

Folder: Covid-19 Assessment 08 Feb 2021

Form: Symptom Log (8)

Generated On: 09 Jun 2021 14:53:49

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:51:43
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:41:55
User entered empty.	Kelsey Kelley (b) (4)	26 Mar 2021 16:12:13

US3032249

Folder: Covid-19 Assessment 08 Feb 2021

Form: Symptom Log (8)

Generated On: 09 Jun 2021 14:53:49

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:51:43
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:41:55
User entered empty.	Kelsey Kelley (b) (4)	26 Mar 2021 16:12:13

US3032249

Folder: Covid-19 Assessment 08 Feb 2021

Form: Symptom Log (8)

Generated On: 09 Jun 2021 14:53:49

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:51:43
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:41:55
User entered empty.	Kelsey Kelley (b) (4)	26 Mar 2021 16:12:13

US3032249

Folder: Covid-19 Assessment 08 Feb 2021

Form: Symptom Log (8)

Generated On: 09 Jun 2021 14:53:49

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:51:43
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:41:55
User entered empty.	Kelsey Kelley (b) (4)	26 Mar 2021 16:12:13

US3032249

Folder: Covid-19 Assessment 08 Feb 2021

Form: Symptom Log (8)

Generated On: 09 Jun 2021 14:53:49

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:51:43
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:41:55
User entered empty.	Kelsey Kelley (b) (4)	26 Mar 2021 16:12:13

US3032249

Folder: Covid-19 Assessment 08 Feb 2021

Form: Symptom Log (8)

Generated On: 09 Jun 2021 14:53:49

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:51:43
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:41:55
User entered empty.	Kelsey Kelley (b) (4)	26 Mar 2021 16:12:13

US3032249

Folder: Covid-19 Assessment 08 Feb 2021

Form: Symptom Log (8)

Generated On: 09 Jun 2021 14:53:49

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:51:43
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:41:55
User entered empty.	Kelsey Kelley (b) (4)	26 Mar 2021 16:12:13

US3032249

Folder: Covid-19 Assessment 08 Feb 2021

Form: Symptom Log (9)

Generated On: 09 Jun 2021 14:53:49

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:51:43
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:41:55
User entered 'Day 9 (Day 9)'	Kelsey Kelley (b) (4)	26 Mar 2021 16:12:23

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Folder: Covid-19 Assessment 08 Feb 2021

Form: Symptom Log (9)

Generated On: 09 Jun 2021 14:53:49

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:51:43
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:41:55
User entered '10 Feb 2021'	(b) (4) Kelsey Kelley (b) (4)	26 Mar 2021 16:12:23

US3032249

Folder: Covid-19 Assessment 08 Feb 2021

Form: Symptom Log (9)

Generated On: 09 Jun 2021 14:53:49

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:51:43
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:41:55
User entered 'I'	Kelsey Kelley (b) (4)	26 Mar 2021 16:12:23

US3032249

Folder: Covid-19 Assessment 08 Feb 2021

Form: Symptom Log (9)

Generated On: 09 Jun 2021 14:53:49

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:51:43
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:41:55
User entered empty.	Kelsey Kelley (b) (4)	26 Mar 2021 16:12:23

US3032249

Folder: Covid-19 Assessment 08 Feb 2021

Form: Symptom Log (9)

Generated On: 09 Jun 2021 14:53:49

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:51:43
User entered empty.	System	26 Mar 2021 16:12:23

US3032249

Folder: Covid-19 Assessment 08 Feb 2021

Form: Symptom Log (9)

Generated On: 09 Jun 2021 14:53:49

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:51:43
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:41:55
User entered empty.	Kelsey Kelley (b) (4)	26 Mar 2021 16:12:23

US3032249

Folder: Covid-19 Assessment 08 Feb 2021

Form: Symptom Log (9)

Generated On: 09 Jun 2021 14:53:49

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:51:43
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:41:55
User entered empty.	Kelsey Kelley (b) (4)	26 Mar 2021 16:12:23

US3032249

Folder: Covid-19 Assessment 08 Feb 2021

Form: Symptom Log (9)

Generated On: 09 Jun 2021 14:53:49

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:51:43
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:41:55
User entered empty.	Kelsey Kelley (b) (4)	26 Mar 2021 16:12:23

US3032249

Folder: Covid-19 Assessment 08 Feb 2021

Form: Symptom Log (9)

Generated On: 09 Jun 2021 14:53:49

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:51:43
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:41:55
User entered empty.	Kelsey Kelley (b) (4)	26 Mar 2021 16:12:23

US3032249

Folder: Covid-19 Assessment 08 Feb 2021

Form: Symptom Log (9)

Generated On: 09 Jun 2021 14:53:49

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:51:43
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:41:55
User entered empty.	Kelsey Kelley (b) (4)	26 Mar 2021 16:12:23

US3032249

Folder: Covid-19 Assessment 08 Feb 2021

Form: Symptom Log (9)

Generated On: 09 Jun 2021 14:53:49

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:51:43
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:41:55
User entered empty.	(b) (4) Kelsey Kelley (b) (4)	26 Mar 2021 16:12:23

US3032249

Folder: Covid-19 Assessment 08 Feb 2021

Form: Symptom Log (9)

Generated On: 09 Jun 2021 14:53:49

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:51:43
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:41:55
User entered empty.	Kelsey Kelley (b) (4)	26 Mar 2021 16:12:23

US3032249

Folder: Covid-19 Assessment 08 Feb 2021

Form: Symptom Log (9)

Generated On: 09 Jun 2021 14:53:49

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:51:43
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:41:55
User entered empty.	Kelsey Kelley (b) (4)	26 Mar 2021 16:12:23

US3032249

Folder: Covid-19 Assessment 08 Feb 2021

Form: Symptom Log (9)

Generated On: 09 Jun 2021 14:53:49

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:51:43
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:41:55
User entered empty.	Kelsey Kelley (b) (4)	26 Mar 2021 16:12:23

US3032249

Folder: Covid-19 Assessment 08 Feb 2021

Form: Symptom Log (9)

Generated On: 09 Jun 2021 14:53:49

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:51:43
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:41:55
User entered empty.	Kelsey Kelley (b) (4)	26 Mar 2021 16:12:23

US3032249

Folder: Covid-19 Assessment 08 Feb 2021

Form: Symptom Log (9)

Generated On: 09 Jun 2021 14:53:49

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:51:43
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:41:55
User entered empty.	Kelsey Kelley (b) (4)	26 Mar 2021 16:12:23

US3032249

Folder: Covid-19 Assessment 08 Feb 2021

Form: Symptom Log (9)

Generated On: 09 Jun 2021 14:53:49

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:51:43
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:41:55
User entered empty.	Kelsey Kelley (b) (4)	26 Mar 2021 16:12:23

US3032249

Folder: Covid-19 Assessment 08 Feb 2021

Form: Symptom Log (9)

Generated On: 09 Jun 2021 14:53:49

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:51:43
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:41:55
User entered empty.	Kelsey Kelley (b) (4)	26 Mar 2021 16:12:23

US3032249

Folder: Covid-19 Assessment 08 Feb 2021

Form: Symptom Log (9)

Generated On: 09 Jun 2021 14:53:49

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:51:43
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:41:55
User entered empty.	Kelsey Kelley (b) (4)	26 Mar 2021 16:12:23

US3032249

Folder: Covid-19 Assessment 08 Feb 2021

Form: Symptom Log (9)

Generated On: 09 Jun 2021 14:53:49

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:51:43
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:41:55
User entered empty.	Kelsey Kelley (b) (4)	26 Mar 2021 16:12:23

US3032249

Folder: Covid-19 Assessment 08 Feb 2021

Form: Symptom Log (9)

Generated On: 09 Jun 2021 14:53:49

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:51:43
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:41:55
User entered empty.	Kelsey Kelley (b) (4)	26 Mar 2021 16:12:23

US3032249

Folder: Covid-19 Assessment 08 Feb 2021

Form: Symptom Log (9)

Generated On: 09 Jun 2021 14:53:49

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:51:43
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:41:55
User entered empty.	Kelsey Kelley (b) (4)	26 Mar 2021 16:12:23

US3032249

Folder: Covid-19 Assessment 08 Feb 2021

Form: Symptom Log (10)

Generated On: 09 Jun 2021 14:53:49

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:51:43
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:41:55
User entered 'Day 10 (Day 10)'	Kelsey Kelley (b) (4)	26 Mar 2021 16:32:02

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Folder: Covid-19 Assessment 08 Feb 2021

Form: Symptom Log (10)

Generated On: 09 Jun 2021 14:53:49

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:51:43
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:41:55
User entered '11 Feb 2021'	Kelsey Kelley (b) (4)	26 Mar 2021 16:32:02

US3032249

Folder: Covid-19 Assessment 08 Feb 2021

Form: Symptom Log (10)

Generated On: 09 Jun 2021 14:53:49

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:51:43
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:41:55
User entered 'I'	Kelsey Kelley (b) (4)	26 Mar 2021 16:32:02

US3032249

Folder: Covid-19 Assessment 08 Feb 2021

Form: Symptom Log (10)

Generated On: 09 Jun 2021 14:53:49

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:51:43
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:41:55
User entered empty.	Kelsey Kelley (b) (4)	26 Mar 2021 16:32:02

US3032249

Folder: Covid-19 Assessment 08 Feb 2021

Form: Symptom Log (10)

Generated On: 09 Jun 2021 14:53:49

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:51:43
User entered empty.	System	26 Mar 2021 16:32:02

US3032249

Folder: Covid-19 Assessment 08 Feb 2021

Form: Symptom Log (10)

Generated On: 09 Jun 2021 14:53:49

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:51:43
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:41:55
User entered empty.	Kelsey Kelley (b) (4)	26 Mar 2021 16:32:02

US3032249

Folder: Covid-19 Assessment 08 Feb 2021

Form: Symptom Log (10)

Generated On: 09 Jun 2021 14:53:49

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:51:43
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:41:55
User entered empty.	Kelsey Kelley (b) (4)	26 Mar 2021 16:32:02

US3032249

Folder: Covid-19 Assessment 08 Feb 2021

Form: Symptom Log (10)

Generated On: 09 Jun 2021 14:53:49

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:51:43
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:41:55
User entered empty.	Kelsey Kelley (b) (4)	26 Mar 2021 16:32:02

US3032249

Folder: Covid-19 Assessment 08 Feb 2021

Form: Symptom Log (10)

Generated On: 09 Jun 2021 14:53:49

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:51:43
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:41:55
User entered empty.	Kelsey Kelley (b) (4)	26 Mar 2021 16:32:02

US3032249

Folder: Covid-19 Assessment 08 Feb 2021

Form: Symptom Log (10)

Generated On: 09 Jun 2021 14:53:49

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:51:43
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:41:55
User entered empty.	Kelsey Kelley (b) (4)	26 Mar 2021 16:32:02

US3032249

Folder: Covid-19 Assessment 08 Feb 2021

Form: Symptom Log (10)

Generated On: 09 Jun 2021 14:53:49

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:51:43
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:41:55
User entered empty.	Kelsey Kelley (b) (4)	26 Mar 2021 16:32:02

US3032249

Folder: Covid-19 Assessment 08 Feb 2021

Form: Symptom Log (10)

Generated On: 09 Jun 2021 14:53:49

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:51:43
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:41:55
User entered empty.	Kelsey Kelley (b) (4)	26 Mar 2021 16:32:02

US3032249

Folder: Covid-19 Assessment 08 Feb 2021

Form: Symptom Log (10)

Generated On: 09 Jun 2021 14:53:49

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:51:43
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:41:55
User entered empty.	Kelsey Kelley (b) (4)	26 Mar 2021 16:32:02

US3032249

Folder: Covid-19 Assessment 08 Feb 2021

Form: Symptom Log (10)

Generated On: 09 Jun 2021 14:53:49

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:51:43
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:41:55
User entered empty.	Kelsey Kelley (b) (4)	26 Mar 2021 16:32:02

US3032249

Folder: Covid-19 Assessment 08 Feb 2021

Form: Symptom Log (10)

Generated On: 09 Jun 2021 14:53:49

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:51:43
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:41:55
User entered empty.	Kelsey Kelley (b) (4)	26 Mar 2021 16:32:02

US3032249

Folder: Covid-19 Assessment 08 Feb 2021

Form: Symptom Log (10)

Generated On: 09 Jun 2021 14:53:49

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:51:43
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:41:55
User entered empty.	Kelsey Kelley (b) (4)	26 Mar 2021 16:32:02

US3032249

Folder: Covid-19 Assessment 08 Feb 2021

Form: Symptom Log (10)

Generated On: 09 Jun 2021 14:53:49

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:51:43
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:41:55
User entered empty.	Kelsey Kelley (b) (4)	26 Mar 2021 16:32:02

US3032249

Folder: Covid-19 Assessment 08 Feb 2021

Form: Symptom Log (10)

Generated On: 09 Jun 2021 14:53:49

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:51:43
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:41:55
User entered empty.	Kelsey Kelley (b) (4)	26 Mar 2021 16:32:02

US3032249

Folder: Covid-19 Assessment 08 Feb 2021

Form: Symptom Log (10)

Generated On: 09 Jun 2021 14:53:49

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:51:43
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:41:55
User entered empty.	Kelsey Kelley (b) (4)	26 Mar 2021 16:32:02

US3032249

Folder: Covid-19 Assessment 08 Feb 2021

Form: Symptom Log (10)

Generated On: 09 Jun 2021 14:53:49

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:51:43
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:41:55
User entered empty.	Kelsey Kelley (b) (4)	26 Mar 2021 16:32:02

US3032249

Folder: Covid-19 Assessment 08 Feb 2021

Form: Symptom Log (10)

Generated On: 09 Jun 2021 14:53:49

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:51:43
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:41:55
User entered empty.	Kelsey Kelley (b) (4)	26 Mar 2021 16:32:02

US3032249

Folder: Covid-19 Assessment 08 Feb 2021

Form: Symptom Log (10)

Generated On: 09 Jun 2021 14:53:49

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:51:43
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:41:55
User entered empty.	Kelsey Kelley (b) (4)	26 Mar 2021 16:32:02

US3032249

Folder: Covid-19 Assessment 08 Feb 2021

Form: Symptom Log (11)

Generated On: 09 Jun 2021 14:53:49

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:51:43
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:41:55
User entered 'Day 11 (Day 11)'	Kelsey Kelley (b) (4)	26 Mar 2021 16:32:18

US3032249

Folder: Covid-19 Assessment 08 Feb 2021

Form: Symptom Log (11)

Generated On: 09 Jun 2021 14:53:49

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:51:43
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:41:55
User entered '12 Feb 2021'	(b) (4) Kelsey Kelley (b) (4)	26 Mar 2021 16:32:18

US3032249

Folder: Covid-19 Assessment 08 Feb 2021

Form: Symptom Log (11)

Generated On: 09 Jun 2021 14:53:49

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:51:43
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:41:55
User entered 'I'	Kelsey Kelley (b) (4)	26 Mar 2021 16:32:18

US3032249

Folder: Covid-19 Assessment 08 Feb 2021

Form: Symptom Log (11)

Generated On: 09 Jun 2021 14:53:49

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:51:43
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:41:55
User entered empty.	Kelsey Kelley (b) (4)	26 Mar 2021 16:32:18

US3032249

Folder: Covid-19 Assessment 08 Feb 2021

Form: Symptom Log (11)

Generated On: 09 Jun 2021 14:53:49

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:51:43
User entered empty.	System	26 Mar 2021 16:32:18

US3032249

Folder: Covid-19 Assessment 08 Feb 2021

Form: Symptom Log (11)

Generated On: 09 Jun 2021 14:53:49

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:51:43
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:41:55
User entered empty.	Kelsey Kelley (b) (4)	26 Mar 2021 16:32:18

US3032249

Folder: Covid-19 Assessment 08 Feb 2021

Form: Symptom Log (11)

Generated On: 09 Jun 2021 14:53:49

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:51:43
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:41:55
User entered empty.	Kelsey Kelley (b) (4)	26 Mar 2021 16:32:18

US3032249

Folder: Covid-19 Assessment 08 Feb 2021

Form: Symptom Log (11)

Generated On: 09 Jun 2021 14:53:49

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:51:43
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:41:55
User entered empty.	Kelsey Kelley (b) (4)	26 Mar 2021 16:32:18

US3032249

Folder: Covid-19 Assessment 08 Feb 2021

Form: Symptom Log (11)

Generated On: 09 Jun 2021 14:53:49

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:51:43
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:41:55
User entered empty.	Kelsey Kelley (b) (4)	26 Mar 2021 16:32:18

US3032249

Folder: Covid-19 Assessment 08 Feb 2021

Form: Symptom Log (11)

Generated On: 09 Jun 2021 14:53:49

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:51:43
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:41:55
User entered empty.	Kelsey Kelley (b) (4)	26 Mar 2021 16:32:18

US3032249

Folder: Covid-19 Assessment 08 Feb 2021

Form: Symptom Log (11)

Generated On: 09 Jun 2021 14:53:49

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:51:43
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:41:55
User entered empty.	Kelsey Kelley (b) (4)	26 Mar 2021 16:32:18

US3032249

Folder: Covid-19 Assessment 08 Feb 2021

Form: Symptom Log (11)

Generated On: 09 Jun 2021 14:53:49

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:51:43
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:41:55
User entered empty.	Kelsey Kelley (b) (4)	26 Mar 2021 16:32:18

US3032249

Folder: Covid-19 Assessment 08 Feb 2021

Form: Symptom Log (11)

Generated On: 09 Jun 2021 14:53:49

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:51:43
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:41:55
User entered empty.	Kelsey Kelley (b) (4)	26 Mar 2021 16:32:18

US3032249

Folder: Covid-19 Assessment 08 Feb 2021

Form: Symptom Log (11)

Generated On: 09 Jun 2021 14:53:49

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:51:43
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:41:55
User entered empty.	Kelsey Kelley (b) (4)	26 Mar 2021 16:32:18

US3032249

Folder: Covid-19 Assessment 08 Feb 2021

Form: Symptom Log (11)

Generated On: 09 Jun 2021 14:53:49

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:51:43
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:41:55
User entered empty.	Kelsey Kelley (b) (4)	26 Mar 2021 16:32:18

US3032249

Folder: Covid-19 Assessment 08 Feb 2021

Form: Symptom Log (11)

Generated On: 09 Jun 2021 14:53:49

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:51:43
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:41:55
User entered empty.	Kelsey Kelley (b) (4)	26 Mar 2021 16:32:18

US3032249

Folder: Covid-19 Assessment 08 Feb 2021

Form: Symptom Log (11)

Generated On: 09 Jun 2021 14:53:49

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:51:43
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:41:55
User entered empty.	Kelsey Kelley (b) (4)	26 Mar 2021 16:32:18

US3032249

Folder: Covid-19 Assessment 08 Feb 2021

Form: Symptom Log (11)

Generated On: 09 Jun 2021 14:53:49

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:51:43
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:41:55
User entered empty.	Kelsey Kelley (b) (4)	26 Mar 2021 16:32:18

US3032249

Folder: Covid-19 Assessment 08 Feb 2021

Form: Symptom Log (11)

Generated On: 09 Jun 2021 14:53:49

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:51:43
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:41:55
User entered empty.	Kelsey Kelley (b) (4)	26 Mar 2021 16:32:18

US3032249

Folder: Covid-19 Assessment 08 Feb 2021

Form: Symptom Log (11)

Generated On: 09 Jun 2021 14:53:49

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:51:43
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:41:55
User entered empty.	Kelsey Kelley (b) (4)	26 Mar 2021 16:32:18

US3032249

Folder: Covid-19 Assessment 08 Feb 2021

Form: Symptom Log (11)

Generated On: 09 Jun 2021 14:53:49

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:51:43
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:41:55
User entered empty.	Kelsey Kelley (b) (4)	26 Mar 2021 16:32:18

US3032249

Folder: Covid-19 Assessment 08 Feb 2021

Form: Symptom Log (11)

Generated On: 09 Jun 2021 14:53:49

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:51:43
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:41:55
User entered empty.	Kelsey Kelley (b) (4)	26 Mar 2021 16:32:18

US3032249

Folder: Covid-19 Assessment 08 Feb 2021

Form: Symptom Log (12)

Generated On: 09 Jun 2021 14:53:49

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:51:43
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:41:55
User entered 'Day 12 (Day 12)'	Kelsey Kelley (b) (4)	26 Mar 2021 16:32:30

US3032249

Folder: Covid-19 Assessment 08 Feb 2021

Form: Symptom Log (12)

Generated On: 09 Jun 2021 14:53:49

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:51:43
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:41:55
User entered '13 Feb 2021'	Kelsey Kelley (b) (4)	26 Mar 2021 16:32:30

US3032249

Folder: Covid-19 Assessment 08 Feb 2021

Form: Symptom Log (12)

Generated On: 09 Jun 2021 14:53:49

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:51:43
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:41:55
User entered 'I'	Kelsey Kelley (b) (4)	26 Mar 2021 16:32:30

US3032249

Folder: Covid-19 Assessment 08 Feb 2021

Form: Symptom Log (12)

Generated On: 09 Jun 2021 14:53:49

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:51:43
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:41:55
User entered empty.	Kelsey Kelley (b) (4)	26 Mar 2021 16:32:30

US3032249

Folder: Covid-19 Assessment 08 Feb 2021

Form: Symptom Log (12)

Generated On: 09 Jun 2021 14:53:49

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:51:43
User entered empty.	System	26 Mar 2021 16:32:30

US3032249

Folder: Covid-19 Assessment 08 Feb 2021

Form: Symptom Log (12)

Generated On: 09 Jun 2021 14:53:49

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:51:43
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:41:55
User entered empty.	Kelsey Kelley (b) (4)	26 Mar 2021 16:32:30

US3032249

Folder: Covid-19 Assessment 08 Feb 2021

Form: Symptom Log (12)

Generated On: 09 Jun 2021 14:53:49

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:51:43
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:41:55
User entered empty.	Kelsey Kelley (b) (4)	26 Mar 2021 16:32:30

US3032249

Folder: Covid-19 Assessment 08 Feb 2021

Form: Symptom Log (12)

Generated On: 09 Jun 2021 14:53:49

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:51:43
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:41:55
User entered empty.	Kelsey Kelley (b) (4)	26 Mar 2021 16:32:30

US3032249

Folder: Covid-19 Assessment 08 Feb 2021

Form: Symptom Log (12)

Generated On: 09 Jun 2021 14:53:49

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:51:43
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:41:55
User entered empty.	Kelsey Kelley (b) (4)	26 Mar 2021 16:32:30

US3032249

Folder: Covid-19 Assessment 08 Feb 2021

Form: Symptom Log (12)

Generated On: 09 Jun 2021 14:53:49

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:51:43
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:41:55
User entered empty.	Kelsey Kelley (b) (4)	26 Mar 2021 16:32:30

US3032249

Folder: Covid-19 Assessment 08 Feb 2021

Form: Symptom Log (12)

Generated On: 09 Jun 2021 14:53:49

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:51:43
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:41:55
User entered empty.	Kelsey Kelley (b) (4)	26 Mar 2021 16:32:30

US3032249

Folder: Covid-19 Assessment 08 Feb 2021

Form: Symptom Log (12)

Generated On: 09 Jun 2021 14:53:49

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:51:43
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:41:55
User entered empty.	Kelsey Kelley (b) (4)	26 Mar 2021 16:32:30

US3032249

Folder: Covid-19 Assessment 08 Feb 2021

Form: Symptom Log (12)

Generated On: 09 Jun 2021 14:53:49

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:51:43
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:41:55
User entered empty.	Kelsey Kelley (b) (4)	26 Mar 2021 16:32:30

US3032249

Folder: Covid-19 Assessment 08 Feb 2021

Form: Symptom Log (12)

Generated On: 09 Jun 2021 14:53:49

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:51:43
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:41:55
User entered empty.	Kelsey Kelley (b) (4)	26 Mar 2021 16:32:30

US3032249

Folder: Covid-19 Assessment 08 Feb 2021

Form: Symptom Log (12)

Generated On: 09 Jun 2021 14:53:49

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:51:43
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:41:55
User entered empty.	Kelsey Kelley (b) (4)	26 Mar 2021 16:32:30

US3032249

Folder: Covid-19 Assessment 08 Feb 2021

Form: Symptom Log (12)

Generated On: 09 Jun 2021 14:53:49

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:51:43
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:41:55
User entered empty.	Kelsey Kelley (b) (4)	26 Mar 2021 16:32:30

US3032249

Folder: Covid-19 Assessment 08 Feb 2021

Form: Symptom Log (12)

Generated On: 09 Jun 2021 14:53:49

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:51:43
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:41:55
User entered empty.	Kelsey Kelley (b) (4)	26 Mar 2021 16:32:30

US3032249

Folder: Covid-19 Assessment 08 Feb 2021

Form: Symptom Log (12)

Generated On: 09 Jun 2021 14:53:49

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:51:43
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:41:55
User entered empty.	Kelsey Kelley (b) (4)	26 Mar 2021 16:32:30

US3032249

Folder: Covid-19 Assessment 08 Feb 2021

Form: Symptom Log (12)

Generated On: 09 Jun 2021 14:53:49

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:51:43
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:41:55
User entered empty.	Kelsey Kelley (b) (4)	26 Mar 2021 16:32:30

US3032249

Folder: Covid-19 Assessment 08 Feb 2021

Form: Symptom Log (12)

Generated On: 09 Jun 2021 14:53:49

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:51:43
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:41:55
User entered empty.	Kelsey Kelley (b) (4)	26 Mar 2021 16:32:30

US3032249

Folder: Covid-19 Assessment 08 Feb 2021

Form: Symptom Log (12)

Generated On: 09 Jun 2021 14:53:49

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:51:43
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:41:55
User entered empty.	Kelsey Kelley (b) (4)	26 Mar 2021 16:32:30

US3032249

Folder: Covid-19 Assessment 08 Feb 2021

Form: Symptom Log (12)

Generated On: 09 Jun 2021 14:53:49

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:51:43
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:41:55
User entered empty.	Kelsey Kelley (b) (4)	26 Mar 2021 16:32:30

US3032249

Folder: Covid-19 Assessment 08 Feb 2021

Form: Symptom Log (13)

Generated On: 09 Jun 2021 14:53:49

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:51:43
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:41:55
User entered 'Day 13 (Day 13)'	Kelsey Kelley (b) (4)	26 Mar 2021 16:56:11

US3032249

Folder: Covid-19 Assessment 08 Feb 2021

Form: Symptom Log (13)

Generated On: 09 Jun 2021 14:53:49

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:51:43
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:41:55
User entered '14 Feb 2021'	Kelsey Kelley (b) (4)	26 Mar 2021 16:56:11

US3032249

Folder: Covid-19 Assessment 08 Feb 2021

Form: Symptom Log (13)

Generated On: 09 Jun 2021 14:53:49

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:51:43
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:41:55
User entered 'I'	Kelsey Kelley (b) (4)	26 Mar 2021 16:56:11

US3032249

Folder: Covid-19 Assessment 08 Feb 2021

Form: Symptom Log (13)

Generated On: 09 Jun 2021 14:53:49

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:51:43
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:41:55
User entered empty.	Kelsey Kelley (b) (4)	26 Mar 2021 16:56:11

US3032249

Folder: Covid-19 Assessment 08 Feb 2021

Form: Symptom Log (13)

Generated On: 09 Jun 2021 14:53:49

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:51:43
User entered empty.	System	26 Mar 2021 16:56:11

US3032249

Folder: Covid-19 Assessment 08 Feb 2021

Form: Symptom Log (13)

Generated On: 09 Jun 2021 14:53:49

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:51:43
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:41:55
User entered empty.	Kelsey Kelley (b) (4)	26 Mar 2021 16:56:11

US3032249

Folder: Covid-19 Assessment 08 Feb 2021

Form: Symptom Log (13)

Generated On: 09 Jun 2021 14:53:49

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:51:43
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:41:55
User entered empty.	Kelsey Kelley (b) (4)	26 Mar 2021 16:56:11

US3032249

Folder: Covid-19 Assessment 08 Feb 2021

Form: Symptom Log (13)

Generated On: 09 Jun 2021 14:53:49

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:51:43
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:41:55
User entered empty.	Kelsey Kelley (b) (4)	26 Mar 2021 16:56:11

US3032249

Folder: Covid-19 Assessment 08 Feb 2021

Form: Symptom Log (13)

Generated On: 09 Jun 2021 14:53:49

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:51:43
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:41:55
User entered empty.	Kelsey Kelley (b) (4)	26 Mar 2021 16:56:11

US3032249

Folder: Covid-19 Assessment 08 Feb 2021

Form: Symptom Log (13)

Generated On: 09 Jun 2021 14:53:49

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:51:43
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:41:55
User entered empty.	Kelsey Kelley (b) (4)	26 Mar 2021 16:56:11

US3032249

Folder: Covid-19 Assessment 08 Feb 2021

Form: Symptom Log (13)

Generated On: 09 Jun 2021 14:53:49

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:51:43
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:41:55
User entered empty.	Kelsey Kelley (b) (4)	26 Mar 2021 16:56:11

US3032249

Folder: Covid-19 Assessment 08 Feb 2021

Form: Symptom Log (13)

Generated On: 09 Jun 2021 14:53:49

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:51:43
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:41:55
User entered empty.	Kelsey Kelley (b) (4)	26 Mar 2021 16:56:11

US3032249

Folder: Covid-19 Assessment 08 Feb 2021

Form: Symptom Log (13)

Generated On: 09 Jun 2021 14:53:49

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:51:43
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:41:55
User entered empty.	Kelsey Kelley (b) (4)	26 Mar 2021 16:56:11

US3032249

Folder: Covid-19 Assessment 08 Feb 2021

Form: Symptom Log (13)

Generated On: 09 Jun 2021 14:53:49

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:51:43
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:41:55
User entered empty.	Kelsey Kelley (b) (4)	26 Mar 2021 16:56:11

US3032249

Folder: Covid-19 Assessment 08 Feb 2021

Form: Symptom Log (13)

Generated On: 09 Jun 2021 14:53:49

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:51:43
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:41:55
User entered empty.	(b) (4) Kelsey Kelley (b) (4)	26 Mar 2021 16:56:11

US3032249

Folder: Covid-19 Assessment 08 Feb 2021

Form: Symptom Log (13)

Generated On: 09 Jun 2021 14:53:49

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:51:43
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:41:55
User entered empty.	Kelsey Kelley (b) (4)	26 Mar 2021 16:56:11

US3032249

Folder: Covid-19 Assessment 08 Feb 2021

Form: Symptom Log (13)

Generated On: 09 Jun 2021 14:53:49

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:51:43
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:41:55
User entered empty.	Kelsey Kelley (b) (4)	26 Mar 2021 16:56:11

US3032249

Folder: Covid-19 Assessment 08 Feb 2021

Form: Symptom Log (13)

Generated On: 09 Jun 2021 14:53:49

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:51:43
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:41:55
User entered empty.	Kelsey Kelley (b) (4)	26 Mar 2021 16:56:11

US3032249

Folder: Covid-19 Assessment 08 Feb 2021

Form: Symptom Log (13)

Generated On: 09 Jun 2021 14:53:49

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:51:43
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:41:55
User entered empty.	Kelsey Kelley (b) (4)	26 Mar 2021 16:56:11

US3032249

Folder: Covid-19 Assessment 08 Feb 2021

Form: Symptom Log (13)

Generated On: 09 Jun 2021 14:53:49

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:51:43
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:41:55
User entered empty.	Kelsey Kelley (b) (4)	26 Mar 2021 16:56:11

US3032249

Folder: Covid-19 Assessment 08 Feb 2021

Form: Symptom Log (13)

Generated On: 09 Jun 2021 14:53:49

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:51:43
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:41:55
User entered empty.	Kelsey Kelley (b) (4)	26 Mar 2021 16:56:11

US3032249

Folder: Covid-19 Assessment 08 Feb 2021

Form: Symptom Log (13)

Generated On: 09 Jun 2021 14:53:49

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:51:43
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:41:55
User entered empty.	Kelsey Kelley (b) (4)	26 Mar 2021 16:56:11

US3032249

Folder: Covid-19 Assessment 08 Feb 2021

Form: Symptom Log (14)

Generated On: 09 Jun 2021 14:53:49

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:51:43
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:41:55
User entered 'Day 14 (Day 14)'	Kelsey Kelley (b) (4)	26 Mar 2021 16:56:24

US3032249

Folder: Covid-19 Assessment 08 Feb 2021

Form: Symptom Log (14)

Generated On: 09 Jun 2021 14:53:49

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:51:43
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:41:55
User entered '15 Feb 2021'	Kelsey Kelley (b) (4)	26 Mar 2021 16:56:24

US3032249

Folder: Covid-19 Assessment 08 Feb 2021

Form: Symptom Log (14)

Generated On: 09 Jun 2021 14:53:49

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:51:43
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:41:55
User entered 'I'	Kelsey Kelley (b) (4)	26 Mar 2021 16:56:24

US3032249

Folder: Covid-19 Assessment 08 Feb 2021

Form: Symptom Log (14)

Generated On: 09 Jun 2021 14:53:49

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:51:43
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:41:55
User entered empty.	Kelsey Kelley (b) (4)	26 Mar 2021 16:56:24

US3032249

Folder: Covid-19 Assessment 08 Feb 2021

Form: Symptom Log (14)

Generated On: 09 Jun 2021 14:53:49

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:51:43
User entered empty.	System	26 Mar 2021 16:56:24

US3032249

Folder: Covid-19 Assessment 08 Feb 2021

Form: Symptom Log (14)

Generated On: 09 Jun 2021 14:53:49

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:51:43
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:41:55
User entered empty.	Kelsey Kelley (b) (4)	26 Mar 2021 16:56:24

US3032249

Folder: Covid-19 Assessment 08 Feb 2021

Form: Symptom Log (14)

Generated On: 09 Jun 2021 14:53:49

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:51:43
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:41:55
User entered empty.	Kelsey Kelley (b) (4)	26 Mar 2021 16:56:24

US3032249

Folder: Covid-19 Assessment 08 Feb 2021

Form: Symptom Log (14)

Generated On: 09 Jun 2021 14:53:49

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:51:43
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:41:55
User entered empty.	Kelsey Kelley (b) (4)	26 Mar 2021 16:56:24

US3032249

Folder: Covid-19 Assessment 08 Feb 2021

Form: Symptom Log (14)

Generated On: 09 Jun 2021 14:53:49

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:51:43
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:41:55
User entered empty.	Kelsey Kelley (b) (4)	26 Mar 2021 16:56:24

US3032249

Folder: Covid-19 Assessment 08 Feb 2021

Form: Symptom Log (14)

Generated On: 09 Jun 2021 14:53:49

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:51:43
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:41:55
User entered empty.	Kelsey Kelley (b) (4)	26 Mar 2021 16:56:24

US3032249

Folder: Covid-19 Assessment 08 Feb 2021

Form: Symptom Log (14)

Generated On: 09 Jun 2021 14:53:49

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:51:43
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:41:55
User entered empty.	Kelsey Kelley (b) (4)	26 Mar 2021 16:56:24

US3032249

Folder: Covid-19 Assessment 08 Feb 2021

Form: Symptom Log (14)

Generated On: 09 Jun 2021 14:53:49

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:51:43
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:41:55
User entered empty.	Kelsey Kelley (b) (4)	26 Mar 2021 16:56:24

US3032249

Folder: Covid-19 Assessment 08 Feb 2021

Form: Symptom Log (14)

Generated On: 09 Jun 2021 14:53:49

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:51:43
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:41:55
User entered empty.	Kelsey Kelley (b) (4)	26 Mar 2021 16:56:24

US3032249

Folder: Covid-19 Assessment 08 Feb 2021

Form: Symptom Log (14)

Generated On: 09 Jun 2021 14:53:49

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:51:43
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:41:55
User entered empty.	Kelsey Kelley (b) (4)	26 Mar 2021 16:56:24

US3032249

Folder: Covid-19 Assessment 08 Feb 2021

Form: Symptom Log (14)

Generated On: 09 Jun 2021 14:53:49

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:51:43
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:41:55
User entered empty.	Kelsey Kelley (b) (4)	26 Mar 2021 16:56:24

US3032249

Folder: Covid-19 Assessment 08 Feb 2021

Form: Symptom Log (14)

Generated On: 09 Jun 2021 14:53:49

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:51:43
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:41:55
User entered empty.	Kelsey Kelley (b) (4)	26 Mar 2021 16:56:24

US3032249

Folder: Covid-19 Assessment 08 Feb 2021

Form: Symptom Log (14)

Generated On: 09 Jun 2021 14:53:49

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:51:43
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:41:55
User entered empty.	Kelsey Kelley (b) (4)	26 Mar 2021 16:56:24

US3032249

Folder: Covid-19 Assessment 08 Feb 2021

Form: Symptom Log (14)

Generated On: 09 Jun 2021 14:53:49

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:51:43
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:41:55
User entered empty.	Kelsey Kelley (b) (4)	26 Mar 2021 16:56:24

US3032249

Folder: Covid-19 Assessment 08 Feb 2021

Form: Symptom Log (14)

Generated On: 09 Jun 2021 14:53:49

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:51:43
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:41:55
User entered empty.	Kelsey Kelley (b) (4)	26 Mar 2021 16:56:24

US3032249

Folder: Covid-19 Assessment 08 Feb 2021

Form: Symptom Log (14)

Generated On: 09 Jun 2021 14:53:49

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:51:43
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:41:55
User entered empty.	Kelsey Kelley (b) (4)	26 Mar 2021 16:56:24

US3032249

Folder: Covid-19 Assessment 08 Feb 2021

Form: Symptom Log (14)

Generated On: 09 Jun 2021 14:53:49

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:51:43
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:41:55
User entered empty.	Kelsey Kelley (b) (4)	26 Mar 2021 16:56:24

US3032249

Folder: Covid-19 Assessment 08 Feb 2021

Form: Symptom Log (14)

Generated On: 09 Jun 2021 14:53:49

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:51:43
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:41:55
User entered empty.	Kelsey Kelley (b) (4)	26 Mar 2021 16:56:24

US3032249

Folder: Covid-19 Assessment 08 Feb 2021

Form: Symptom Log (15)

Generated On: 09 Jun 2021 14:53:49

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:51:43
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:41:55
User entered 'Day 15 (Day 15)'	Kelsey Kelley (b) (4)	26 Mar 2021 16:56:37

US3032249

Folder: Covid-19 Assessment 08 Feb 2021

Form: Symptom Log (15)

Generated On: 09 Jun 2021 14:53:49

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:51:43
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:41:55
User entered '16 Feb 2021'	Kelsey Kelley (b) (4)	26 Mar 2021 16:56:37

US3032249

Folder: Covid-19 Assessment 08 Feb 2021

Form: Symptom Log (15)

Generated On: 09 Jun 2021 14:53:49

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:51:43
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:41:55
User entered 'I'	Kelsey Kelley (b) (4)	26 Mar 2021 16:56:37

US3032249

Folder: Covid-19 Assessment 08 Feb 2021

Form: Symptom Log (15)

Generated On: 09 Jun 2021 14:53:49

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:51:43
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:41:55
User entered empty.	Kelsey Kelley (b) (4)	26 Mar 2021 16:56:37

US3032249

Folder: Covid-19 Assessment 08 Feb 2021

Form: Symptom Log (15)

Generated On: 09 Jun 2021 14:53:49

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:51:43
User entered empty.	System	26 Mar 2021 16:56:37

US3032249

Folder: Covid-19 Assessment 08 Feb 2021

Form: Symptom Log (15)

Generated On: 09 Jun 2021 14:53:49

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:51:43
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:41:55
User entered empty.	Kelsey Kelley (b) (4)	26 Mar 2021 16:56:37

US3032249

Folder: Covid-19 Assessment 08 Feb 2021

Form: Symptom Log (15)

Generated On: 09 Jun 2021 14:53:49

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:51:43
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:41:55
User entered empty.	(b) (4) Kelsey Kelley (b) (4)	26 Mar 2021 16:56:37

US3032249

Folder: Covid-19 Assessment 08 Feb 2021

Form: Symptom Log (15)

Generated On: 09 Jun 2021 14:53:49

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:51:43
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:41:55
User entered empty.	Kelsey Kelley (b) (4)	26 Mar 2021 16:56:37

US3032249

Folder: Covid-19 Assessment 08 Feb 2021

Form: Symptom Log (15)

Generated On: 09 Jun 2021 14:53:49

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:51:43
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:41:55
User entered empty.	Kelsey Kelley (b) (4)	26 Mar 2021 16:56:37

US3032249

Folder: Covid-19 Assessment 08 Feb 2021

Form: Symptom Log (15)

Generated On: 09 Jun 2021 14:53:49

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:51:43
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:41:55
User entered empty.	Kelsey Kelley (b) (4)	26 Mar 2021 16:56:37

US3032249

Folder: Covid-19 Assessment 08 Feb 2021

Form: Symptom Log (15)

Generated On: 09 Jun 2021 14:53:49

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:51:43
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:41:55
User entered empty.	Kelsey Kelley (b) (4)	26 Mar 2021 16:56:37

US3032249

Folder: Covid-19 Assessment 08 Feb 2021

Form: Symptom Log (15)

Generated On: 09 Jun 2021 14:53:49

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:51:43
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:41:55
User entered empty.	Kelsey Kelley (b) (4)	26 Mar 2021 16:56:37

US3032249

Folder: Covid-19 Assessment 08 Feb 2021

Form: Symptom Log (15)

Generated On: 09 Jun 2021 14:53:49

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:51:43
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:41:55
User entered empty.	Kelsey Kelley (b) (4)	26 Mar 2021 16:56:37

US3032249

Folder: Covid-19 Assessment 08 Feb 2021

Form: Symptom Log (15)

Generated On: 09 Jun 2021 14:53:49

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:51:43
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:41:55
User entered empty.	Kelsey Kelley (b) (4)	26 Mar 2021 16:56:37

US3032249

Folder: Covid-19 Assessment 08 Feb 2021

Form: Symptom Log (15)

Generated On: 09 Jun 2021 14:53:49

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:51:43
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:41:55
User entered empty.	(b) (4) Kelsey Kelley (b) (4)	26 Mar 2021 16:56:37

US3032249

Folder: Covid-19 Assessment 08 Feb 2021

Form: Symptom Log (15)

Generated On: 09 Jun 2021 14:53:49

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:51:43
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:41:55
User entered empty.	Kelsey Kelley (b) (4)	26 Mar 2021 16:56:37

US3032249

Folder: Covid-19 Assessment 08 Feb 2021

Form: Symptom Log (15)

Generated On: 09 Jun 2021 14:53:49

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:51:43
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:41:55
User entered empty.	Kelsey Kelley (b) (4)	26 Mar 2021 16:56:37

US3032249

Folder: Covid-19 Assessment 08 Feb 2021

Form: Symptom Log (15)

Generated On: 09 Jun 2021 14:53:49

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:51:43
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:41:55
User entered empty.	Kelsey Kelley (b) (4)	26 Mar 2021 16:56:37

US3032249

Folder: Covid-19 Assessment 08 Feb 2021

Form: Symptom Log (15)

Generated On: 09 Jun 2021 14:53:49

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:51:43
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:41:55
User entered empty.	Kelsey Kelley (b) (4)	26 Mar 2021 16:56:37

US3032249

Folder: Covid-19 Assessment 08 Feb 2021

Form: Symptom Log (15)

Generated On: 09 Jun 2021 14:53:49

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:51:43
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:41:55
User entered empty.	Kelsey Kelley (b) (4)	26 Mar 2021 16:56:37

US3032249

Folder: Covid-19 Assessment 08 Feb 2021

Form: Symptom Log (15)

Generated On: 09 Jun 2021 14:53:49

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:51:43
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:41:55
User entered empty.	Kelsey Kelley (b) (4)	26 Mar 2021 16:56:37

US3032249

Folder: Covid-19 Assessment 08 Feb 2021

Form: Symptom Log (15)

Generated On: 09 Jun 2021 14:53:49

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:51:43
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:41:55
User entered empty.	Kelsey Kelley (b) (4)	26 Mar 2021 16:56:37

US3032249

Folder: Covid-19 Assessment 08 Feb 2021

Form: Symptom Log (16)

Generated On: 09 Jun 2021 14:53:49

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:51:43
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:41:55
User entered 'Day 16 (Day 16)'	Kelsey Kelley (b) (4)	26 Mar 2021 16:56:46

US3032249

Folder: Covid-19 Assessment 08 Feb 2021

Form: Symptom Log (16)

Generated On: 09 Jun 2021 14:53:49

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:51:43
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:41:55
User entered '17 Feb 2021'	Kelsey Kelley (b) (4)	26 Mar 2021 16:56:46

US3032249

Folder: Covid-19 Assessment 08 Feb 2021

Form: Symptom Log (16)

Generated On: 09 Jun 2021 14:53:49

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:51:43
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:41:55
User entered 'I'	Kelsey Kelley (b) (4)	26 Mar 2021 16:56:46

US3032249

Folder: Covid-19 Assessment 08 Feb 2021

Form: Symptom Log (16)

Generated On: 09 Jun 2021 14:53:49

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:51:43
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:41:55
User entered empty.	Kelsey Kelley (b) (4)	26 Mar 2021 16:56:46

US3032249

Folder: Covid-19 Assessment 08 Feb 2021

Form: Symptom Log (16)

Generated On: 09 Jun 2021 14:53:49

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:51:43
User entered empty.	System	26 Mar 2021 16:56:46

US3032249

Folder: Covid-19 Assessment 08 Feb 2021

Form: Symptom Log (16)

Generated On: 09 Jun 2021 14:53:49

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:51:43
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:41:55
User entered empty.	Kelsey Kelley (b) (4)	26 Mar 2021 16:56:46

US3032249

Folder: Covid-19 Assessment 08 Feb 2021

Form: Symptom Log (16)

Generated On: 09 Jun 2021 14:53:49

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:51:43
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:41:55
User entered empty.	Kelsey Kelley (b) (4)	26 Mar 2021 16:56:46

US3032249

Folder: Covid-19 Assessment 08 Feb 2021

Form: Symptom Log (16)

Generated On: 09 Jun 2021 14:53:49

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:51:43
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:41:55
User entered empty.	Kelsey Kelley (b) (4)	26 Mar 2021 16:56:46

US3032249

Folder: Covid-19 Assessment 08 Feb 2021

Form: Symptom Log (16)

Generated On: 09 Jun 2021 14:53:49

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:51:43
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:41:55
User entered empty.	Kelsey Kelley (b) (4)	26 Mar 2021 16:56:46

US3032249

Folder: Covid-19 Assessment 08 Feb 2021

Form: Symptom Log (16)

Generated On: 09 Jun 2021 14:53:49

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:51:43
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:41:55
User entered empty.	Kelsey Kelley (b) (4)	26 Mar 2021 16:56:46

US3032249

Folder: Covid-19 Assessment 08 Feb 2021

Form: Symptom Log (16)

Generated On: 09 Jun 2021 14:53:49

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:51:43
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:41:55
User entered empty.	Kelsey Kelley (b) (4)	26 Mar 2021 16:56:46

US3032249

Folder: Covid-19 Assessment 08 Feb 2021

Form: Symptom Log (16)

Generated On: 09 Jun 2021 14:53:49

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:51:43
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:41:55
User entered empty.	Kelsey Kelley (b) (4)	26 Mar 2021 16:56:46

US3032249

Folder: Covid-19 Assessment 08 Feb 2021

Form: Symptom Log (16)

Generated On: 09 Jun 2021 14:53:49

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:51:43
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:41:55
User entered empty.	Kelsey Kelley (b) (4)	26 Mar 2021 16:56:46

US3032249

Folder: Covid-19 Assessment 08 Feb 2021

Form: Symptom Log (16)

Generated On: 09 Jun 2021 14:53:49

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:51:43
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:41:55
User entered empty.	Kelsey Kelley (b) (4)	26 Mar 2021 16:56:46

US3032249

Folder: Covid-19 Assessment 08 Feb 2021

Form: Symptom Log (16)

Generated On: 09 Jun 2021 14:53:49

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:51:43
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:41:55
User entered empty.	Kelsey Kelley (b) (4)	26 Mar 2021 16:56:46

US3032249

Folder: Covid-19 Assessment 08 Feb 2021

Form: Symptom Log (16)

Generated On: 09 Jun 2021 14:53:49

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:51:43
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:41:55
User entered empty.	Kelsey Kelley (b) (4)	26 Mar 2021 16:56:46

US3032249

Folder: Covid-19 Assessment 08 Feb 2021

Form: Symptom Log (16)

Generated On: 09 Jun 2021 14:53:49

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:51:43
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:41:55
User entered empty.	Kelsey Kelley (b) (4)	26 Mar 2021 16:56:46

US3032249

Folder: Covid-19 Assessment 08 Feb 2021

Form: Symptom Log (16)

Generated On: 09 Jun 2021 14:53:49

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:51:43
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:41:55
User entered empty.	Kelsey Kelley (b) (4)	26 Mar 2021 16:56:46

US3032249

Folder: Covid-19 Assessment 08 Feb 2021

Form: Symptom Log (16)

Generated On: 09 Jun 2021 14:53:49

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:51:43
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:41:55
User entered empty.	Kelsey Kelley (b) (4)	26 Mar 2021 16:56:46

US3032249

Folder: Covid-19 Assessment 08 Feb 2021

Form: Symptom Log (16)

Generated On: 09 Jun 2021 14:53:49

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:51:43
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:41:55
User entered empty.	Kelsey Kelley (b) (4)	26 Mar 2021 16:56:46

US3032249

Folder: Covid-19 Assessment 08 Feb 2021

Form: Symptom Log (16)

Generated On: 09 Jun 2021 14:53:49

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:51:43
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:41:55
User entered empty.	Kelsey Kelley (b) (4)	26 Mar 2021 16:56:46

US3032249

Folder: Covid-19 Assessment 08 Feb 2021

Form: Symptom Log (16)

Generated On: 09 Jun 2021 14:53:49

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:51:43
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:41:55
User entered empty.	Kelsey Kelley (b) (4)	26 Mar 2021 16:56:46

US3032249

Folder: Covid-19 Assessment 08 Feb 2021

Form: Symptom Log (17)

Generated On: 09 Jun 2021 14:53:49

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:51:43
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:41:55
User entered 'Day 17 (Day 17)'	Kelsey Kelley (b) (4)	26 Mar 2021 16:56:59

US3032249

Folder: Covid-19 Assessment 08 Feb 2021

Form: Symptom Log (17)

Generated On: 09 Jun 2021 14:53:49

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:51:43
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:41:55
User entered '18 Feb 2021'	Kelsey Kelley (b) (4)	26 Mar 2021 16:56:59

US3032249

Folder: Covid-19 Assessment 08 Feb 2021

Form: Symptom Log (17)

Generated On: 09 Jun 2021 14:53:49

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:51:43
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:41:55
User entered 'I'	Kelsey Kelley (b) (4)	26 Mar 2021 16:56:59

US3032249

Folder: Covid-19 Assessment 08 Feb 2021

Form: Symptom Log (17)

Generated On: 09 Jun 2021 14:53:49

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:51:43
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:41:55
User entered empty.	Kelsey Kelley (b) (4)	26 Mar 2021 16:56:59

US3032249

Folder: Covid-19 Assessment 08 Feb 2021

Form: Symptom Log (17)

Generated On: 09 Jun 2021 14:53:49

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:51:43
User entered empty.	System	26 Mar 2021 16:56:59

US3032249

Folder: Covid-19 Assessment 08 Feb 2021

Form: Symptom Log (17)

Generated On: 09 Jun 2021 14:53:49

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:51:43
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:41:55
User entered empty.	Kelsey Kelley (b) (4)	26 Mar 2021 16:56:59

US3032249

Folder: Covid-19 Assessment 08 Feb 2021

Form: Symptom Log (17)

Generated On: 09 Jun 2021 14:53:49

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:51:43
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:41:55
User entered empty.	Kelsey Kelley (b) (4)	26 Mar 2021 16:56:59

US3032249

Folder: Covid-19 Assessment 08 Feb 2021

Form: Symptom Log (17)

Generated On: 09 Jun 2021 14:53:49

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:51:43
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:41:55
User entered empty.	Kelsey Kelley (b) (4)	26 Mar 2021 16:56:59

US3032249

Folder: Covid-19 Assessment 08 Feb 2021

Form: Symptom Log (17)

Generated On: 09 Jun 2021 14:53:49

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:51:43
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:41:55
User entered empty.	Kelsey Kelley (b) (4)	26 Mar 2021 16:56:59

US3032249

Folder: Covid-19 Assessment 08 Feb 2021

Form: Symptom Log (17)

Generated On: 09 Jun 2021 14:53:49

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:51:43
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:41:55
User entered empty.	Kelsey Kelley (b) (4)	26 Mar 2021 16:56:59

US3032249

Folder: Covid-19 Assessment 08 Feb 2021

Form: Symptom Log (17)

Generated On: 09 Jun 2021 14:53:49

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:51:43
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:41:55
User entered empty.	Kelsey Kelley (b) (4)	26 Mar 2021 16:56:59

US3032249

Folder: Covid-19 Assessment 08 Feb 2021

Form: Symptom Log (17)

Generated On: 09 Jun 2021 14:53:49

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:51:43
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:41:55
User entered empty.	Kelsey Kelley (b) (4)	26 Mar 2021 16:56:59

US3032249

Folder: Covid-19 Assessment 08 Feb 2021

Form: Symptom Log (17)

Generated On: 09 Jun 2021 14:53:49

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:51:43
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:41:55
User entered empty.	Kelsey Kelley (b) (4)	26 Mar 2021 16:56:59

US3032249

Folder: Covid-19 Assessment 08 Feb 2021

Form: Symptom Log (17)

Generated On: 09 Jun 2021 14:53:49

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:51:43
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:41:55
User entered empty.	Kelsey Kelley (b) (4)	26 Mar 2021 16:56:59

US3032249

Folder: Covid-19 Assessment 08 Feb 2021

Form: Symptom Log (17)

Generated On: 09 Jun 2021 14:53:49

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:51:43
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:41:55
User entered empty.	Kelsey Kelley (b) (4)	26 Mar 2021 16:56:59

US3032249

Folder: Covid-19 Assessment 08 Feb 2021

Form: Symptom Log (17)

Generated On: 09 Jun 2021 14:53:49

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:51:43
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:41:55
User entered empty.	Kelsey Kelley (b) (4)	26 Mar 2021 16:56:59

US3032249

Folder: Covid-19 Assessment 08 Feb 2021

Form: Symptom Log (17)

Generated On: 09 Jun 2021 14:53:49

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:51:43
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:41:55
User entered empty.	Kelsey Kelley (b) (4)	26 Mar 2021 16:56:59

US3032249

Folder: Covid-19 Assessment 08 Feb 2021

Form: Symptom Log (17)

Generated On: 09 Jun 2021 14:53:49

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:51:43
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:41:55
User entered empty.	Kelsey Kelley (b) (4)	26 Mar 2021 16:56:59

US3032249

Folder: Covid-19 Assessment 08 Feb 2021

Form: Symptom Log (17)

Generated On: 09 Jun 2021 14:53:49

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:51:43
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:41:55
User entered empty.	Kelsey Kelley (b) (4)	26 Mar 2021 16:56:59

US3032249

Folder: Covid-19 Assessment 08 Feb 2021

Form: Symptom Log (17)

Generated On: 09 Jun 2021 14:53:49

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:51:43
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:41:55
User entered empty.	Kelsey Kelley (b) (4)	26 Mar 2021 16:56:59

US3032249

Folder: Covid-19 Assessment 08 Feb 2021

Form: Symptom Log (17)

Generated On: 09 Jun 2021 14:53:49

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:51:43
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:41:55
User entered empty.	Kelsey Kelley (b) (4)	26 Mar 2021 16:56:59

US3032249

Folder: Covid-19 Assessment 08 Feb 2021

Form: Symptom Log (17)

Generated On: 09 Jun 2021 14:53:49

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:51:43
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:41:55
User entered empty.	Kelsey Kelley (b) (4)	26 Mar 2021 16:56:59

US3032249

Folder: Covid-19 Assessment 08 Feb 2021

Form: Symptom Log (18)

Generated On: 09 Jun 2021 14:53:49

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:51:43
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:41:55
User entered 'Day 18 (Day 18)'	Kelsey Kelley (b) (4)	26 Mar 2021 16:57:09

US3032249

Folder: Covid-19 Assessment 08 Feb 2021

Form: Symptom Log (18)

Generated On: 09 Jun 2021 14:53:49

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:51:43
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:41:55
User entered '19 Feb 2021'	Kelsey Kelley (b) (4)	26 Mar 2021 16:57:09

US3032249

Folder: Covid-19 Assessment 08 Feb 2021

Form: Symptom Log (18)

Generated On: 09 Jun 2021 14:53:49

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:51:43
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:41:55
User entered 'I'	Kelsey Kelley (b) (4)	26 Mar 2021 16:57:09

US3032249

Folder: Covid-19 Assessment 08 Feb 2021

Form: Symptom Log (18)

Generated On: 09 Jun 2021 14:53:49

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:51:43
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:41:55
User entered empty.	Kelsey Kelley (b) (4)	26 Mar 2021 16:57:09

US3032249

Folder: Covid-19 Assessment 08 Feb 2021

Form: Symptom Log (18)

Generated On: 09 Jun 2021 14:53:49

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:51:43
User entered empty.	System	26 Mar 2021 16:57:09

US3032249

Folder: Covid-19 Assessment 08 Feb 2021

Form: Symptom Log (18)

Generated On: 09 Jun 2021 14:53:49

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:51:43
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:41:55
User entered empty.	Kelsey Kelley (b) (4)	26 Mar 2021 16:57:09

US3032249

Folder: Covid-19 Assessment 08 Feb 2021

Form: Symptom Log (18)

Generated On: 09 Jun 2021 14:53:49

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:51:43
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:41:55
User entered empty.	Kelsey Kelley (b) (4)	26 Mar 2021 16:57:09

US3032249

Folder: Covid-19 Assessment 08 Feb 2021

Form: Symptom Log (18)

Generated On: 09 Jun 2021 14:53:49

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:51:43
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:41:55
User entered empty.	Kelsey Kelley (b) (4)	26 Mar 2021 16:57:09

US3032249

Folder: Covid-19 Assessment 08 Feb 2021

Form: Symptom Log (18)

Generated On: 09 Jun 2021 14:53:49

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:51:43
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:41:55
User entered empty.	Kelsey Kelley (b) (4)	26 Mar 2021 16:57:09

US3032249

Folder: Covid-19 Assessment 08 Feb 2021

Form: Symptom Log (18)

Generated On: 09 Jun 2021 14:53:49

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:51:43
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:41:55
User entered empty.	Kelsey Kelley (b) (4)	26 Mar 2021 16:57:09

US3032249

Folder: Covid-19 Assessment 08 Feb 2021

Form: Symptom Log (18)

Generated On: 09 Jun 2021 14:53:49

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:51:43
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:41:55
User entered empty.	Kelsey Kelley (b) (4)	26 Mar 2021 16:57:09

US3032249

Folder: Covid-19 Assessment 08 Feb 2021

Form: Symptom Log (18)

Generated On: 09 Jun 2021 14:53:49

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:51:43
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:41:55
User entered empty.	Kelsey Kelley (b) (4)	26 Mar 2021 16:57:09

US3032249

Folder: Covid-19 Assessment 08 Feb 2021

Form: Symptom Log (18)

Generated On: 09 Jun 2021 14:53:49

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:51:43
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:41:55
User entered empty.	Kelsey Kelley (b) (4)	26 Mar 2021 16:57:09

US3032249

Folder: Covid-19 Assessment 08 Feb 2021

Form: Symptom Log (18)

Generated On: 09 Jun 2021 14:53:49

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:51:43
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:41:55
User entered empty.	Kelsey Kelley (b) (4)	26 Mar 2021 16:57:09

US3032249

Folder: Covid-19 Assessment 08 Feb 2021

Form: Symptom Log (18)

Generated On: 09 Jun 2021 14:53:49

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:51:43
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:41:55
User entered empty.	Kelsey Kelley (b) (4)	26 Mar 2021 16:57:09

US3032249

Folder: Covid-19 Assessment 08 Feb 2021

Form: Symptom Log (18)

Generated On: 09 Jun 2021 14:53:49

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:51:43
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:41:55
User entered empty.	Kelsey Kelley (b) (4)	26 Mar 2021 16:57:09

US3032249

Folder: Covid-19 Assessment 08 Feb 2021

Form: Symptom Log (18)

Generated On: 09 Jun 2021 14:53:49

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:51:43
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:41:55
User entered empty.	Kelsey Kelley (b) (4)	26 Mar 2021 16:57:09

US3032249

Folder: Covid-19 Assessment 08 Feb 2021

Form: Symptom Log (18)

Generated On: 09 Jun 2021 14:53:49

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:51:43
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:41:55
User entered empty.	Kelsey Kelley (b) (4)	26 Mar 2021 16:57:09

US3032249

Folder: Covid-19 Assessment 08 Feb 2021

Form: Symptom Log (18)

Generated On: 09 Jun 2021 14:53:49

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:51:43
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:41:55
User entered empty.	Kelsey Kelley (b) (4)	26 Mar 2021 16:57:09

US3032249

Folder: Covid-19 Assessment 08 Feb 2021

Form: Symptom Log (18)

Generated On: 09 Jun 2021 14:53:49

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:51:43
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:41:55
User entered empty.	Kelsey Kelley (b) (4)	26 Mar 2021 16:57:09

US3032249

Folder: Covid-19 Assessment 08 Feb 2021

Form: Symptom Log (18)

Generated On: 09 Jun 2021 14:53:49

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:51:43
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:41:55
User entered empty.	Kelsey Kelley (b) (4)	26 Mar 2021 16:57:09

US3032249

Folder: Covid-19 Assessment 08 Feb 2021

Form: Symptom Log (18)

Generated On: 09 Jun 2021 14:53:49

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:51:43
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:41:55
User entered empty.	Kelsey Kelley (b) (4)	26 Mar 2021 16:57:09

US3032249

Folder: Covid-19 Assessment 08 Feb 2021

Form: Symptom Log (19)

Generated On: 09 Jun 2021 14:53:49

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:51:43
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:41:55
User entered 'Day 19 (Day 19)'	Kelsey Kelley (b) (4)	26 Mar 2021 16:57:21

US3032249

Folder: Covid-19 Assessment 08 Feb 2021

Form: Symptom Log (19)

Generated On: 09 Jun 2021 14:53:49

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:51:43
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:41:55
User entered '20 Feb 2021'	(b) (4) Kelsey Kelley (b) (4)	26 Mar 2021 16:57:21

US3032249

Folder: Covid-19 Assessment 08 Feb 2021

Form: Symptom Log (19)

Generated On: 09 Jun 2021 14:53:49

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:51:43
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:41:55
User entered 'I'	Kelsey Kelley (b) (4)	26 Mar 2021 16:57:21

US3032249

Folder: Covid-19 Assessment 08 Feb 2021

Form: Symptom Log (19)

Generated On: 09 Jun 2021 14:53:49

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:51:43
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:41:55
User entered empty.	Kelsey Kelley (b) (4)	26 Mar 2021 16:57:21

US3032249

Folder: Covid-19 Assessment 08 Feb 2021

Form: Symptom Log (19)

Generated On: 09 Jun 2021 14:53:49

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:51:43
User entered empty.	System	26 Mar 2021 16:57:21

US3032249

Folder: Covid-19 Assessment 08 Feb 2021

Form: Symptom Log (19)

Generated On: 09 Jun 2021 14:53:49

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:51:43
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:41:55
User entered empty.	Kelsey Kelley (b) (4)	26 Mar 2021 16:57:21

US3032249

Folder: Covid-19 Assessment 08 Feb 2021

Form: Symptom Log (19)

Generated On: 09 Jun 2021 14:53:49

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:51:43
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:41:55
User entered empty.	(b) (4) Kelsey Kelley (b) (4)	26 Mar 2021 16:57:21

US3032249

Folder: Covid-19 Assessment 08 Feb 2021

Form: Symptom Log (19)

Generated On: 09 Jun 2021 14:53:49

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:51:43
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:41:55
User entered empty.	Kelsey Kelley (b) (4)	26 Mar 2021 16:57:21

US3032249

Folder: Covid-19 Assessment 08 Feb 2021

Form: Symptom Log (19)

Generated On: 09 Jun 2021 14:53:49

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:51:43
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:41:55
User entered empty.	Kelsey Kelley (b) (4)	26 Mar 2021 16:57:21

US3032249

Folder: Covid-19 Assessment 08 Feb 2021

Form: Symptom Log (19)

Generated On: 09 Jun 2021 14:53:49

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:51:43
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:41:55
User entered empty.	Kelsey Kelley (b) (4)	26 Mar 2021 16:57:21

US3032249

Folder: Covid-19 Assessment 08 Feb 2021

Form: Symptom Log (19)

Generated On: 09 Jun 2021 14:53:49

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:51:43
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:41:55
User entered empty.	Kelsey Kelley (b) (4)	26 Mar 2021 16:57:21

US3032249

Folder: Covid-19 Assessment 08 Feb 2021

Form: Symptom Log (19)

Generated On: 09 Jun 2021 14:53:49

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:51:43
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:41:55
User entered empty.	Kelsey Kelley (b) (4)	26 Mar 2021 16:57:21

US3032249

Folder: Covid-19 Assessment 08 Feb 2021

Form: Symptom Log (19)

Generated On: 09 Jun 2021 14:53:49

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:51:43
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:41:55
User entered empty.	Kelsey Kelley (b) (4)	26 Mar 2021 16:57:21

US3032249

Folder: Covid-19 Assessment 08 Feb 2021

Form: Symptom Log (19)

Generated On: 09 Jun 2021 14:53:49

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:51:43
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:41:55
User entered empty.	Kelsey Kelley (b) (4)	26 Mar 2021 16:57:21

US3032249

Folder: Covid-19 Assessment 08 Feb 2021

Form: Symptom Log (19)

Generated On: 09 Jun 2021 14:53:49

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:51:43
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:41:55
User entered empty.	(b) (4) Kelsey Kelley (b) (4)	26 Mar 2021 16:57:21

US3032249

Folder: Covid-19 Assessment 08 Feb 2021

Form: Symptom Log (19)

Generated On: 09 Jun 2021 14:53:49

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:51:43
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:41:55
User entered empty.	(b) (4) Kelsey Kelley (b) (4)	26 Mar 2021 16:57:21

US3032249

Folder: Covid-19 Assessment 08 Feb 2021

Form: Symptom Log (19)

Generated On: 09 Jun 2021 14:53:49

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:51:43
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:41:55
User entered empty.	Kelsey Kelley (b) (4)	26 Mar 2021 16:57:21

US3032249

Folder: Covid-19 Assessment 08 Feb 2021

Form: Symptom Log (19)

Generated On: 09 Jun 2021 14:53:49

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:51:43
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:41:55
User entered empty.	Kelsey Kelley (b) (4)	26 Mar 2021 16:57:21

US3032249

Folder: Covid-19 Assessment 08 Feb 2021

Form: Symptom Log (19)

Generated On: 09 Jun 2021 14:53:49

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:51:43
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:41:55
User entered empty.	Kelsey Kelley (b) (4)	26 Mar 2021 16:57:21

US3032249

Folder: Covid-19 Assessment 08 Feb 2021

Form: Symptom Log (19)

Generated On: 09 Jun 2021 14:53:49

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:51:43
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:41:55
User entered empty.	Kelsey Kelley (b) (4)	26 Mar 2021 16:57:21

US3032249

Folder: Covid-19 Assessment 08 Feb 2021

Form: Symptom Log (19)

Generated On: 09 Jun 2021 14:53:49

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:51:43
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:41:55
User entered empty.	Kelsey Kelley (b) (4)	26 Mar 2021 16:57:21

US3032249

Folder: Covid-19 Assessment 08 Feb 2021

Form: Symptom Log (19)

Generated On: 09 Jun 2021 14:53:49

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:51:43
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:41:55
User entered empty.	Kelsey Kelley (b) (4)	26 Mar 2021 16:57:21

US3032249

Folder: Covid-19 Assessment 08 Feb 2021

Form: Symptom Log (20)

Generated On: 09 Jun 2021 14:53:49

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:51:43
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:41:55
User entered 'Day 20 (Day 20)'	Kelsey Kelley (b) (4)	26 Mar 2021 16:57:35

US3032249

Folder: Covid-19 Assessment 08 Feb 2021

Form: Symptom Log (20)

Generated On: 09 Jun 2021 14:53:49

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:51:43
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:41:55
User entered '21 Feb 2021'	Kelsey Kelley (b) (4)	26 Mar 2021 16:57:35

US3032249

Folder: Covid-19 Assessment 08 Feb 2021

Form: Symptom Log (20)

Generated On: 09 Jun 2021 14:53:49

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:51:43
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:41:55
User entered 'I'	Kelsey Kelley (b) (4)	26 Mar 2021 16:57:35

US3032249

Folder: Covid-19 Assessment 08 Feb 2021

Form: Symptom Log (20)

Generated On: 09 Jun 2021 14:53:49

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:51:43
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:41:55
User entered empty.	Kelsey Kelley (b) (4)	26 Mar 2021 16:57:35

US3032249

Folder: Covid-19 Assessment 08 Feb 2021

Form: Symptom Log (20)

Generated On: 09 Jun 2021 14:53:49

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:51:43
User entered empty.	System	26 Mar 2021 16:57:35

US3032249

Folder: Covid-19 Assessment 08 Feb 2021

Form: Symptom Log (20)

Generated On: 09 Jun 2021 14:53:49

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:51:43
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:41:55
User entered empty.	(b) (4) Kelsey Kelley (b) (4)	26 Mar 2021 16:57:35

US3032249

Folder: Covid-19 Assessment 08 Feb 2021

Form: Symptom Log (20)

Generated On: 09 Jun 2021 14:53:49

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:51:43
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:41:55
User entered empty.	Kelsey Kelley (b) (4)	26 Mar 2021 16:57:35

US3032249

Folder: Covid-19 Assessment 08 Feb 2021

Form: Symptom Log (20)

Generated On: 09 Jun 2021 14:53:49

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:51:43
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:41:55
User entered empty.	Kelsey Kelley (b) (4)	26 Mar 2021 16:57:35

US3032249

Folder: Covid-19 Assessment 08 Feb 2021

Form: Symptom Log (20)

Generated On: 09 Jun 2021 14:53:49

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:51:43
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:41:55
User entered empty.	Kelsey Kelley (b) (4)	26 Mar 2021 16:57:35

US3032249

Folder: Covid-19 Assessment 08 Feb 2021

Form: Symptom Log (20)

Generated On: 09 Jun 2021 14:53:49

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:51:43
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:41:55
User entered empty.	Kelsey Kelley (b) (4)	26 Mar 2021 16:57:35

US3032249

Folder: Covid-19 Assessment 08 Feb 2021

Form: Symptom Log (20)

Generated On: 09 Jun 2021 14:53:49

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:51:43
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:41:55
User entered empty.	Kelsey Kelley (b) (4)	26 Mar 2021 16:57:35

US3032249

Folder: Covid-19 Assessment 08 Feb 2021

Form: Symptom Log (20)

Generated On: 09 Jun 2021 14:53:49

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:51:43
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:41:55
User entered empty.	Kelsey Kelley (b) (4)	26 Mar 2021 16:57:35

US3032249

Folder: Covid-19 Assessment 08 Feb 2021

Form: Symptom Log (20)

Generated On: 09 Jun 2021 14:53:49

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:51:43
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:41:55
User entered empty.	Kelsey Kelley (b) (4)	26 Mar 2021 16:57:35

US3032249

Folder: Covid-19 Assessment 08 Feb 2021

Form: Symptom Log (20)

Generated On: 09 Jun 2021 14:53:49

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:51:43
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:41:55
User entered empty.	Kelsey Kelley (b) (4)	26 Mar 2021 16:57:35

US3032249

Folder: Covid-19 Assessment 08 Feb 2021

Form: Symptom Log (20)

Generated On: 09 Jun 2021 14:53:49

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:51:43
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:41:55
User entered empty.	Kelsey Kelley (b) (4)	26 Mar 2021 16:57:35

US3032249

Folder: Covid-19 Assessment 08 Feb 2021

Form: Symptom Log (20)

Generated On: 09 Jun 2021 14:53:49

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:51:43
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:41:55
User entered empty.	Kelsey Kelley (b) (4)	26 Mar 2021 16:57:35

US3032249

Folder: Covid-19 Assessment 08 Feb 2021

Form: Symptom Log (20)

Generated On: 09 Jun 2021 14:53:49

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:51:43
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:41:55
User entered empty.	Kelsey Kelley (b) (4)	26 Mar 2021 16:57:35

US3032249

Folder: Covid-19 Assessment 08 Feb 2021

Form: Symptom Log (20)

Generated On: 09 Jun 2021 14:53:49

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:51:43
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:41:55
User entered empty.	Kelsey Kelley (b) (4)	26 Mar 2021 16:57:35

US3032249

Folder: Covid-19 Assessment 08 Feb 2021

Form: Symptom Log (20)

Generated On: 09 Jun 2021 14:53:49

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:51:43
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:41:55
User entered empty.	Kelsey Kelley (b) (4)	26 Mar 2021 16:57:35

US3032249

Folder: Covid-19 Assessment 08 Feb 2021

Form: Symptom Log (20)

Generated On: 09 Jun 2021 14:53:49

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:51:43
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:41:55
User entered empty.	Kelsey Kelley (b) (4)	26 Mar 2021 16:57:35

US3032249

Folder: Covid-19 Assessment 08 Feb 2021

Form: Symptom Log (20)

Generated On: 09 Jun 2021 14:53:49

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:51:43
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:41:55
User entered empty.	Kelsey Kelley (b) (4)	26 Mar 2021 16:57:35

US3032249

Folder: Covid-19 Assessment 08 Feb 2021

Form: Symptom Log (20)

Generated On: 09 Jun 2021 14:53:49

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:51:43
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:41:55
User entered empty.	Kelsey Kelley (b) (4)	26 Mar 2021 16:57:35

US3032249

Folder: Covid-19 Assessment 08 Feb 2021

Form: Symptom Log (21)

Generated On: 09 Jun 2021 14:53:49

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:51:43
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:41:55
User entered 'Day 21 (Day 21)'	Kelsey Kelley (b) (4)	26 Mar 2021 16:57:44

US3032249

Folder: Covid-19 Assessment 08 Feb 2021

Form: Symptom Log (21)

Generated On: 09 Jun 2021 14:53:49

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:51:43
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:41:55
User entered '22 Feb 2021'	Kelsey Kelley (b) (4)	26 Mar 2021 16:57:44

US3032249

Folder: Covid-19 Assessment 08 Feb 2021

Form: Symptom Log (21)

Generated On: 09 Jun 2021 14:53:49

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:51:43
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:41:55
User entered 'I'	Kelsey Kelley (b) (4)	26 Mar 2021 16:57:44

US3032249

Folder: Covid-19 Assessment 08 Feb 2021

Form: Symptom Log (21)

Generated On: 09 Jun 2021 14:53:49

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:51:43
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:41:55
User entered empty.	Kelsey Kelley (b) (4)	26 Mar 2021 16:57:44

US3032249

Folder: Covid-19 Assessment 08 Feb 2021

Form: Symptom Log (21)

Generated On: 09 Jun 2021 14:53:49

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:51:43
User entered empty.	System	26 Mar 2021 16:57:44

US3032249

Folder: Covid-19 Assessment 08 Feb 2021

Form: Symptom Log (21)

Generated On: 09 Jun 2021 14:53:49

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:51:43
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:41:55
User entered empty.	Kelsey Kelley (b) (4)	26 Mar 2021 16:57:44

US3032249

Folder: Covid-19 Assessment 08 Feb 2021

Form: Symptom Log (21)

Generated On: 09 Jun 2021 14:53:49

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:51:43
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:41:55
User entered empty.	Kelsey Kelley (b) (4)	26 Mar 2021 16:57:44

US3032249

Folder: Covid-19 Assessment 08 Feb 2021

Form: Symptom Log (21)

Generated On: 09 Jun 2021 14:53:49

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:51:43
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:41:55
User entered empty.	Kelsey Kelley (b) (4)	26 Mar 2021 16:57:44

US3032249

Folder: Covid-19 Assessment 08 Feb 2021

Form: Symptom Log (21)

Generated On: 09 Jun 2021 14:53:49

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:51:43
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:41:55
User entered empty.	Kelsey Kelley (b) (4)	26 Mar 2021 16:57:44

US3032249

Folder: Covid-19 Assessment 08 Feb 2021

Form: Symptom Log (21)

Generated On: 09 Jun 2021 14:53:49

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:51:43
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:41:55
User entered empty.	Kelsey Kelley (b) (4)	26 Mar 2021 16:57:44

US3032249

Folder: Covid-19 Assessment 08 Feb 2021

Form: Symptom Log (21)

Generated On: 09 Jun 2021 14:53:49

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:51:43
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:41:55
User entered empty.	Kelsey Kelley (b) (4)	26 Mar 2021 16:57:44

US3032249

Folder: Covid-19 Assessment 08 Feb 2021

Form: Symptom Log (21)

Generated On: 09 Jun 2021 14:53:49

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:51:43
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:41:55
User entered empty.	Kelsey Kelley (b) (4)	26 Mar 2021 16:57:44

US3032249

Folder: Covid-19 Assessment 08 Feb 2021

Form: Symptom Log (21)

Generated On: 09 Jun 2021 14:53:49

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:51:43
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:41:55
User entered empty.	Kelsey Kelley (b) (4)	26 Mar 2021 16:57:44

US3032249

Folder: Covid-19 Assessment 08 Feb 2021

Form: Symptom Log (21)

Generated On: 09 Jun 2021 14:53:49

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:51:43
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:41:55
User entered empty.	Kelsey Kelley (b) (4)	26 Mar 2021 16:57:44

US3032249

Folder: Covid-19 Assessment 08 Feb 2021

Form: Symptom Log (21)

Generated On: 09 Jun 2021 14:53:49

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:51:43
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:41:55
User entered empty.	Kelsey Kelley (b) (4)	26 Mar 2021 16:57:44

US3032249

Folder: Covid-19 Assessment 08 Feb 2021

Form: Symptom Log (21)

Generated On: 09 Jun 2021 14:53:49

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:51:43
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:41:55
User entered empty.	Kelsey Kelley (b) (4)	26 Mar 2021 16:57:44

US3032249

Folder: Covid-19 Assessment 08 Feb 2021

Form: Symptom Log (21)

Generated On: 09 Jun 2021 14:53:49

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:51:43
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:41:55
User entered empty.	Kelsey Kelley (b) (4)	26 Mar 2021 16:57:44

US3032249

Folder: Covid-19 Assessment 08 Feb 2021

Form: Symptom Log (21)

Generated On: 09 Jun 2021 14:53:49

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:51:43
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:41:55
User entered empty.	Kelsey Kelley (b) (4)	26 Mar 2021 16:57:44

US3032249

Folder: Covid-19 Assessment 08 Feb 2021

Form: Symptom Log (21)

Generated On: 09 Jun 2021 14:53:49

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:51:43
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:41:55
User entered empty.	Kelsey Kelley (b) (4)	26 Mar 2021 16:57:44

US3032249

Folder: Covid-19 Assessment 08 Feb 2021

Form: Symptom Log (21)

Generated On: 09 Jun 2021 14:53:49

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:51:43
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:41:55
User entered empty.	Kelsey Kelley (b) (4)	26 Mar 2021 16:57:44

US3032249

Folder: Covid-19 Assessment 08 Feb 2021

Form: Symptom Log (21)

Generated On: 09 Jun 2021 14:53:49

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:51:43
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:41:55
User entered empty.	Kelsey Kelley (b) (4)	26 Mar 2021 16:57:44

US3032249

Folder: Covid-19 Assessment 08 Feb 2021

Form: Symptom Log (21)

Generated On: 09 Jun 2021 14:53:49

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:51:43
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:41:55
User entered empty.	Kelsey Kelley (b) (4)	26 Mar 2021 16:57:44

US3032249

Folder: Covid-19 Assessment 08 Feb 2021

Form: Symptom Log (22)

Generated On: 09 Jun 2021 14:53:49

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:51:43
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:41:55
User entered 'Day 22 (Day 22)'	Kelsey Kelley (b) (4)	26 Mar 2021 16:58:07

US3032249

Folder: Covid-19 Assessment 08 Feb 2021

Form: Symptom Log (22)

Generated On: 09 Jun 2021 14:53:49

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:51:43
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:41:55
User closed query 'Data entered is non-conformant. Please correct.' (Site from System).	(b) (4)	26 Mar 2021 16:58:13
User entered '23 Feb 2021' reason for change: Data Entry Error	System	26 Mar 2021 16:58:13
User opened query 'Data entered is non-conformant. Please correct.' (Site from System).	Kelsey Kelley (b) (4)	26 Mar 2021 16:58:13
User entered '23 Feb ' (non-conformant).	(b) (4)	26 Mar 2021 16:58:07
	System	26 Mar 2021 16:58:07
	Kelsey Kelley (b) (4)	26 Mar 2021 16:58:07
	(b) (4)	

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Folder: Covid-19 Assessment 08 Feb 2021

Form: Symptom Log (22)

Generated On: 09 Jun 2021 14:53:49

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:51:43
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:41:55
User entered '1' reason for change: Data Entry Error	(b) (4)	
	Kelsey Kelley (b) (4)	26 Mar 2021 16:58:13
User entered '0'	(b) (4)	
	Kelsey Kelley (b) (4)	26 Mar 2021 16:58:07
	(b) (4)	

US3032249

Folder: Covid-19 Assessment 08 Feb 2021

Form: Symptom Log (22)

Generated On: 09 Jun 2021 14:53:49

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:51:43
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:41:55
User entered empty.	Kelsey Kelley (b) (4)	26 Mar 2021 16:58:07

US3032249

Folder: Covid-19 Assessment 08 Feb 2021

Form: Symptom Log (22)

Generated On: 09 Jun 2021 14:53:49

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:51:43
User entered empty.	System	26 Mar 2021 16:58:07

US3032249

Folder: Covid-19 Assessment 08 Feb 2021

Form: Symptom Log (22)

Generated On: 09 Jun 2021 14:53:49

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:51:43
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:41:55
User entered empty.	Kelsey Kelley (b) (4)	26 Mar 2021 16:58:07

US3032249

Folder: Covid-19 Assessment 08 Feb 2021

Form: Symptom Log (22)

Generated On: 09 Jun 2021 14:53:49

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:51:43
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:41:55
User entered empty.	Kelsey Kelley (b) (4)	26 Mar 2021 16:58:07

US3032249

Folder: Covid-19 Assessment 08 Feb 2021

Form: Symptom Log (22)

Generated On: 09 Jun 2021 14:53:49

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:51:43
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:41:55
User entered empty.	Kelsey Kelley (b) (4)	26 Mar 2021 16:58:07

US3032249

Folder: Covid-19 Assessment 08 Feb 2021

Form: Symptom Log (22)

Generated On: 09 Jun 2021 14:53:49

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:51:43
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:41:55
User entered empty.	Kelsey Kelley (b) (4)	26 Mar 2021 16:58:07

US3032249

Folder: Covid-19 Assessment 08 Feb 2021

Form: Symptom Log (22)

Generated On: 09 Jun 2021 14:53:49

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:51:43
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:41:55
User entered empty.	Kelsey Kelley (b) (4)	26 Mar 2021 16:58:07

US3032249

Folder: Covid-19 Assessment 08 Feb 2021

Form: Symptom Log (22)

Generated On: 09 Jun 2021 14:53:49

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:51:43
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:41:55
User entered empty.	Kelsey Kelley (b) (4)	26 Mar 2021 16:58:07

US3032249

Folder: Covid-19 Assessment 08 Feb 2021

Form: Symptom Log (22)

Generated On: 09 Jun 2021 14:53:49

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:51:43
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:41:55
User entered empty.	Kelsey Kelley (b) (4)	26 Mar 2021 16:58:07

US3032249

Folder: Covid-19 Assessment 08 Feb 2021

Form: Symptom Log (22)

Generated On: 09 Jun 2021 14:53:49

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:51:43
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:41:55
User entered empty.	Kelsey Kelley (b) (4)	26 Mar 2021 16:58:07

US3032249

Folder: Covid-19 Assessment 08 Feb 2021

Form: Symptom Log (22)

Generated On: 09 Jun 2021 14:53:49

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:51:43
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:41:55
User entered empty.	Kelsey Kelley (b) (4)	26 Mar 2021 16:58:07

US3032249

Folder: Covid-19 Assessment 08 Feb 2021

Form: Symptom Log (22)

Generated On: 09 Jun 2021 14:53:49

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:51:43
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:41:55
User entered empty.	Kelsey Kelley (b) (4)	26 Mar 2021 16:58:07

US3032249

Folder: Covid-19 Assessment 08 Feb 2021

Form: Symptom Log (22)

Generated On: 09 Jun 2021 14:53:49

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:51:43
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:41:55
User entered empty.	Kelsey Kelley (b) (4)	26 Mar 2021 16:58:07

US3032249

Folder: Covid-19 Assessment 08 Feb 2021

Form: Symptom Log (22)

Generated On: 09 Jun 2021 14:53:49

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:51:43
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:41:55
User entered empty.	Kelsey Kelley (b) (4)	26 Mar 2021 16:58:07

US3032249

Folder: Covid-19 Assessment 08 Feb 2021

Form: Symptom Log (22)

Generated On: 09 Jun 2021 14:53:49

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:51:43
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:41:55
User entered empty.	Kelsey Kelley (b) (4)	26 Mar 2021 16:58:07

US3032249

Folder: Covid-19 Assessment 08 Feb 2021

Form: Symptom Log (22)

Generated On: 09 Jun 2021 14:53:49

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:51:43
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:41:55
User entered empty.	Kelsey Kelley (b) (4)	26 Mar 2021 16:58:07

US3032249

Folder: Covid-19 Assessment 08 Feb 2021

Form: Symptom Log (22)

Generated On: 09 Jun 2021 14:53:49

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:51:43
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:41:55
User entered empty.	Kelsey Kelley (b) (4)	26 Mar 2021 16:58:07

US3032249

Folder: Covid-19 Assessment 08 Feb 2021

Form: Symptom Log (22)

Generated On: 09 Jun 2021 14:53:49

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:51:43
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:41:55
User entered empty.	Kelsey Kelley (b) (4)	26 Mar 2021 16:58:07

US3032249

Folder: Covid-19 Assessment 08 Feb 2021

Form: Symptom Log (22)

Generated On: 09 Jun 2021 14:53:49

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:51:43
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:41:55
User entered empty.	Kelsey Kelley (b) (4)	26 Mar 2021 16:58:07

US3032249

Folder: Covid-19 Assessment 08 Feb 2021

Form: Symptom Log (23)

Generated On: 09 Jun 2021 14:53:49

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:51:43
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:41:55
User entered 'Day 23 (Day 23)'	Kelsey Kelley (b) (4)	26 Mar 2021 16:58:36

US3032249

Folder: Covid-19 Assessment 08 Feb 2021

Form: Symptom Log (23)

Generated On: 09 Jun 2021 14:53:49

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:51:43
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:41:55
User entered '24 Feb 2021'	Kelsey Kelley (b) (4)	26 Mar 2021 16:58:36

US3032249

Folder: Covid-19 Assessment 08 Feb 2021

Form: Symptom Log (23)

Generated On: 09 Jun 2021 14:53:49

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:51:43
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:41:55
User entered 'I'	Kelsey Kelley (b) (4)	26 Mar 2021 16:58:36

US3032249

Folder: Covid-19 Assessment 08 Feb 2021

Form: Symptom Log (23)

Generated On: 09 Jun 2021 14:53:49

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:51:43
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:41:55
User entered empty.	Kelsey Kelley (b) (4)	26 Mar 2021 16:58:36

US3032249

Folder: Covid-19 Assessment 08 Feb 2021

Form: Symptom Log (23)

Generated On: 09 Jun 2021 14:53:49

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:51:43
User entered empty.	System	26 Mar 2021 16:58:36

US3032249

Folder: Covid-19 Assessment 08 Feb 2021

Form: Symptom Log (23)

Generated On: 09 Jun 2021 14:53:49

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:51:43
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:41:55
User entered empty.	Kelsey Kelley (b) (4)	26 Mar 2021 16:58:36

US3032249

Folder: Covid-19 Assessment 08 Feb 2021

Form: Symptom Log (23)

Generated On: 09 Jun 2021 14:53:49

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:51:43
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:41:55
User entered empty.	Kelsey Kelley (b) (4)	26 Mar 2021 16:58:36

US3032249

Folder: Covid-19 Assessment 08 Feb 2021

Form: Symptom Log (23)

Generated On: 09 Jun 2021 14:53:49

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:51:43
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:41:55
User entered empty.	Kelsey Kelley (b) (4)	26 Mar 2021 16:58:36

US3032249

Folder: Covid-19 Assessment 08 Feb 2021

Form: Symptom Log (23)

Generated On: 09 Jun 2021 14:53:49

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:51:43
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:41:55
User entered empty.	Kelsey Kelley (b) (4)	26 Mar 2021 16:58:36

US3032249

Folder: Covid-19 Assessment 08 Feb 2021

Form: Symptom Log (23)

Generated On: 09 Jun 2021 14:53:49

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:51:43
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:41:55
User entered empty.	Kelsey Kelley (b) (4)	26 Mar 2021 16:58:36

US3032249

Folder: Covid-19 Assessment 08 Feb 2021

Form: Symptom Log (23)

Generated On: 09 Jun 2021 14:53:49

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:51:43
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:41:55
User entered empty.	Kelsey Kelley (b) (4)	26 Mar 2021 16:58:36

US3032249

Folder: Covid-19 Assessment 08 Feb 2021

Form: Symptom Log (23)

Generated On: 09 Jun 2021 14:53:49

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:51:43
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:41:55
User entered empty.	Kelsey Kelley (b) (4)	26 Mar 2021 16:58:36

US3032249

Folder: Covid-19 Assessment 08 Feb 2021

Form: Symptom Log (23)

Generated On: 09 Jun 2021 14:53:49

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:51:43
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:41:55
User entered empty.	Kelsey Kelley (b) (4)	26 Mar 2021 16:58:36

US3032249

Folder: Covid-19 Assessment 08 Feb 2021

Form: Symptom Log (23)

Generated On: 09 Jun 2021 14:53:49

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:51:43
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:41:55
User entered empty.	Kelsey Kelley (b) (4)	26 Mar 2021 16:58:36

US3032249

Folder: Covid-19 Assessment 08 Feb 2021

Form: Symptom Log (23)

Generated On: 09 Jun 2021 14:53:49

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:51:43
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:41:55
User entered empty.	Kelsey Kelley (b) (4)	26 Mar 2021 16:58:36

US3032249

Folder: Covid-19 Assessment 08 Feb 2021

Form: Symptom Log (23)

Generated On: 09 Jun 2021 14:53:49

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:51:43
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:41:55
User entered empty.	Kelsey Kelley (b) (4)	26 Mar 2021 16:58:36

US3032249

Folder: Covid-19 Assessment 08 Feb 2021

Form: Symptom Log (23)

Generated On: 09 Jun 2021 14:53:49

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:51:43
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:41:55
User entered empty.	Kelsey Kelley (b) (4)	26 Mar 2021 16:58:36

US3032249

Folder: Covid-19 Assessment 08 Feb 2021

Form: Symptom Log (23)

Generated On: 09 Jun 2021 14:53:49

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:51:43
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:41:55
User entered empty.	Kelsey Kelley (b) (4)	26 Mar 2021 16:58:36

US3032249

Folder: Covid-19 Assessment 08 Feb 2021

Form: Symptom Log (23)

Generated On: 09 Jun 2021 14:53:49

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:51:43
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:41:55
User entered empty.	Kelsey Kelley (b) (4)	26 Mar 2021 16:58:36

US3032249

Folder: Covid-19 Assessment 08 Feb 2021

Form: Symptom Log (23)

Generated On: 09 Jun 2021 14:53:49

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:51:43
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:41:55
User entered empty.	Kelsey Kelley (b) (4)	26 Mar 2021 16:58:36

US3032249

Folder: Covid-19 Assessment 08 Feb 2021

Form: Symptom Log (23)

Generated On: 09 Jun 2021 14:53:49

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:51:43
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:41:55
User entered empty.	Kelsey Kelley (b) (4)	26 Mar 2021 16:58:36

US3032249

Folder: Covid-19 Assessment 08 Feb 2021

Form: Symptom Log (23)

Generated On: 09 Jun 2021 14:53:49

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:51:43
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:41:55
User entered empty.	Kelsey Kelley (b) (4)	26 Mar 2021 16:58:36

US3032249

Folder: Covid-19 Assessment 08 Feb 2021

Form: Symptom Log (24)

Generated On: 09 Jun 2021 14:53:49

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:51:43
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:41:55
User entered 'Day 24 (Day 24)'	Kelsey Kelley (b) (4)	26 Mar 2021 16:58:57

US3032249

Folder: Covid-19 Assessment 08 Feb 2021

Form: Symptom Log (24)

Generated On: 09 Jun 2021 14:53:49

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:51:43
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:41:55
User entered '25 Feb 2021'	Kelsey Kelley (b) (4)	26 Mar 2021 16:58:57

US3032249

Folder: Covid-19 Assessment 08 Feb 2021

Form: Symptom Log (24)

Generated On: 09 Jun 2021 14:53:49

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:51:43
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:41:55
User entered 'I'	Kelsey Kelley (b) (4)	26 Mar 2021 16:58:57

US3032249

Folder: Covid-19 Assessment 08 Feb 2021

Form: Symptom Log (24)

Generated On: 09 Jun 2021 14:53:49

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:51:43
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:41:55
User entered empty.	Kelsey Kelley (b) (4)	26 Mar 2021 16:58:57

US3032249

Folder: Covid-19 Assessment 08 Feb 2021

Form: Symptom Log (24)

Generated On: 09 Jun 2021 14:53:49

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:51:43
User entered empty.	System	26 Mar 2021 16:58:57

US3032249

Folder: Covid-19 Assessment 08 Feb 2021

Form: Symptom Log (24)

Generated On: 09 Jun 2021 14:53:49

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:51:43
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:41:55
User entered empty.	Kelsey Kelley (b) (4)	26 Mar 2021 16:58:57

US3032249

Folder: Covid-19 Assessment 08 Feb 2021

Form: Symptom Log (24)

Generated On: 09 Jun 2021 14:53:49

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:51:43
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:41:55
User entered empty.	Kelsey Kelley (b) (4)	26 Mar 2021 16:58:57

US3032249

Folder: Covid-19 Assessment 08 Feb 2021

Form: Symptom Log (24)

Generated On: 09 Jun 2021 14:53:49

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:51:43
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:41:55
User entered empty.	Kelsey Kelley (b) (4)	26 Mar 2021 16:58:57

US3032249

Folder: Covid-19 Assessment 08 Feb 2021

Form: Symptom Log (24)

Generated On: 09 Jun 2021 14:53:49

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:51:43
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:41:55
User entered empty.	Kelsey Kelley (b) (4)	26 Mar 2021 16:58:57

US3032249

Folder: Covid-19 Assessment 08 Feb 2021

Form: Symptom Log (24)

Generated On: 09 Jun 2021 14:53:49

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:51:43
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:41:55
User entered empty.	Kelsey Kelley (b) (4)	26 Mar 2021 16:58:57

US3032249

Folder: Covid-19 Assessment 08 Feb 2021

Form: Symptom Log (24)

Generated On: 09 Jun 2021 14:53:49

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:51:43
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:41:55
User entered empty.	Kelsey Kelley (b) (4)	26 Mar 2021 16:58:57

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Folder: Covid-19 Assessment 08 Feb 2021

Form: Symptom Log (24)

Generated On: 09 Jun 2021 14:53:49

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:51:43
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:41:55
User entered empty.	Kelsey Kelley (b) (4)	26 Mar 2021 16:58:57

US3032249

Folder: Covid-19 Assessment 08 Feb 2021

Form: Symptom Log (24)

Generated On: 09 Jun 2021 14:53:49

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:51:43
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:41:55
User entered empty.	Kelsey Kelley (b) (4)	26 Mar 2021 16:58:57

US3032249

Folder: Covid-19 Assessment 08 Feb 2021

Form: Symptom Log (24)

Generated On: 09 Jun 2021 14:53:49

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:51:43
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:41:55
User entered empty.	Kelsey Kelley (b) (4)	26 Mar 2021 16:58:57

US3032249

Folder: Covid-19 Assessment 08 Feb 2021

Form: Symptom Log (24)

Generated On: 09 Jun 2021 14:53:49

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:51:43
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:41:55
User entered empty.	Kelsey Kelley (b) (4)	26 Mar 2021 16:58:57

US3032249

Folder: Covid-19 Assessment 08 Feb 2021

Form: Symptom Log (24)

Generated On: 09 Jun 2021 14:53:49

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:51:43
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:41:55
User entered empty.	Kelsey Kelley (b) (4)	26 Mar 2021 16:58:57

US3032249

Folder: Covid-19 Assessment 08 Feb 2021

Form: Symptom Log (24)

Generated On: 09 Jun 2021 14:53:49

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:51:43
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:41:55
User entered empty.	(b) (4) Kelsey Kelley (b) (4)	26 Mar 2021 16:58:57
	(b) (4)	

US3032249

Folder: Covid-19 Assessment 08 Feb 2021

Form: Symptom Log (24)

Generated On: 09 Jun 2021 14:53:49

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:51:43
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:41:55
User entered empty.	Kelsey Kelley (b) (4)	26 Mar 2021 16:58:57

US3032249

Folder: Covid-19 Assessment 08 Feb 2021

Form: Symptom Log (24)

Generated On: 09 Jun 2021 14:53:49

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:51:43
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:41:55
User entered empty.	Kelsey Kelley (b) (4)	26 Mar 2021 16:58:57

US3032249

Folder: Covid-19 Assessment 08 Feb 2021

Form: Symptom Log (24)

Generated On: 09 Jun 2021 14:53:49

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:51:43
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:41:55
User entered empty.	Kelsey Kelley (b) (4)	26 Mar 2021 16:58:57

US3032249

Folder: Covid-19 Assessment 08 Feb 2021

Form: Symptom Log (24)

Generated On: 09 Jun 2021 14:53:49

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:51:43
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:41:55
User entered empty.	Kelsey Kelley (b) (4)	26 Mar 2021 16:58:57

US3032249

Folder: Covid-19 Assessment 08 Feb 2021

Form: Symptom Log (24)

Generated On: 09 Jun 2021 14:53:49

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:51:43
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:41:55
User entered empty.	Kelsey Kelley (b) (4)	26 Mar 2021 16:58:57

US3032249

Folder: Covid-19 Assessment 08 Feb 2021

Form: Symptom Log (25)

Generated On: 09 Jun 2021 14:53:49

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:51:43
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:41:55
User entered 'Day 25 (Day 25)'	Kelsey Kelley (b) (4)	26 Mar 2021 16:59:08

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Folder: Covid-19 Assessment 08 Feb 2021

Form: Symptom Log (25)

Generated On: 09 Jun 2021 14:53:49

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:51:43
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:41:55
User entered '26 Feb 2021'	Kelsey Kelley (b) (4)	26 Mar 2021 16:59:08

US3032249

Folder: Covid-19 Assessment 08 Feb 2021

Form: Symptom Log (25)

Generated On: 09 Jun 2021 14:53:49

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:51:43
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:41:55
User entered 'I'	Kelsey Kelley (b) (4)	26 Mar 2021 16:59:08

US3032249

Folder: Covid-19 Assessment 08 Feb 2021

Form: Symptom Log (25)

Generated On: 09 Jun 2021 14:53:49

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:51:43
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:41:55
User entered empty.	Kelsey Kelley (b) (4)	26 Mar 2021 16:59:08

US3032249

Folder: Covid-19 Assessment 08 Feb 2021

Form: Symptom Log (25)

Generated On: 09 Jun 2021 14:53:49

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:51:43
User entered empty.	System	26 Mar 2021 16:59:08

US3032249

Folder: Covid-19 Assessment 08 Feb 2021

Form: Symptom Log (25)

Generated On: 09 Jun 2021 14:53:49

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:51:43
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:41:55
User entered empty.	Kelsey Kelley (b) (4)	26 Mar 2021 16:59:08

US3032249

Folder: Covid-19 Assessment 08 Feb 2021

Form: Symptom Log (25)

Generated On: 09 Jun 2021 14:53:49

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:51:43
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:41:55
User entered empty.	Kelsey Kelley (b) (4)	26 Mar 2021 16:59:08

US3032249

Folder: Covid-19 Assessment 08 Feb 2021

Form: Symptom Log (25)

Generated On: 09 Jun 2021 14:53:49

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:51:43
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:41:55
User entered empty.	Kelsey Kelley (b) (4)	26 Mar 2021 16:59:08

US3032249

Folder: Covid-19 Assessment 08 Feb 2021

Form: Symptom Log (25)

Generated On: 09 Jun 2021 14:53:49

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:51:43
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:41:55
User entered empty.	Kelsey Kelley (b) (4)	26 Mar 2021 16:59:08

US3032249

Folder: Covid-19 Assessment 08 Feb 2021

Form: Symptom Log (25)

Generated On: 09 Jun 2021 14:53:49

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:51:43
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:41:55
User entered empty.	Kelsey Kelley (b) (4)	26 Mar 2021 16:59:08

US3032249

Folder: Covid-19 Assessment 08 Feb 2021

Form: Symptom Log (25)

Generated On: 09 Jun 2021 14:53:49

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:51:43
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:41:55
User entered empty.	Kelsey Kelley (b) (4)	26 Mar 2021 16:59:08

US3032249

Folder: Covid-19 Assessment 08 Feb 2021

Form: Symptom Log (25)

Generated On: 09 Jun 2021 14:53:49

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:51:43
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:41:55
User entered empty.	Kelsey Kelley (b) (4)	26 Mar 2021 16:59:08

US3032249

Folder: Covid-19 Assessment 08 Feb 2021

Form: Symptom Log (25)

Generated On: 09 Jun 2021 14:53:49

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:51:43
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:41:55
User entered empty.	Kelsey Kelley (b) (4)	26 Mar 2021 16:59:08

US3032249

Folder: Covid-19 Assessment 08 Feb 2021

Form: Symptom Log (25)

Generated On: 09 Jun 2021 14:53:49

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:51:43
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:41:55
User entered empty.	Kelsey Kelley (b) (4)	26 Mar 2021 16:59:08

US3032249

Folder: Covid-19 Assessment 08 Feb 2021

Form: Symptom Log (25)

Generated On: 09 Jun 2021 14:53:49

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:51:43
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:41:55
User entered empty.	Kelsey Kelley (b) (4)	26 Mar 2021 16:59:08

US3032249

Folder: Covid-19 Assessment 08 Feb 2021

Form: Symptom Log (25)

Generated On: 09 Jun 2021 14:53:49

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:51:43
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:41:55
User entered empty.	Kelsey Kelley (b) (4)	26 Mar 2021 16:59:08

US3032249

Folder: Covid-19 Assessment 08 Feb 2021

Form: Symptom Log (25)

Generated On: 09 Jun 2021 14:53:49

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:51:43
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:41:55
User entered empty.	Kelsey Kelley (b) (4)	26 Mar 2021 16:59:08

US3032249

Folder: Covid-19 Assessment 08 Feb 2021

Form: Symptom Log (25)

Generated On: 09 Jun 2021 14:53:49

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:51:43
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:41:55
User entered empty.	Kelsey Kelley (b) (4)	26 Mar 2021 16:59:08

US3032249

Folder: Covid-19 Assessment 08 Feb 2021

Form: Symptom Log (25)

Generated On: 09 Jun 2021 14:53:49

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:51:43
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:41:55
User entered empty.	Kelsey Kelley (b) (4)	26 Mar 2021 16:59:08

US3032249

Folder: Covid-19 Assessment 08 Feb 2021

Form: Symptom Log (25)

Generated On: 09 Jun 2021 14:53:49

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:51:43
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:41:55
User entered empty.	(b) (4) Kelsey Kelley (b) (4)	26 Mar 2021 16:59:08

US3032249

Folder: Covid-19 Assessment 08 Feb 2021

Form: Symptom Log (25)

Generated On: 09 Jun 2021 14:53:49

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:51:43
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:41:55
User entered empty.	Kelsey Kelley (b) (4)	26 Mar 2021 16:59:08

US3032249

Folder: Covid-19 Assessment 08 Feb 2021

Form: Symptom Log (25)

Generated On: 09 Jun 2021 14:53:49

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:51:43
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:41:55
User entered empty.	Kelsey Kelley (b) (4)	26 Mar 2021 16:59:08

US3032249

Folder: Covid-19 Assessment 08 Feb 2021

Form: Symptom Log (26)

Generated On: 09 Jun 2021 14:53:49

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:51:43
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:41:55
User entered 'Day 26 (Day 26)'	Kelsey Kelley (b) (4)	26 Mar 2021 16:59:31

US3032249

Folder: Covid-19 Assessment 08 Feb 2021

Form: Symptom Log (26)

Generated On: 09 Jun 2021 14:53:49

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:51:43
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:41:55
User entered '27 Feb 2021'	(b) (4) Kelsey Kelley (b) (4)	26 Mar 2021 16:59:31

US3032249

Folder: Covid-19 Assessment 08 Feb 2021

Form: Symptom Log (26)

Generated On: 09 Jun 2021 14:53:49

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:51:43
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:41:55
User entered 'I'	Kelsey Kelley (b) (4)	26 Mar 2021 16:59:31

US3032249

Folder: Covid-19 Assessment 08 Feb 2021

Form: Symptom Log (26)

Generated On: 09 Jun 2021 14:53:49

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:51:43
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:41:55
User entered empty.	Kelsey Kelley (b) (4)	26 Mar 2021 16:59:31

US3032249

Folder: Covid-19 Assessment 08 Feb 2021

Form: Symptom Log (26)

Generated On: 09 Jun 2021 14:53:49

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:51:43
User entered empty.	System	26 Mar 2021 16:59:31

US3032249

Folder: Covid-19 Assessment 08 Feb 2021

Form: Symptom Log (26)

Generated On: 09 Jun 2021 14:53:49

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:51:43
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:41:55
User entered empty.	Kelsey Kelley (b) (4)	26 Mar 2021 16:59:31

US3032249

Folder: Covid-19 Assessment 08 Feb 2021

Form: Symptom Log (26)

Generated On: 09 Jun 2021 14:53:49

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:51:43
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:41:55
User entered empty.	Kelsey Kelley (b) (4)	26 Mar 2021 16:59:31

US3032249

Folder: Covid-19 Assessment 08 Feb 2021

Form: Symptom Log (26)

Generated On: 09 Jun 2021 14:53:49

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:51:43
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:41:55
User entered empty.	Kelsey Kelley (b) (4)	26 Mar 2021 16:59:31

US3032249

Folder: Covid-19 Assessment 08 Feb 2021

Form: Symptom Log (26)

Generated On: 09 Jun 2021 14:53:49

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:51:43
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:41:55
User entered empty.	Kelsey Kelley (b) (4)	26 Mar 2021 16:59:31

US3032249

Folder: Covid-19 Assessment 08 Feb 2021

Form: Symptom Log (26)

Generated On: 09 Jun 2021 14:53:49

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:51:43
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:41:55
User entered empty.	(b) (4) Kelsey Kelley (b) (4)	26 Mar 2021 16:59:31

US3032249

Folder: Covid-19 Assessment 08 Feb 2021

Form: Symptom Log (26)

Generated On: 09 Jun 2021 14:53:49

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:51:43
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:41:55
User entered empty.	Kelsey Kelley (b) (4)	26 Mar 2021 16:59:31

US3032249

Folder: Covid-19 Assessment 08 Feb 2021

Form: Symptom Log (26)

Generated On: 09 Jun 2021 14:53:49

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:51:43
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:41:55
User entered empty.	Kelsey Kelley (b) (4)	26 Mar 2021 16:59:31

US3032249

Folder: Covid-19 Assessment 08 Feb 2021

Form: Symptom Log (26)

Generated On: 09 Jun 2021 14:53:49

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:51:43
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:41:55
User entered empty.	Kelsey Kelley (b) (4)	26 Mar 2021 16:59:31

US3032249

Folder: Covid-19 Assessment 08 Feb 2021

Form: Symptom Log (26)

Generated On: 09 Jun 2021 14:53:49

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:51:43
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:41:55
User entered empty.	Kelsey Kelley (b) (4)	26 Mar 2021 16:59:31

US3032249

Folder: Covid-19 Assessment 08 Feb 2021

Form: Symptom Log (26)

Generated On: 09 Jun 2021 14:53:49

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:51:43
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:41:55
User entered empty.	(b) (4) Kelsey Kelley (b) (4)	26 Mar 2021 16:59:31

US3032249

Folder: Covid-19 Assessment 08 Feb 2021

Form: Symptom Log (26)

Generated On: 09 Jun 2021 14:53:49

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:51:43
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:41:55
User entered empty.	Kelsey Kelley (b) (4)	26 Mar 2021 16:59:31

US3032249

Folder: Covid-19 Assessment 08 Feb 2021

Form: Symptom Log (26)

Generated On: 09 Jun 2021 14:53:49

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:51:43
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:41:55
User entered empty.	Kelsey Kelley (b) (4)	26 Mar 2021 16:59:31

US3032249

Folder: Covid-19 Assessment 08 Feb 2021

Form: Symptom Log (26)

Generated On: 09 Jun 2021 14:53:49

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:51:43
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:41:55
User entered empty.	Kelsey Kelley (b) (4)	26 Mar 2021 16:59:31

US3032249

Folder: Covid-19 Assessment 08 Feb 2021

Form: Symptom Log (26)

Generated On: 09 Jun 2021 14:53:49

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:51:43
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:41:55
User entered empty.	Kelsey Kelley (b) (4)	26 Mar 2021 16:59:31

US3032249

Folder: Covid-19 Assessment 08 Feb 2021

Form: Symptom Log (26)

Generated On: 09 Jun 2021 14:53:49

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:51:43
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:41:55
User entered empty.	Kelsey Kelley (b) (4)	26 Mar 2021 16:59:31

US3032249

Folder: Covid-19 Assessment 08 Feb 2021

Form: Symptom Log (26)

Generated On: 09 Jun 2021 14:53:49

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:51:43
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:41:55
User entered empty.	Kelsey Kelley (b) (4)	26 Mar 2021 16:59:31

US3032249

Folder: Covid-19 Assessment 08 Feb 2021

Form: Symptom Log (26)

Generated On: 09 Jun 2021 14:53:49

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:51:43
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:41:55
User entered empty.	Kelsey Kelley (b) (4)	26 Mar 2021 16:59:31

US3032249

Folder: Covid-19 Assessment 08 Feb 2021

Form: Symptom Log (27)

Generated On: 09 Jun 2021 14:53:49

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:51:43
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:41:55
User entered 'Day 27 (Day 27)'	Kelsey Kelley (b) (4)	26 Mar 2021 16:59:47

US3032249

Folder: Covid-19 Assessment 08 Feb 2021

Form: Symptom Log (27)

Generated On: 09 Jun 2021 14:53:49

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:51:43
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:41:55
User entered '28 Feb 2021'	(b) (4) Kelsey Kelley (b) (4)	26 Mar 2021 16:59:47
	(b) (4)	

US3032249

Folder: Covid-19 Assessment 08 Feb 2021

Form: Symptom Log (27)

Generated On: 09 Jun 2021 14:53:49

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:51:43
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:41:55
User entered 'I'	Kelsey Kelley (b) (4)	26 Mar 2021 16:59:47

US3032249

Folder: Covid-19 Assessment 08 Feb 2021

Form: Symptom Log (27)

Generated On: 09 Jun 2021 14:53:49

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:51:43
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:41:55
User entered empty.	Kelsey Kelley (b) (4)	26 Mar 2021 16:59:47

US3032249

Folder: Covid-19 Assessment 08 Feb 2021

Form: Symptom Log (27)

Generated On: 09 Jun 2021 14:53:49

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:51:43
User entered empty.	System	26 Mar 2021 16:59:47

US3032249

Folder: Covid-19 Assessment 08 Feb 2021

Form: Symptom Log (27)

Generated On: 09 Jun 2021 14:53:49

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:51:43
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:41:55
User entered empty.	Kelsey Kelley (b) (4)	26 Mar 2021 16:59:47

US3032249

Folder: Covid-19 Assessment 08 Feb 2021

Form: Symptom Log (27)

Generated On: 09 Jun 2021 14:53:49

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:51:43
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:41:55
User entered empty.	Kelsey Kelley (b) (4)	26 Mar 2021 16:59:47

US3032249

Folder: Covid-19 Assessment 08 Feb 2021

Form: Symptom Log (27)

Generated On: 09 Jun 2021 14:53:49

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:51:43
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:41:55
User entered empty.	Kelsey Kelley (b) (4)	26 Mar 2021 16:59:47

US3032249

Folder: Covid-19 Assessment 08 Feb 2021

Form: Symptom Log (27)

Generated On: 09 Jun 2021 14:53:49

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:51:43
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:41:55
User entered empty.	Kelsey Kelley (b) (4)	26 Mar 2021 16:59:47

US3032249

Folder: Covid-19 Assessment 08 Feb 2021

Form: Symptom Log (27)

Generated On: 09 Jun 2021 14:53:49

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:51:43
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:41:55
User entered empty.	Kelsey Kelley (b) (4)	26 Mar 2021 16:59:47

US3032249

Folder: Covid-19 Assessment 08 Feb 2021

Form: Symptom Log (27)

Generated On: 09 Jun 2021 14:53:49

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:51:43
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:41:55
User entered empty.	Kelsey Kelley (b) (4)	26 Mar 2021 16:59:47

US3032249

Folder: Covid-19 Assessment 08 Feb 2021

Form: Symptom Log (27)

Generated On: 09 Jun 2021 14:53:49

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:51:43
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:41:55
User entered empty.	Kelsey Kelley (b) (4)	26 Mar 2021 16:59:47

US3032249

Folder: Covid-19 Assessment 08 Feb 2021

Form: Symptom Log (27)

Generated On: 09 Jun 2021 14:53:49

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:51:43
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:41:55
User entered empty.	Kelsey Kelley (b) (4)	26 Mar 2021 16:59:47

US3032249

Folder: Covid-19 Assessment 08 Feb 2021

Form: Symptom Log (27)

Generated On: 09 Jun 2021 14:53:49

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:51:43
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:41:55
User entered empty.	Kelsey Kelley (b) (4)	26 Mar 2021 16:59:47

US3032249

Folder: Covid-19 Assessment 08 Feb 2021

Form: Symptom Log (27)

Generated On: 09 Jun 2021 14:53:49

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:51:43
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:41:55
User entered empty.	Kelsey Kelley (b) (4)	26 Mar 2021 16:59:47

US3032249

Folder: Covid-19 Assessment 08 Feb 2021

Form: Symptom Log (27)

Generated On: 09 Jun 2021 14:53:49

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:51:43
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:41:55
User entered empty.	Kelsey Kelley (b) (4)	26 Mar 2021 16:59:47

US3032249

Folder: Covid-19 Assessment 08 Feb 2021

Form: Symptom Log (27)

Generated On: 09 Jun 2021 14:53:49

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:51:43
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:41:55
User entered empty.	Kelsey Kelley (b) (4)	26 Mar 2021 16:59:47

US3032249

Folder: Covid-19 Assessment 08 Feb 2021

Form: Symptom Log (27)

Generated On: 09 Jun 2021 14:53:49

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:51:43
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:41:55
User entered empty.	Kelsey Kelley (b) (4)	26 Mar 2021 16:59:47

US3032249

Folder: Covid-19 Assessment 08 Feb 2021

Form: Symptom Log (27)

Generated On: 09 Jun 2021 14:53:49

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:51:43
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:41:55
User entered empty.	Kelsey Kelley (b) (4)	26 Mar 2021 16:59:47

US3032249

Folder: Covid-19 Assessment 08 Feb 2021

Form: Symptom Log (27)

Generated On: 09 Jun 2021 14:53:49

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:51:43
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:41:55
User entered empty.	Kelsey Kelley (b) (4)	26 Mar 2021 16:59:47

US3032249

Folder: Covid-19 Assessment 08 Feb 2021

Form: Symptom Log (27)

Generated On: 09 Jun 2021 14:53:49

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:51:43
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:41:55
User entered empty.	Kelsey Kelley (b) (4)	26 Mar 2021 16:59:47

US3032249

Folder: Covid-19 Assessment 08 Feb 2021

Form: Symptom Log (27)

Generated On: 09 Jun 2021 14:53:49

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:51:43
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:41:55
User entered empty.	Kelsey Kelley (b) (4)	26 Mar 2021 16:59:47

US3032249

Folder: Covid-19 Assessment 08 Feb 2021

Form: Symptom Log (28)

Generated On: 09 Jun 2021 14:53:49

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:51:43
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:41:55
User entered 'Day 28 (Day 28)'	Kelsey Kelley (b) (4)	26 Mar 2021 17:00:22

US3032249

Folder: Covid-19 Assessment 08 Feb 2021

Form: Symptom Log (28)

Generated On: 09 Jun 2021 14:53:49

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:51:43
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:41:55
User entered '01 Mar 2021'	(b) (4) Kelsey Kelley (b) (4)	26 Mar 2021 17:00:22
	(b) (4)	

US3032249

Folder: Covid-19 Assessment 08 Feb 2021

Form: Symptom Log (28)

Generated On: 09 Jun 2021 14:53:49

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:51:43
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:41:55
User entered 'I'	Kelsey Kelley (b) (4)	26 Mar 2021 17:00:22

US3032249

Folder: Covid-19 Assessment 08 Feb 2021

Form: Symptom Log (28)

Generated On: 09 Jun 2021 14:53:49

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:51:43
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:41:55
User entered empty.	Kelsey Kelley (b) (4)	26 Mar 2021 17:00:22

US3032249

Folder: Covid-19 Assessment 08 Feb 2021

Form: Symptom Log (28)

Generated On: 09 Jun 2021 14:53:49

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:51:43
User entered empty.	System	26 Mar 2021 17:00:22

US3032249

Folder: Covid-19 Assessment 08 Feb 2021

Form: Symptom Log (28)

Generated On: 09 Jun 2021 14:53:49

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:51:43
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:41:55
User entered empty.	Kelsey Kelley (b) (4)	26 Mar 2021 17:00:22

US3032249

Folder: Covid-19 Assessment 08 Feb 2021

Form: Symptom Log (28)

Generated On: 09 Jun 2021 14:53:49

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:51:43
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:41:55
User entered empty.	Kelsey Kelley (b) (4)	26 Mar 2021 17:00:22

US3032249

Folder: Covid-19 Assessment 08 Feb 2021

Form: Symptom Log (28)

Generated On: 09 Jun 2021 14:53:49

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:51:43
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:41:55
User entered empty.	Kelsey Kelley (b) (4)	26 Mar 2021 17:00:22

US3032249

Folder: Covid-19 Assessment 08 Feb 2021

Form: Symptom Log (28)

Generated On: 09 Jun 2021 14:53:49

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:51:43
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:41:55
User entered empty.	Kelsey Kelley (b) (4)	26 Mar 2021 17:00:22

US3032249

Folder: Covid-19 Assessment 08 Feb 2021

Form: Symptom Log (28)

Generated On: 09 Jun 2021 14:53:49

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:51:43
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:41:55
User entered empty.	Kelsey Kelley (b) (4)	26 Mar 2021 17:00:22

US3032249

Folder: Covid-19 Assessment 08 Feb 2021

Form: Symptom Log (28)

Generated On: 09 Jun 2021 14:53:49

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:51:43
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:41:55
User entered empty.	Kelsey Kelley (b) (4)	26 Mar 2021 17:00:22

US3032249

Folder: Covid-19 Assessment 08 Feb 2021

Form: Symptom Log (28)

Generated On: 09 Jun 2021 14:53:49

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:51:43
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:41:55
User entered empty.	Kelsey Kelley (b) (4)	26 Mar 2021 17:00:22

US3032249

Folder: Covid-19 Assessment 08 Feb 2021

Form: Symptom Log (28)

Generated On: 09 Jun 2021 14:53:49

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:51:43
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:41:55
User entered empty.	Kelsey Kelley (b) (4)	26 Mar 2021 17:00:22

US3032249

Folder: Covid-19 Assessment 08 Feb 2021

Form: Symptom Log (28)

Generated On: 09 Jun 2021 14:53:49

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:51:43
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:41:55
User entered empty.	Kelsey Kelley (b) (4)	26 Mar 2021 17:00:22

US3032249

Folder: Covid-19 Assessment 08 Feb 2021

Form: Symptom Log (28)

Generated On: 09 Jun 2021 14:53:49

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:51:43
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:41:55
User entered empty.	Kelsey Kelley (b) (4)	26 Mar 2021 17:00:22

US3032249

Folder: Covid-19 Assessment 08 Feb 2021

Form: Symptom Log (28)

Generated On: 09 Jun 2021 14:53:49

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:51:43
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:41:55
User entered empty.	Kelsey Kelley (b) (4)	26 Mar 2021 17:00:22

US3032249

Folder: Covid-19 Assessment 08 Feb 2021

Form: Symptom Log (28)

Generated On: 09 Jun 2021 14:53:49

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:51:43
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:41:55
User entered empty.	Kelsey Kelley (b) (4)	26 Mar 2021 17:00:22

US3032249

Folder: Covid-19 Assessment 08 Feb 2021

Form: Symptom Log (28)

Generated On: 09 Jun 2021 14:53:49

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:51:43
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:41:55
User entered empty.	Kelsey Kelley (b) (4)	26 Mar 2021 17:00:22

US3032249

Folder: Covid-19 Assessment 08 Feb 2021

Form: Symptom Log (28)

Generated On: 09 Jun 2021 14:53:49

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:51:43
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:41:55
User entered empty.	Kelsey Kelley (b) (4)	26 Mar 2021 17:00:22

US3032249

Folder: Covid-19 Assessment 08 Feb 2021

Form: Symptom Log (28)

Generated On: 09 Jun 2021 14:53:49

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:51:43
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:41:55
User entered empty.	Kelsey Kelley (b) (4)	26 Mar 2021 17:00:22

US3032249

Folder: Covid-19 Assessment 08 Feb 2021

Form: Symptom Log (28)

Generated On: 09 Jun 2021 14:53:49

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:51:43
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:41:55
User entered empty.	Kelsey Kelley (b) (4)	26 Mar 2021 17:00:22

US3032249

Folder: Covid-19 Assessment 08 Feb 2021

Form: Symptom Log (28)

Generated On: 09 Jun 2021 14:53:49

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:51:43
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:41:55
User entered empty.	Kelsey Kelley (b) (4)	26 Mar 2021 17:00:22

US3032249

Folder: Covid-19 Assessment 08 Feb 2021

Form: COVID Diagnostic Test

Generated On: 09 Jun 2021 14:53:49

[Date of Visit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 03:42:39
User signature succeeded.	Keith Vrbicky (b) (4)	03 May 2021 16:17:39
DataPoint Un-verified.	(b) (4) (b) (4), (b) (6)	29 Apr 2021 16:56:18
DataPoint Verified.		29 Apr 2021 16:52:39
Signature has been broken.	Samantha Wieseler (b) (4)	26 Apr 2021 20:46:31
User entered '9 Feb 2021' reason for change: Data Entry Error	(b) (4)	
User signature succeeded.	Samantha Wieseler (b) (4)	26 Apr 2021 20:46:31
	(b) (4)	
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:41:55
	(b) (4)	
User entered '8 Feb 2021'	Kelsey Kelley (b) (4)	23 Mar 2021 15:25:02
	(b) (4)	

US3032249

Folder: Covid-19 Assessment 08 Feb 2021

Form: COVID Diagnostic Test

Generated On: 09 Jun 2021 14:53:49

[Was the Subject Tested For SARS-CoV-2 by RT-PCR?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 03:42:39
DataPoint Un-verified.		29 Apr 2021 17:49:23
DataPoint Verified.		29 Apr 2021 17:49:11
User closed query 'Please consider changing to YES per your SAE narrative that the subject was tested outside of the study. The local test should be recorded on this page.' (Site from CRA).		29 Apr 2021 17:45:08
DataPoint Un-verified.		29 Apr 2021 16:56:31
DataPoint Verified.		29 Apr 2021 16:51:47
User signature succeeded.	Keith Vrbicky (b) (4)	23 Apr 2021 19:37:17
Query 'Please consider changing to YES per your SAE narrative that the subject was tested outside of the study. The local test should be recorded on this page.' answered with 'updated' (Site from CRA).	(b) (4)	
Signature has been broken.	Samantha Wieseler (b) (4)	23 Apr 2021 13:04:33
	(b) (4)	
	Samantha Wieseler (b) (4)	23 Apr 2021 13:03:10
	(b) (4)	
User entered 'Yes (Y)' reason for change: Data Entry Error	Samantha Wieseler (b) (4)	23 Apr 2021 13:03:10
	(b) (4)	
User opened query 'Please consider changing to YES per your SAE narrative that the subject was tested outside of the study. The local test should be recorded on this page.' (Site from CRA).	(b) (4), (b) (6)	22 Apr 2021 22:09:16
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:41:55
	(b) (4)	
User entered 'No (N)'	Kelsey Kelley (b) (4)	23 Mar 2021 15:25:02
	(b) (4)	

US3032249

Folder: Covid-19 Assessment 08 Feb 2021

Form: COVID Diagnostic Test

Generated On: 09 Jun 2021 14:53:49

Did Subject Test Positive For SARS-CoV-2 by RT-PCR?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 03:42:39
DataPoint Un-verified.		29 Apr 2021 16:56:46
DataPoint Verified.		29 Apr 2021 16:53:50
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).		21 Apr 2021 00:59:21
User closed query 'Per CDM: The AE form has 'COVID 19' with a start date of 02Feb2021 and 'Is this event a confirmed diagnosis of Symptomatic Covid-19?' = Yes but Did the subject test positive for SARS-COV-2 by RT-PCR is No. Please review and reconcile, else clarify.' (Site from DM).		21 Apr 2021 00:59:05
User signature succeeded.	Keith Vrbicky (b) (4)	14 Apr 2021 19:23:00
Query 'Per CDM: The AE form has 'COVID 19' with a start date of 02Feb2021 and 'Is this event a confirmed diagnosis of Symptomatic Covid-19?' = Yes but Did the subject test positive for SARS-COV-2 by RT-PCR is No. Please review and reconcile, else clarify.' answered with 'updated' (Site from DM).	(b) (4) Samantha Wieseler (b) (4)	12 Apr 2021 21:26:54
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 'AE is already in AE pages' (Site from System).	Samantha Wieseler (b) (4)	12 Apr 2021 21:26:48
User opened query 'Did Subject Test Positive For SARS-CoV-2 by RT-PCR is Yes. Please confirm test result was positive and enter COVID-19 diagnosis on the Adverse Events form.' (Site from System).	System	12 Apr 2021 21:25:24
Signature has been broken.	Samantha Wieseler (b) (4)	12 Apr 2021 21:25:24
User entered 'Yes (Y)' reason for change: Data Entry Error	(b) (4) Samantha Wieseler (b) (4)	12 Apr 2021 21:25:24

US3032249

Folder: Covid-19 Assessment 08 Feb 2021

Form: COVID Diagnostic Test

Generated On: 09 Jun 2021 14:53:49

Did Subject Test Positive For SARS-CoV-2 by RT-PCR?

Audit	User	Time (GMT)
User opened query 'Per CDM: The AE form has 'COVID 19' with a start date of 02Feb2021 and 'Is this event a confirmed diagnosis of Symptomatic Covid-19?' = Yes but Did the subject test positive for SARS-COV-2 by RT-PCR is No. Please review and reconcile, else clarify.' (Site from DM). User signature succeeded.	(b) (4), (b) (6) Keith Vrbicky (b) (4)	12 Apr 2021 15:47:32 06 Apr 2021 15:41:55
User closed query 'Data is required. Please complete.' (Site from System).	System	23 Mar 2021 15:25:10
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	23 Mar 2021 15:25:10
User entered 'No (N)' reason for change: Data Entry Error	Kelsey Kelley (b) (4)	23 Mar 2021 15:25:10
User opened query 'Data is required. Please complete.' (Site from System).	System	23 Mar 2021 15:25:02
User entered empty.	Kelsey Kelley (b) (4)	23 Mar 2021 15:25:02

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Folder: Covid-19 Assessment 08 Feb 2021

Form: COVID Diagnostic Test

Generated On: 09 Jun 2021 14:53:49

[Date of Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 03:42:39
DataPoint Un-verified.		29 Apr 2021 16:55:06
DataPoint Verified.		29 Apr 2021 16:54:36
User signature succeeded.	Keith Vrbicky (b) (4)	14 Apr 2021 19:23:00
Signature has been broken.	(b) (4) Samantha Wieseler (b) (4)	12 Apr 2021 21:26:35
User entered '09 Feb 2021' reason for change: Data Entry Error	(b) (4) Samantha Wieseler (b) (4)	12 Apr 2021 21:26:35
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:41:55
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4) (b) (4), (b) (6)	25 Mar 2021 02:51:20
Query 'Data is required. Please complete.' answered with 'test not performed' (Site from System).	Kelsey Kelley (b) (4)	23 Mar 2021 15:25:21
User opened query 'Data is required. Please complete.' (Site from System).	(b) (4) System	23 Mar 2021 15:25:02
User entered empty.	Kelsey Kelley (b) (4) (b) (4)	23 Mar 2021 15:25:02

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Type of Test Performed

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 03:42:39
DataPoint Un-verified.		29 Apr 2021 16:55:29
DataPoint Verified.		29 Apr 2021 16:54:49
User signature succeeded.	Keith Vrbicky (b) (4)	14 Apr 2021 19:23:00
Signature has been broken.	(b) (4) Samantha Wieseler (b) (4)	12 Apr 2021 21:26:35
User entered 'Nasopharyngeal Swab (Nasopharyngeal Swab)' reason for change: Data Entry Error	(b) (4) Samantha Wieseler (b) (4)	12 Apr 2021 21:26:35
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:41:55
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4) (b) (4), (b) (6)	25 Mar 2021 02:51:22
Query 'Data is required. Please complete.' answered with 'test not performed' (Site from System).	Kelsey Kelley (b) (4)	23 Mar 2021 15:25:28
User opened query 'Data is required. Please complete.' (Site from System).	(b) (4) System	23 Mar 2021 15:25:02
User entered empty.	Kelsey Kelley (b) (4) (b) (4)	23 Mar 2021 15:25:02

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[Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 03:42:39
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:41:55
User entered empty.	(b) (4) Kelsey Kelley (b) (4)	23 Mar 2021 15:25:02

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[Was this diagnostic test performed at a lab other than the Study Central Lab?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 03:42:39
User closed query 'Please verify and enter Yes and two fields below for local lab you have noted in narrative of COVID SAE.' (Site from CRA). User signature succeeded.	(b) (4)	03 May 2021 12:24:33
Query 'Please verify and enter Yes and two fields below for local lab you have noted in narrative of COVID SAE.' answered with 'updated' (Site from CRA).	Keith Vrbicky (b) (4)	23 Apr 2021 19:37:17
Signature has been broken.	(b) (4)	
	Samantha Wieseler (b) (4)	23 Apr 2021 13:04:38
	(b) (4)	
User entered 'Yes (Y)' reason for change: Data Entry Error	Samantha Wieseler (b) (4)	23 Apr 2021 13:03:10
User opened query 'Please verify and enter Yes and two fields below for local lab you have noted in narrative of COVID SAE.' (Site from CRA). User signature succeeded.	(b) (4)	
	(b) (4), (b) (6)	22 Apr 2021 22:08:36
User closed query 'Data is required. Please complete.' (Site from System).	Keith Vrbicky (b) (4)	06 Apr 2021 15:41:55
Query 'Data is required. Please complete.' answered with 'test not performed ' (Site from System).	(b) (4)	
User opened query 'Data is required. Please complete.' (Site from System).	(b) (4), (b) (6)	25 Mar 2021 02:51:23
User entered empty.		
	Kelsey Kelley (b) (4)	23 Mar 2021 15:25:35
	(b) (4)	
	System	23 Mar 2021 15:25:02
	Kelsey Kelley (b) (4)	23 Mar 2021 15:25:02
	(b) (4)	

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[Lab/ Institution Test Performed](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 03:42:39
DataPoint Un-verified.		29 Apr 2021 16:55:51
DataPoint Verified.		29 Apr 2021 16:53:14
User signature succeeded.	Keith Vrbicky (b) (4)	23 Apr 2021 19:37:17
User closed query 'Data is required. Please provide.' (Site from System).	(b) (4)	
Signature has been broken.	System	23 Apr 2021 13:04:25
User entered 'Faith Regional Health Services' reason for change: Data Entry Error	Samantha Wieseler (b) (4)	23 Apr 2021 13:04:25
User opened query 'Data is required. Please provide.' (Site from System).	(b) (4)	
User signature succeeded.	System	23 Apr 2021 13:03:10
User entered empty.	Keith Vrbicky (b) (4)	06 Apr 2021 15:41:55
	(b) (4)	
	Kelsey Kelley (b) (4)	23 Mar 2021 15:25:02
	(b) (4)	

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[CLIA Certified?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 03:42:39
DataPoint Un-verified.		29 Apr 2021 16:56:04
DataPoint Verified.		29 Apr 2021 16:53:01
User signature succeeded.	Keith Vrbicky (b) (4)	23 Apr 2021 19:37:17
User closed query 'Data is required. Please provide.' (Site from System).	(b) (4)	23 Apr 2021 13:04:25
Signature has been broken.	Samantha Wieseler (b) (4)	23 Apr 2021 13:04:25
User entered 'Yes (Y)' reason for change: Data Entry Error	(b) (4)	23 Apr 2021 13:04:25
User opened query 'Data is required. Please provide.' (Site from System).	Samantha Wieseler (b) (4)	23 Apr 2021 13:03:10
User signature succeeded.	System	23 Apr 2021 13:03:10
User entered empty.	Keith Vrbicky (b) (4)	06 Apr 2021 15:41:55
	(b) (4)	
	Kelsey Kelley (b) (4)	23 Mar 2021 15:25:02
	(b) (4)	

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[COVID-19 Positive \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 03:42:39
User entered '1'	System	12 Apr 2021 21:25:24
User entered '0'	System	23 Mar 2021 15:25:10

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Form: Covid-19 Severity Assessment

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[Did the subject have Respiratory Rates \$\geq\$ 30 per Minute?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:52:05
User signature succeeded.	Keith Vrbicky (b) (4)	14 Apr 2021 19:23:00
User entered 'No (N)'	Samantha Wieseler (b) (4)	13 Apr 2021 17:40:20

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Folder: Covid-19 Assessment 08 Feb 2021

Form: Covid-19 Severity Assessment

Generated On: 09 Jun 2021 14:53:49

[Start Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:52:05
User signature succeeded.	Keith Vrbicky (b) (4)	14 Apr 2021 19:23:00
User entered empty.	Samantha Wieseler (b) (4)	13 Apr 2021 17:40:20

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Folder: Covid-19 Assessment 08 Feb 2021

Form: Covid-19 Severity Assessment

Generated On: 09 Jun 2021 14:53:49

[End Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:52:05
User signature succeeded.	Keith Vrbicky (b) (4)	14 Apr 2021 19:23:00
User entered empty.	Samantha Wieseler (b) (4)	13 Apr 2021 17:40:20

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Folder: Covid-19 Assessment 08 Feb 2021

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[Respiratory Rate](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:52:05
User signature succeeded.	Keith Vrbicky (b) (4)	14 Apr 2021 19:23:00
User entered empty.	Samantha Wieseler (b) (4)	13 Apr 2021 17:40:20

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Folder: Covid-19 Assessment 08 Feb 2021

Form: Covid-19 Severity Assessment

Generated On: 09 Jun 2021 14:53:49

[Did the subject have Heart Rate \$\geq\$ 125 beats per minute](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:52:05
User signature succeeded.	Keith Vrbicky (b) (4)	14 Apr 2021 19:23:00
User entered 'No (N)'	Samantha Wieseler (b) (4)	13 Apr 2021 17:40:20

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[Start Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:52:05
User signature succeeded.	Keith Vrbicky (b) (4)	14 Apr 2021 19:23:00
User entered empty.	Samantha Wieseler (b) (4)	13 Apr 2021 17:40:20

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Folder: Covid-19 Assessment 08 Feb 2021

Form: Covid-19 Severity Assessment

Generated On: 09 Jun 2021 14:53:49

[End Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:52:05
User signature succeeded.	Keith Vrbicky (b) (4)	14 Apr 2021 19:23:00
User entered empty.	Samantha Wieseler (b) (4)	13 Apr 2021 17:40:20

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[Heart Rate](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:52:05
User signature succeeded.	Keith Vrbicky (b) (4)	14 Apr 2021 19:23:00
User entered empty.	Samantha Wieseler (b) (4)	13 Apr 2021 17:40:20

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Generated On: 09 Jun 2021 14:53:49

[Did the subject have Oxygen Saturation of SpO2 \$\leq\$ 93% on room air at sea level?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:52:05
User signature succeeded.	Keith Vrbicky (b) (4)	14 Apr 2021 19:23:00
User entered 'Yes (Y)'	Samantha Wieseler (b) (4)	13 Apr 2021 17:40:20

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Form: Covid-19 Severity Assessment

Generated On: 09 Jun 2021 14:53:49

[Start Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:52:05
User signature succeeded.	Keith Vrbicky (b) (4)	14 Apr 2021 19:23:00
User entered '02 Feb 2021'	Samantha Wieseler (b) (4)	13 Apr 2021 17:40:20

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Folder: Covid-19 Assessment 08 Feb 2021

Form: Covid-19 Severity Assessment

Generated On: 09 Jun 2021 14:53:49

[End Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:52:05
User signature succeeded.	Keith Vrbicky (b) (4)	14 Apr 2021 19:23:00
User entered '02 Feb 2021'	Samantha Wieseler (b) (4)	13 Apr 2021 17:40:20

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[Oxygen Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:52:05
User signature succeeded.	Keith Vrbicky (b) (4)	14 Apr 2021 19:23:00
User entered '88'	Samantha Wieseler (b) (4)	13 Apr 2021 17:40:20

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Folder: Covid-19 Assessment 08 Feb 2021

Form: Covid-19 Severity Assessment

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[Did the subject have PaO2/FIO2 Ratio < 300 mm Hg?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:52:05
User signature succeeded.	Keith Vrbicky (b) (4)	14 Apr 2021 19:23:00
User entered 'No (N)'	Samantha Wieseler (b) (4)	13 Apr 2021 17:40:20

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Folder: Covid-19 Assessment 08 Feb 2021

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[Start Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:52:05
User signature succeeded.	Keith Vrbicky (b) (4)	14 Apr 2021 19:23:00
User entered empty.	Samantha Wieseler (b) (4)	13 Apr 2021 17:40:20

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Folder: Covid-19 Assessment 08 Feb 2021

Form: Covid-19 Severity Assessment

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[End Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:52:05
User signature succeeded.	Keith Vrbicky (b) (4)	14 Apr 2021 19:23:00
User entered empty.	Samantha Wieseler (b) (4)	13 Apr 2021 17:40:20

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[PaO2](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:52:05
User signature succeeded.	Keith Vrbicky (b) (4)	14 Apr 2021 19:23:00
User entered empty.	Samantha Wieseler (b) (4)	13 Apr 2021 17:40:20

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Folder: Covid-19 Assessment 08 Feb 2021

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[Did the subject have Respiratory failure?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:52:05
User signature succeeded.	Keith Vrbicky (b) (4)	14 Apr 2021 19:23:00
User entered 'No (N)'	Samantha Wieseler (b) (4)	13 Apr 2021 17:40:20

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Folder: Covid-19 Assessment 08 Feb 2021

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[Start Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:52:05
User signature succeeded.	Keith Vrbicky (b) (4)	14 Apr 2021 19:23:00
User entered empty.	Samantha Wieseler (b) (4)	13 Apr 2021 17:40:20

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Form: Covid-19 Severity Assessment

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[Did the subject have Acute Respiratory Distress Syndrome \(ARDS\)?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:52:05
User signature succeeded.	Keith Vrbicky (b) (4)	14 Apr 2021 19:23:00
User entered 'No (N)'	Samantha Wieseler (b) (4)	13 Apr 2021 17:40:20

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Folder: Covid-19 Assessment 08 Feb 2021

Form: Covid-19 Severity Assessment

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[Start Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:52:05
User signature succeeded.	Keith Vrbicky (b) (4)	14 Apr 2021 19:23:00
User entered empty.	Samantha Wieseler (b) (4)	13 Apr 2021 17:40:20

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Folder: Covid-19 Assessment 08 Feb 2021

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[High-Flow Oxygen?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:52:05
User signature succeeded.	Keith Vrbicky (b) (4)	14 Apr 2021 19:23:00
User entered 'No (N)'	Samantha Wieseler (b) (4)	13 Apr 2021 17:40:20

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Folder: Covid-19 Assessment 08 Feb 2021

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[Start Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:52:05
User signature succeeded.	Keith Vrbicky (b) (4)	14 Apr 2021 19:23:00
User entered empty.	Samantha Wieseler (b) (4)	13 Apr 2021 17:40:20

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Folder: Covid-19 Assessment 08 Feb 2021

Form: Covid-19 Severity Assessment

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[End Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:52:05
User signature succeeded.	Keith Vrbicky (b) (4)	14 Apr 2021 19:23:00
User entered empty.	Samantha Wieseler (b) (4)	13 Apr 2021 17:40:20

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[Non-Invasive Ventilation?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:52:05
User signature succeeded.	Keith Vrbicky (b) (4)	14 Apr 2021 19:23:00
User entered 'No (N)'	(b) (4) Samantha Wieseler (b) (4)	13 Apr 2021 17:40:20

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[Start Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:52:05
User signature succeeded.	Keith Vrbicky (b) (4)	14 Apr 2021 19:23:00
User entered empty.	Samantha Wieseler (b) (4)	13 Apr 2021 17:40:20

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Folder: Covid-19 Assessment 08 Feb 2021

Form: Covid-19 Severity Assessment

Generated On: 09 Jun 2021 14:53:49

[End Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:52:05
User signature succeeded.	Keith Vrbicky (b) (4)	14 Apr 2021 19:23:00
User entered empty.	Samantha Wieseler (b) (4)	13 Apr 2021 17:40:20

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[Mechanical Ventilation?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:52:05
User signature succeeded.	Keith Vrbicky (b) (4)	14 Apr 2021 19:23:00
User entered 'No (N)'	Samantha Wieseler (b) (4)	13 Apr 2021 17:40:20

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Folder: Covid-19 Assessment 08 Feb 2021

Form: Covid-19 Severity Assessment

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[Start Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:52:05
User signature succeeded.	Keith Vrbicky (b) (4)	14 Apr 2021 19:23:00
User entered empty.	Samantha Wieseler (b) (4)	13 Apr 2021 17:40:20

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Folder: Covid-19 Assessment 08 Feb 2021

Form: Covid-19 Severity Assessment

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[End Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:52:05
User signature succeeded.	Keith Vrbicky (b) (4)	14 Apr 2021 19:23:00
User entered empty.	Samantha Wieseler (b) (4)	13 Apr 2021 17:40:20

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[ECMO?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:52:05
User signature succeeded.	Keith Vrbicky (b) (4)	14 Apr 2021 19:23:00
User entered 'No (N)'	Samantha Wieseler (b) (4)	13 Apr 2021 17:40:20

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Folder: Covid-19 Assessment 08 Feb 2021

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[Start Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:52:05
User signature succeeded.	Keith Vrbicky (b) (4)	14 Apr 2021 19:23:00
User entered empty.	Samantha Wieseler (b) (4)	13 Apr 2021 17:40:20

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Folder: Covid-19 Assessment 08 Feb 2021

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[End Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:52:05
User signature succeeded.	Keith Vrbicky (b) (4)	14 Apr 2021 19:23:00
User entered empty.	Samantha Wieseler (b) (4)	13 Apr 2021 17:40:20

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Systolic Blood Pressure < 90 mmHg, Diastolic Blood Pressure < 60 mmHg

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:52:05
User signature succeeded.	Keith Vrbicky (b) (4)	14 Apr 2021 19:23:00
User entered 'No (N)'	Samantha Wieseler (b) (4)	13 Apr 2021 17:40:20

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Folder: Covid-19 Assessment 08 Feb 2021

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Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:52:05
User signature succeeded.	Keith Vrbicky (b) (4)	14 Apr 2021 19:23:00
User entered empty.	Samantha Wieseler (b) (4)	13 Apr 2021 17:40:20

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[End Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:52:05
User signature succeeded.	Keith Vrbicky (b) (4)	14 Apr 2021 19:23:00
User entered empty.	Samantha Wieseler (b) (4)	13 Apr 2021 17:40:20

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[Evidence of Shock Requires
Vasopressors](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:52:05
User signature succeeded.	Keith Vrbicky (b) (4)	14 Apr 2021 19:23:00
User entered 'No (N)'	Samantha Wieseler (b) (4)	13 Apr 2021 17:40:20

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Folder: Covid-19 Assessment 08 Feb 2021

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Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:52:05
User signature succeeded.	Keith Vrbicky (b) (4)	14 Apr 2021 19:23:00
User entered empty.	Samantha Wieseler (b) (4)	13 Apr 2021 17:40:20

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[End Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:52:05
User signature succeeded.	Keith Vrbicky (b) (4)	14 Apr 2021 19:23:00
User entered empty.	Samantha Wieseler (b) (4)	13 Apr 2021 17:40:20

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[Acute Renal Dysfunction?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:52:05
User signature succeeded.	Keith Vrbicky (b) (4)	14 Apr 2021 19:23:00
User entered 'No (N)'	Samantha Wieseler (b) (4)	13 Apr 2021 17:40:20

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Folder: Covid-19 Assessment 08 Feb 2021

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[Start Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:52:05
User signature succeeded.	Keith Vrbicky (b) (4)	14 Apr 2021 19:23:00
User entered empty.	Samantha Wieseler (b) (4)	13 Apr 2021 17:40:20

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[Hepatic Dysfunction?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:52:05
User signature succeeded.	Keith Vrbicky (b) (4)	14 Apr 2021 19:23:00
User entered 'No (N)'	Samantha Wieseler (b) (4)	13 Apr 2021 17:40:20

US3032249

Folder: Covid-19 Assessment 08 Feb 2021

Form: Covid-19 Severity Assessment

Generated On: 09 Jun 2021 14:53:49

[Start Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:52:05
User signature succeeded.	Keith Vrbicky (b) (4)	14 Apr 2021 19:23:00
User entered empty.	Samantha Wieseler (b) (4)	13 Apr 2021 17:40:20

US3032249

Folder: Covid-19 Assessment 08 Feb 2021

Form: Covid-19 Severity Assessment

Generated On: 09 Jun 2021 14:53:49

[Neurologic Dysfunction?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:52:05
User signature succeeded.	Keith Vrbicky (b) (4)	14 Apr 2021 19:23:00
User entered 'No (N)'	Samantha Wieseler (b) (4)	13 Apr 2021 17:40:20

US3032249

Folder: Covid-19 Assessment 08 Feb 2021

Form: Covid-19 Severity Assessment

Generated On: 09 Jun 2021 14:53:49

[Start Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:52:05
User signature succeeded.	Keith Vrbicky (b) (4)	14 Apr 2021 19:23:00
User entered empty.	Samantha Wieseler (b) (4)	13 Apr 2021 17:40:20

US3032249

Folder: Covid-19 Assessment 08 Feb 2021

Form: Covid-19 Severity Assessment

Generated On: 09 Jun 2021 14:53:49

[Clinical Evidence](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:52:05
User signature succeeded.	Keith Vrbicky (b) (4)	14 Apr 2021 19:23:00
User entered 'Yes (Y)'	(b) (4) Samantha Wieseler (b) (4)	13 Apr 2021 17:40:20

US3032249

Folder: Covid-19 Assessment 08 Feb 2021

Form: Covid-19 Severity Assessment

Generated On: 09 Jun 2021 14:53:49

[Date of Assessment](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:52:05
User signature succeeded.	Keith Vrbicky (b) (4)	14 Apr 2021 19:23:00
User entered '09 Feb 2021'	Samantha Wieseler (b) (4)	13 Apr 2021 17:40:20

US3032249

Folder: Covid-19 Assessment 08 Feb 2021

Form: Covid-19 Severity Assessment

Generated On: 09 Jun 2021 14:53:49

[Radiographical Evidence](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:52:05
User signature succeeded.	Keith Vrbicky (b) (4)	14 Apr 2021 19:23:00
User entered 'No (N)'	(b) (4) Samantha Wieseler (b) (4)	13 Apr 2021 17:40:20

US3032249

Folder: Covid-19 Assessment 08 Feb 2021

Form: Covid-19 Severity Assessment

Generated On: 09 Jun 2021 14:53:49

[Date of Assessment](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:52:05
User signature succeeded.	Keith Vrbicky (b) (4)	14 Apr 2021 19:23:00
User entered empty.	Samantha Wieseler (b) (4)	13 Apr 2021 17:40:20

US3032249

Folder: Covid-19 Assessment 08 Feb 2021

Form: Covid-19 Severity Assessment

Generated On: 09 Jun 2021 14:53:49

[Admission to an intensive care unit due to SARS-CoV-2](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:52:05
User signature succeeded.	Keith Vrbicky (b) (4)	14 Apr 2021 19:23:00
User entered 'No (N)'	Samantha Wieseler (b) (4)	13 Apr 2021 17:40:20

US3032249

Folder: Covid-19 Assessment 08 Feb 2021

Form: Covid-19 Severity Assessment

Generated On: 09 Jun 2021 14:53:49

[Start Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:52:05
User signature succeeded.	Keith Vrbicky (b) (4)	14 Apr 2021 19:23:00
User entered empty.	Samantha Wieseler (b) (4)	13 Apr 2021 17:40:20

US3032249

Folder: Covid-19 Assessment 08 Feb 2021

Form: Covid-19 Severity Assessment

Generated On: 09 Jun 2021 14:53:49

[End Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:52:05
User signature succeeded.	Keith Vrbicky (b) (4)	14 Apr 2021 19:23:00
User entered empty.	Samantha Wieseler (b) (4)	13 Apr 2021 17:40:20

US3032249

Folder: Covid-19 Assessment 08 Feb 2021

Form: Generate Next COVID-19 Assessment

Generated On: 09 Jun 2021 14:53:49

[Generate Next COVID-19 Assessment](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:52:10
User signature succeeded.	Keith Vrbicky (b) (4)	04 Mar 2021 16:04:32
User entered 'No (N)'	Kelsey Kelley (b) (4)	03 Mar 2021 19:48:50

US3032249

Folder: Illness Visit (1)

Form: Saliva Collection (1)

Generated On: 09 Jun 2021 14:53:49

[Visit](#)

Audit	User	Time (GMT)
User accepted default value 'Day 3 (Day 3)'	Kelsey Kelley (b) (4) (b) (4)	23 Mar 2021 15:27:49

US3032249

Folder: Illness Visit (1)

Form: Saliva Collection (1)

Generated On: 09 Jun 2021 14:53:49

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:41:55
User entered 'No (N)'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	23 Mar 2021 15:27:49

US3032249

Folder: Illness Visit (1)

Form: Saliva Collection (1)

Generated On: 09 Jun 2021 14:53:49

[Date of Collection](#)

Audit	User	Time (GMT)
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:41:55
User entered empty.	(b) (4) Kelsey Kelley (b) (4) (b) (4)	23 Mar 2021 15:27:49

US3032249

Folder: Illness Visit (1)

Form: Saliva Collection (2)

Generated On: 09 Jun 2021 14:53:49

[Visit](#)

Audit	User	Time (GMT)
User accepted default value 'Day 5 (Day 5)'	Kelsey Kelley (b) (4) (b) (4)	23 Mar 2021 15:27:49

US3032249

Folder: Illness Visit (1)

Form: Saliva Collection (2)

Generated On: 09 Jun 2021 14:53:49

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:41:55
	(b) (4)	
User entered 'No (N)'	Kelsey Kelley (b) (4)	23 Mar 2021 15:27:49
	(b) (4)	

US3032249

Folder: Illness Visit (1)

Form: Saliva Collection (2)

Generated On: 09 Jun 2021 14:53:49

[Date of Collection](#)

Audit	User	Time (GMT)
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:41:55
User entered empty.	(b) (4) Kelsey Kelley (b) (4) (b) (4)	23 Mar 2021 15:27:49

US3032249

Folder: Illness Visit (1)

Form: Saliva Collection (3)

Generated On: 09 Jun 2021 14:53:49

[Visit](#)

Audit	User	Time (GMT)
User accepted default value 'Day 7 (Day 7)'	Kelsey Kelley (b) (4) (b) (4)	23 Mar 2021 15:27:49

US3032249

Folder: Illness Visit (1)

Form: Saliva Collection (3)

Generated On: 09 Jun 2021 14:53:49

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:41:55
	(b) (4)	
User entered 'No (N)'	Kelsey Kelley (b) (4)	23 Mar 2021 15:27:49
	(b) (4)	

US3032249

Folder: Illness Visit (1)

Form: Saliva Collection (3)

Generated On: 09 Jun 2021 14:53:49

[Date of Collection](#)

Audit	User	Time (GMT)
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:41:55
User entered empty.	(b) (4) Kelsey Kelley (b) (4) (b) (4)	23 Mar 2021 15:27:49

US3032249

Folder: Illness Visit (1)

Form: Saliva Collection (4)

Generated On: 09 Jun 2021 14:53:49

[Visit](#)

Audit	User	Time (GMT)
User accepted default value 'Day 9 (Day 9)'	Kelsey Kelley (b) (4) (b) (4)	23 Mar 2021 15:27:49

US3032249

Folder: Illness Visit (1)

Form: Saliva Collection (4)

Generated On: 09 Jun 2021 14:53:49

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:41:55
User entered 'No (N)'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	23 Mar 2021 15:27:49

US3032249

Folder: Illness Visit (1)

Form: Saliva Collection (4)

Generated On: 09 Jun 2021 14:53:49

[Date of Collection](#)

Audit	User	Time (GMT)
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:41:55
User entered empty.	(b) (4) Kelsey Kelley (b) (4) (b) (4)	23 Mar 2021 15:27:49

US3032249

Folder: Illness Visit (1)

Form: Saliva Collection (5)

Generated On: 09 Jun 2021 14:53:49

[Visit](#)

Audit	User	Time (GMT)
User accepted default value 'Day 14 (Day 14)'	Kelsey Kelley (b) (4) (b) (4)	23 Mar 2021 15:27:49

US3032249

Folder: Illness Visit (1)

Form: Saliva Collection (5)

Generated On: 09 Jun 2021 14:53:49

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:41:55
User entered 'No (N)'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	23 Mar 2021 15:27:49

US3032249

Folder: Illness Visit (1)

Form: Saliva Collection (5)

Generated On: 09 Jun 2021 14:53:49

[Date of Collection](#)

Audit	User	Time (GMT)
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:41:55
	(b) (4)	
User entered empty.	Kelsey Kelley (b) (4)	23 Mar 2021 15:27:49
	(b) (4)	

US3032249

Folder: Illness Visit (1)

Form: Saliva Collection (6)

Generated On: 09 Jun 2021 14:53:49

[Visit](#)

Audit	User	Time (GMT)
User accepted default value 'Day 21 (Day 21)'	Kelsey Kelley (b) (4) (b) (4)	23 Mar 2021 15:27:49

US3032249

Folder: Illness Visit (1)

Form: Saliva Collection (6)

Generated On: 09 Jun 2021 14:53:49

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:41:55
	(b) (4)	
User entered 'No (N)'	Kelsey Kelley (b) (4)	23 Mar 2021 15:27:49
	(b) (4)	

US3032249

Folder: Illness Visit (1)

Form: Saliva Collection (6)

Generated On: 09 Jun 2021 14:53:49

[Date of Collection](#)

Audit	User	Time (GMT)
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:41:55
User entered empty.	(b) (4) Kelsey Kelley (b) (4) (b) (4)	23 Mar 2021 15:27:49

US3032249

Folder: Illness Visit (1)

Form: Saliva Collection (7)

Generated On: 09 Jun 2021 14:53:49

[Visit](#)

Audit	User	Time (GMT)
User closed query 'Per GCL LAB reconciliation: Saliva: PPD reports Day 28 sample with Accession # 1F656937124 is reported with 22MAR2021 Date of Collection however in EDC is marked as No. Please review the Accession # in Preclarus to confirm the correct date and sample label and amend EDC or Preclarus Thank you.' (Site from DM).	(b) (4), (b) (6)	08 Apr 2021 07:03:29
Query 'Per GCL LAB reconciliation: Saliva: PPD reports Day 28 sample with Accession # 1F656937124 is reported with 22MAR2021 Date of Collection however in EDC is marked as No. Please review the Accession # in Preclarus to confirm the correct date and sample label and amend EDC or Preclarus Thank you.' answered with 'Updated ' (Site from DM).	Kelsey Kelley (b) (4) (b) (4)	05 Apr 2021 20:34:20
User opened query 'Per GCL LAB reconciliation: Saliva: PPD reports Day 28 sample with Accession # 1F656937124 is reported with 22MAR2021 Date of Collection however in EDC is marked as No. Please review the Accession # in Preclarus to confirm the correct date and sample label and amend EDC or Preclarus Thank you.' (Site from DM).	(b) (4), (b) (6)	05 Apr 2021 11:11:34
User accepted default value 'Day 28 (Day 28)'	Kelsey Kelley (b) (4) (b) (4)	23 Mar 2021 15:27:49

US3032249

Folder: Illness Visit (1)

Form: Saliva Collection (7)

Generated On: 09 Jun 2021 14:53:49

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:41:55
	(b) (4)	
User entered 'Yes (Y)' reason for change: Data Entry Error	Kelsey Kelley (b) (4)	05 Apr 2021 20:34:11
	(b) (4)	
User entered 'No (N)'	Kelsey Kelley (b) (4)	23 Mar 2021 15:27:49
	(b) (4)	

US3032249

Folder: Illness Visit (1)

Form: Saliva Collection (7)

Generated On: 09 Jun 2021 14:53:49

[Date of Collection](#)

Audit	User	Time (GMT)
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:41:55
	(b) (4)	
User entered '22 Mar 2021' reason for change: Data Entry Error	Kelsey Kelley (b) (4)	05 Apr 2021 20:34:11
	(b) (4)	
User entered empty.	Kelsey Kelley (b) (4)	23 Mar 2021 15:27:49
	(b) (4)	

US3032249

Folder: Illness Visit Day 1 (1)

Form: Visit Date

Generated On: 09 Jun 2021 14:53:49

[Was this visit performed?](#)

Audit	User	Time (GMT)
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:41:55
	(b) (4)	
User entered 'No (N)'	Kelsey Kelley (b) (4)	23 Mar 2021 15:26:15
	(b) (4)	

US3032249

Folder: Illness Visit Day 1 (1)

Form: Visit Date

Generated On: 09 Jun 2021 14:53:49

[Visit date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:41:55
	(b) (4)	
User entered empty.	Kelsey Kelley (b) (4)	23 Mar 2021 15:26:15
	(b) (4)	

US3032249

Folder: Illness Visit Day 1 (1)

Form: Visit Date

Generated On: 09 Jun 2021 14:53:49

[Was visit performed at the participant's home or at the clinic?](#)

Audit	User	Time (GMT)
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:41:55
	(b) (4)	
User entered empty.	Kelsey Kelley (b) (4)	23 Mar 2021 15:26:15
	(b) (4)	

US3032249

Folder: Illness Visit Day 1 (1)

Form: Visit Date

Generated On: 09 Jun 2021 14:53:49

[Folder OID](#)

Audit	User	Time (GMT)
User entered 'SICKD1'	System	23 Mar 2021 15:26:15

US3032249

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 14:53:49

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:41:55
User entered 'No (N)'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	23 Mar 2021 15:26:19

US3032249

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 14:53:49

Date of assessment (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:41:55
User entered empty.	(b) (4) Kelsey Kelley (b) (4) (b) (4)	23 Mar 2021 15:26:19

US3032249

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 14:53:49

Time of assessment (00:00-23:59)

Audit	User	Time (GMT)
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:41:55
User entered empty.	(b) (4) Kelsey Kelley (b) (4) (b) (4)	23 Mar 2021 15:26:19

US3032249

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 14:53:49

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	23 Mar 2021 15:26:19

US3032249

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 14:53:49

[Temperature \(xxx.x\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:41:55
User entered empty.	(b) (4) Kelsey Kelley (b) (4) (b) (4)	23 Mar 2021 15:26:19

US3032249

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 14:53:49

[Route of measurement](#)

Audit	User	Time (GMT)
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:41:55
User entered empty.	(b) (4) Kelsey Kelley (b) (4) (b) (4)	23 Mar 2021 15:26:19

US3032249

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 14:53:49

[If Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:41:55
	(b) (4)	
User entered empty.	Kelsey Kelley (b) (4)	23 Mar 2021 15:26:19
	(b) (4)	

US3032249

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 14:53:49

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:41:55
User entered empty.	(b) (4) Kelsey Kelley (b) (4) (b) (4)	23 Mar 2021 15:26:19

US3032249

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 14:53:49

[Pulse units](#)

Audit	User	Time (GMT)
User entered empty.	System	23 Mar 2021 15:26:19

US3032249

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 14:53:49

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:41:55
User entered empty.	(b) (4) Kelsey Kelley (b) (4) (b) (4)	23 Mar 2021 15:26:19

US3032249

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 14:53:49

[Respiratory Rate units](#)

Audit	User	Time (GMT)
User entered empty.	System	23 Mar 2021 15:26:19

US3032249

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 14:53:49

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:41:55
User entered empty.	(b) (4) Kelsey Kelley (b) (4) (b) (4)	23 Mar 2021 15:26:19

US3032249

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 14:53:49

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered empty.	System	23 Mar 2021 15:26:19

US3032249

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 14:53:49

[Diastolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:41:55
User entered empty.	(b) (4) Kelsey Kelley (b) (4) (b) (4)	23 Mar 2021 15:26:19

US3032249

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 14:53:49

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered empty.	System	23 Mar 2021 15:26:19

US3032249

Folder: Illness Visit Day 1 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 14:53:49

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:41:55
User entered 'No (N)'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	23 Mar 2021 15:26:23

US3032249

Folder: Illness Visit Day 1 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 14:53:49

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:41:55
	(b) (4)	
User entered empty.	Kelsey Kelley (b) (4)	23 Mar 2021 15:26:23
	(b) (4)	

US3032249

Folder: Illness Visit Day 1 (1)

Form: Blood Sample Collection for Immunologic Assessment of SARS-CoV-2 Infection

Generated On: 09 Jun 2021 14:53:49

[Was Blood Sample Taken for Immunologic Assessment of SARS_COV-2 Infection?](#)

Audit	User	Time (GMT)
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:41:55
	(b) (4)	
User entered 'No (N)'	Kelsey Kelley (b) (4)	23 Mar 2021 15:26:28
	(b) (4)	

US3032249

Folder: Illness Visit Day 1 (1)

Form: Blood Sample Collection for Immunologic Assessment of SARS-CoV-2 Infection

Generated On: 09 Jun 2021 14:53:49

[Date of Collection](#)

Audit	User	Time (GMT)
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:41:55
	(b) (4)	
User entered empty.	Kelsey Kelley (b) (4)	23 Mar 2021 15:26:28
	(b) (4)	

US3032249

Folder: Convalescence Visit Day 28 (1)

Form: Visit Date

Generated On: 09 Jun 2021 14:53:49

[Was this visit performed?](#)

Audit	User	Time (GMT)
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:41:17
	(b) (4)	
User entered 'Yes (Y)'	Kelsey Kelley (b) (4)	23 Mar 2021 15:28:32
	(b) (4)	

US3032249

Folder: Convalescence Visit Day 28 (1)

Form: Visit Date

Generated On: 09 Jun 2021 14:53:49

[Visit date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:41:17
	(b) (4)	
User closed query 'Data entered is non-conformant. Please correct.' (Site from System).	System	23 Mar 2021 15:28:43
User entered '22 Mar 2021' reason for change: Data Entry Error	Kelsey Kelley (b) (4)	23 Mar 2021 15:28:43
	(b) (4)	
User opened query 'Data entered is non-conformant. Please correct.' (Site from System).	System	23 Mar 2021 15:28:32
User entered '22 Mar 201' (non-conformant).	Kelsey Kelley (b) (4)	23 Mar 2021 15:28:32
	(b) (4)	

US3032249

Folder: Convalescence Visit Day 28 (1)

Form: Visit Date

Generated On: 09 Jun 2021 14:53:49

[Was visit performed at the participant's home or at the clinic?](#)

Audit	User	Time (GMT)
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:41:17
User entered 'Clinic (Clinic)'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	23 Mar 2021 15:28:32

US3032249

Folder: Convalescence Visit Day 28 (1)

Form: Visit Date

Generated On: 09 Jun 2021 14:53:49

[Folder OID](#)

Audit	User	Time (GMT)
User entered 'SICKD28'	System	23 Mar 2021 15:28:32

US3032249

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 14:53:49

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:41:55
User entered 'Yes (Y)'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	23 Mar 2021 15:30:02

US3032249

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 14:53:49

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:41:55
User entered '22 Mar 2021'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	23 Mar 2021 15:30:02

US3032249

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 14:53:49

Time of assessment (00:00-23:59)

Audit	User	Time (GMT)
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:41:55
User entered '16:49'	(b) (4) Kelsey Kelley (b) (4)	23 Mar 2021 15:30:02
	(b) (4)	

US3032249

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 14:53:49

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered '22 Mar 2021 16:49'	System	23 Mar 2021 15:30:02

US3032249

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 14:53:49

[Height \(xxx.x\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:41:55
	(b) (4)	
User entered '160.67' cm	Kelsey Kelley (b) (4)	23 Mar 2021 15:30:02
	(b) (4)	
DataPoint set to visible.	System	23 Mar 2021 15:28:32

US3032249

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 14:53:49

[Weight \(xxx.x\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:41:55
	(b) (4)	
User entered '93.44' kg	Kelsey Kelley (b) (4)	23 Mar 2021 15:30:02
	(b) (4)	
DataPoint set to visible.	System	23 Mar 2021 15:28:32

US3032249

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 14:53:49

[Temperature \(xxx.x\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:41:55
	(b) (4)	
User entered '36.7' C	Kelsey Kelley (b) (4)	23 Mar 2021 15:30:02
	(b) (4)	

US3032249

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 14:53:49

[Route of measurement](#)

Audit	User	Time (GMT)
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:41:55
User entered 'Oral (Oral)'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	23 Mar 2021 15:30:02

US3032249

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 14:53:49

[If Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:41:55
	(b) (4)	
User entered empty.	Kelsey Kelley (b) (4)	23 Mar 2021 15:30:02
	(b) (4)	

US3032249

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 14:53:49

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:41:55
	(b) (4)	
User entered '77'	Kelsey Kelley (b) (4)	23 Mar 2021 15:30:02
	(b) (4)	

US3032249

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 14:53:49

[Pulse units](#)

Audit	User	Time (GMT)
User entered 'bpm'	System	23 Mar 2021 15:30:02

US3032249

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 14:53:49

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:41:55
User entered '18'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	23 Mar 2021 15:30:02

US3032249

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 14:53:49

[Respiratory Rate units](#)

Audit	User	Time (GMT)
User entered 'breaths/min'	System	23 Mar 2021 15:30:02

US3032249

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 14:53:49

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:41:55
User entered '121'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	23 Mar 2021 15:30:02

US3032249

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 14:53:49

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	23 Mar 2021 15:30:02

US3032249

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 14:53:49

[Diastolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:41:55
User entered '67'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	23 Mar 2021 15:30:02

US3032249

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 14:53:49

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	23 Mar 2021 15:30:02

US3032249

Folder: Convalescence Visit Day 28 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 14:53:49

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:41:17
	(b) (4)	
User entered 'Yes (Y)'	Kelsey Kelley (b) (4)	23 Mar 2021 15:30:38
	(b) (4)	

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Folder: Convalescence Visit Day 28 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 14:53:49

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:41:17
	(b) (4)	
User entered '22 Mar 2021'	Kelsey Kelley (b) (4)	23 Mar 2021 15:30:38
	(b) (4)	

US3032249

Folder: Convalescence Visit Day 28 (1)

Form: Blood Sample Collection for Immunologic Assessment of SARS-CoV-2 Infection

Generated On: 09 Jun 2021 14:53:49

[Was Blood Sample Taken for Immunologic Assessment of SARS_COV-2 Infection?](#)

Audit	User	Time (GMT)
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:41:17
	(b) (4)	
User entered 'Yes (Y)'	Kelsey Kelley (b) (4)	23 Mar 2021 15:31:03
	(b) (4)	

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Folder: Convalescence Visit Day 28 (1)

Form: Blood Sample Collection for Immunologic Assessment of SARS-CoV-2 Infection

Generated On: 09 Jun 2021 14:53:49

[Date of Collection](#)

Audit	User	Time (GMT)
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:41:17
User entered '22 Mar 2021'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	23 Mar 2021 15:31:03

US3032249

Folder: Participant Decision Visit / OL-D1 (1)

Form: Visit Date

Generated On: 09 Jun 2021 14:53:49

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:40:23
DataPoint Verified.		25 Feb 2021 01:48:16
User signature succeeded.	Keith Vrbicky (b) (4)	30 Jan 2021 16:52:32
User entered 'Yes (Y)'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	28 Jan 2021 19:02:05

US3032249

Folder: Participant Decision Visit / OL-D1 (1)

Form: Visit Date

Generated On: 09 Jun 2021 14:53:49

[Visit date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:40:23
DataPoint Verified.		25 Feb 2021 01:48:16
User signature succeeded.	Keith Vrbicky (b) (4)	30 Jan 2021 16:52:32
User entered '28 Jan 2021'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	28 Jan 2021 19:02:05

US3032249

Folder: Participant Decision Visit / OL-D1 (1)

Form: Visit Date

Generated On: 09 Jun 2021 14:53:49

[Was visit performed at the participant's home or at the clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:40:23
DataPoint Verified.		25 Feb 2021 01:48:16
User signature succeeded.	Keith Vrbicky (b) (4)	30 Jan 2021 16:52:32
User entered 'Clinic (Clinic)'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	28 Jan 2021 19:02:05

US3032249

Folder: Participant Decision Visit / OL-D1 (1)

Form: Visit Date

Generated On: 09 Jun 2021 14:53:49

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:40:23
User entered 'UNBLND_DECIDE'	System	28 Jan 2021 19:02:05

US3032249

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 09 Jun 2021 14:53:49

[Date of updated informed consent \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:40:23
DataPoint Verified.		25 Feb 2021 01:48:39
User signature succeeded.	Keith Vrbicky (b) (4)	30 Jan 2021 16:52:32
User entered '28 Jan 2021'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	28 Jan 2021 19:02:34

US3032249

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 09 Jun 2021 14:53:49

[N/A - Subject Unblinded under Amendment 5 and Discontinued from Study](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:40:23
User signature succeeded.	Keith Vrbicky (b) (4)	18 Mar 2021 21:21:02
User entered '0'	(b) (4) Linden DeBoer (b) (4)	15 Mar 2021 23:35:37
Amendment Manager inserted this DataPoint.	(b) (4) System	06 Mar 2021 13:11:31

US3032249

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 09 Jun 2021 14:53:49

[Was the participant unblinded?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:40:23
DataPoint Verified.		25 Feb 2021 01:48:39
User signature succeeded.	Keith Vrbicky (b) (4)	30 Jan 2021 16:52:32
User entered 'Yes (Y)'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	28 Jan 2021 19:02:34

US3032249

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 09 Jun 2021 14:53:49

[Under what version of the Protocol was the Participant unblinded?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:40:23
User signature succeeded.	Keith Vrbicky (b) (4)	18 Mar 2021 21:21:02
User entered 'Amendment 6 or later (Amendment 6 or later)'	(b) (4)	
	Linden DeBoer (b) (4)	15 Mar 2021 23:35:37
Amendment Manager inserted this DataPoint.	(b) (4)	
	System	06 Mar 2021 13:11:31

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Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 09 Jun 2021 14:53:49

Date of unblinding (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:40:23
DataPoint Verified.		25 Feb 2021 01:48:39
User signature succeeded.	Keith Vrbicky (b) (4)	30 Jan 2021 16:52:32
User entered '28 Jan 2021'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	28 Jan 2021 19:02:34

US3032249

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 09 Jun 2021 14:53:49

[Participant randomization assignment](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:40:23
DataPoint Verified.		25 Feb 2021 01:48:39
User signature succeeded.	Keith Vrbicky (b) (4)	30 Jan 2021 16:52:32
User entered 'Placebo (Placebo)'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	28 Jan 2021 19:02:34

US3032249

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 09 Jun 2021 14:53:49

[Actual Dose 1](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:40:23
DataPoint Verified.		25 Feb 2021 01:48:39
User signature succeeded.	Keith Vrbicky (b) (4)	30 Jan 2021 16:52:32
User entered 'Placebo (Placebo)'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	28 Jan 2021 19:02:34

US3032249

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 09 Jun 2021 14:53:49

[Actual Dose 2](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:40:23
DataPoint Verified.		25 Feb 2021 01:48:39
User signature succeeded.	Keith Vrbicky (b) (4)	30 Jan 2021 16:52:32
User entered 'Placebo (Placebo)'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	28 Jan 2021 19:02:34

US3032249

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 09 Jun 2021 14:53:49

[Will participant receive mRNA-1273?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:40:23
DataPoint Verified.		25 Feb 2021 01:48:39
User signature succeeded.	Keith Vrbicky (b) (4)	30 Jan 2021 16:52:32
User entered 'Yes (Y)'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	28 Jan 2021 19:02:34

US3032249

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 09 Jun 2021 14:53:49

[Placebo Only Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:40:23
User entered '1'	System	28 Jan 2021 19:02:34

US3032249

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 09 Jun 2021 14:53:49

[Continuing with mRNA-1273](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:40:23
User entered 'I'	System	28 Jan 2021 19:02:34

US3032249

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 14:53:49

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:40:23
DataPoint Verified.		25 Feb 2021 01:49:55
User signature succeeded.	Keith Vrbicky (b) (4)	30 Jan 2021 16:52:32
User entered missing code ND - Not Done.	(b) (4) Kelsey Kelley (b) (4) (b) (4)	28 Jan 2021 19:03:33

US3032249

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 14:53:49

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:40:23
DataPoint Verified.		25 Feb 2021 01:49:55
User signature succeeded.	Keith Vrbicky (b) (4)	30 Jan 2021 16:52:32
User entered missing code ND - Not Done.	(b) (4) Kelsey Kelley (b) (4) (b) (4)	28 Jan 2021 19:03:33

US3032249

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 14:53:49

[BMI \(xxx.x\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:40:23
User entered empty.	System	28 Jan 2021 19:03:33
DataPoint set to visible.	System	28 Jan 2021 19:02:34

US3032249

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 14:53:49

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:40:23
DataPoint Verified.		25 Feb 2021 01:49:55
User signature succeeded.	Keith Vrbicky (b) (4)	30 Jan 2021 16:52:32
User entered missing code ND - Not Done.	(b) (4) Kelsey Kelley (b) (4) (b) (4)	28 Jan 2021 19:03:33

US3032249

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 14:53:49

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:40:23
DataPoint Verified.		25 Feb 2021 01:49:55
User signature succeeded.	Keith Vrbicky (b) (4)	30 Jan 2021 16:52:32
User entered missing code ND - Not Done.	(b) (4) Kelsey Kelley (b) (4) (b) (4)	28 Jan 2021 19:03:33

US3032249

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 14:53:49

[BMI \(xxx.x\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:40:23
User entered empty.	System	28 Jan 2021 19:03:33
DataPoint set to visible.	System	28 Jan 2021 19:02:34

US3032249

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:53:49

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:40:23
User accepted default value 'Pre-Dose (PREDOSE)'	Kelsey Kelley (b) (4) (b) (4)	28 Jan 2021 19:05:01

US3032249

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:53:49

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:40:23
DataPoint Verified.		25 Feb 2021 01:49:55
User signature succeeded.	Keith Vrbicky (b) (4)	30 Jan 2021 16:52:32
User entered 'Yes (Y)'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	28 Jan 2021 19:05:01

US3032249

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:53:49

Date of assessment (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:40:23
DataPoint Verified.		25 Feb 2021 01:49:55
User signature succeeded.	Keith Vrbicky (b) (4)	30 Jan 2021 16:52:32
User entered '28 Jan 2021'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	28 Jan 2021 19:05:01

US3032249

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:53:49

[Time of assessment \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:40:23
DataPoint Verified.		25 Feb 2021 01:49:55
User signature succeeded.	Keith Vrbicky (b) (4)	30 Jan 2021 16:52:32
User entered '10:29'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	28 Jan 2021 19:05:01

US3032249

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:53:49

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:40:23
User entered '28 Jan 2021 10:29'	System	28 Jan 2021 19:05:01

US3032249

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:53:49

[Temperature \(xxx.x\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:40:23
DataPoint Verified.		25 Feb 2021 01:49:55
User signature succeeded.	Keith Vrbicky (b) (4)	30 Jan 2021 16:52:32
User entered '36.9' C	(b) (4) Kelsey Kelley (b) (4) (b) (4)	28 Jan 2021 19:05:01

US3032249

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:53:49

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:40:23
DataPoint Verified.		25 Feb 2021 01:49:55
User signature succeeded.	Keith Vrbicky (b) (4)	30 Jan 2021 16:52:32
User entered 'Oral (Oral)'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	28 Jan 2021 19:05:01

US3032249

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:53:49

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:40:23
DataPoint Verified.		25 Feb 2021 01:49:55
User signature succeeded.	Keith Vrbicky (b) (4)	30 Jan 2021 16:52:32
User entered empty.	(b) (4) Kelsey Kelley (b) (4) (b) (4)	28 Jan 2021 19:05:01

US3032249

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:53:49

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:40:23
DataPoint Verified.		25 Feb 2021 01:49:55
User signature succeeded.	Keith Vrbicky (b) (4)	30 Jan 2021 16:52:32
User entered '72'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	28 Jan 2021 19:05:01

US3032249

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:53:49

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:40:23
User entered 'bpm'	System	28 Jan 2021 19:05:01

US3032249

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:53:49

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:40:23
DataPoint Verified.		25 Feb 2021 01:49:55
User signature succeeded.	Keith Vrbicky (b) (4)	30 Jan 2021 16:52:32
User entered '16'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	28 Jan 2021 19:05:01

US3032249

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:53:49

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:40:23
User entered 'breaths/min'	System	28 Jan 2021 19:05:01

US3032249

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:53:49

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:40:23
DataPoint Verified.		25 Feb 2021 01:49:55
User signature succeeded.	Keith Vrbicky (b) (4)	30 Jan 2021 16:52:32
User entered '135'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	28 Jan 2021 19:05:01

US3032249

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:53:49

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:40:23
User entered 'mmHg'	System	28 Jan 2021 19:05:01

US3032249

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:53:49

[Diastolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:40:23
DataPoint Verified.		25 Feb 2021 01:49:55
User signature succeeded.	Keith Vrbicky (b) (4)	30 Jan 2021 16:52:32
User entered '69'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	28 Jan 2021 19:05:01

US3032249

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:53:49

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:40:23
User entered 'mmHg'	System	28 Jan 2021 19:05:01

US3032249

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 14:53:49

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:40:23
DataPoint Verified.		25 Feb 2021 01:49:55
User signature succeeded.	Keith Vrbicky (b) (4)	30 Jan 2021 16:52:32
User entered missing code ND - Not Done.	(b) (4) Kelsey Kelley (b) (4) (b) (4)	28 Jan 2021 19:03:33

US3032249

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 14:53:49

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:40:23
DataPoint Verified.		25 Feb 2021 01:49:55
User signature succeeded.	Keith Vrbicky (b) (4)	30 Jan 2021 16:52:32
User entered missing code ND - Not Done.	(b) (4) Kelsey Kelley (b) (4) (b) (4)	28 Jan 2021 19:03:33

US3032249

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 14:53:49

BMI (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:40:23
User entered empty.	System	28 Jan 2021 19:03:33
DataPoint set to visible.	System	28 Jan 2021 19:02:34

US3032249

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:53:49

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:40:23
User accepted default value 'Post-Dose (POSTDOSE)'	Kelsey Kelley (b) (4) (b) (4)	28 Jan 2021 19:03:33

US3032249

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:53:49

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:40:23
DataPoint Verified.		25 Feb 2021 01:49:55
User signature succeeded.	Keith Vrbicky (b) (4)	30 Jan 2021 16:52:32
User entered 'Yes (Y)'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	28 Jan 2021 19:03:33

US3032249

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:53:49

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:40:23
DataPoint Verified.		25 Feb 2021 01:49:55
User signature succeeded.	Keith Vrbicky (b) (4)	30 Jan 2021 16:52:32
User entered '28 Jan 2021'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	28 Jan 2021 19:03:33

US3032249

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:53:49

[Time of assessment \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:40:23
DataPoint Verified.		25 Feb 2021 01:49:55
User signature succeeded.	Keith Vrbicky (b) (4)	30 Jan 2021 16:52:32
User entered '11:41'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	28 Jan 2021 19:03:33

US3032249

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:53:49

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:40:23
User entered '28 Jan 2021 11:41'	System	28 Jan 2021 19:03:33

US3032249

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:53:49

[Temperature \(xxx.x\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:40:23
DataPoint Verified.		25 Feb 2021 01:49:55
User signature succeeded.	Keith Vrbicky (b) (4)	30 Jan 2021 16:52:32
User entered '36.5' C	(b) (4) Kelsey Kelley (b) (4) (b) (4)	28 Jan 2021 19:03:33

US3032249

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:53:49

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:40:23
DataPoint Verified.		25 Feb 2021 01:49:55
User signature succeeded.	Keith Vrbicky (b) (4)	30 Jan 2021 16:52:32
User entered 'Oral (Oral)'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	28 Jan 2021 19:03:33

US3032249

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:53:49

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:40:23
DataPoint Verified.		25 Feb 2021 01:49:55
User signature succeeded.	Keith Vrbicky (b) (4)	30 Jan 2021 16:52:32
User entered empty.	(b) (4) Kelsey Kelley (b) (4) (b) (4)	28 Jan 2021 19:03:33

US3032249

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:53:49

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:40:23
DataPoint Verified.		25 Feb 2021 01:49:55
User signature succeeded.	Keith Vrbicky (b) (4)	30 Jan 2021 16:52:32
User entered '71'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	28 Jan 2021 19:03:33

US3032249

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:53:49

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:40:23
User entered 'bpm'	System	28 Jan 2021 19:03:33

US3032249

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:53:49

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:40:23
DataPoint Verified.		25 Feb 2021 01:49:55
User signature succeeded.	Keith Vrbicky (b) (4)	30 Jan 2021 16:52:32
User entered '14'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	28 Jan 2021 19:03:33

US3032249

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:53:49

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:40:23
User entered 'breaths/min'	System	28 Jan 2021 19:03:33

US3032249

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:53:49

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:40:23
DataPoint Verified.		25 Feb 2021 01:49:55
User signature succeeded.	Keith Vrbicky (b) (4)	30 Jan 2021 16:52:32
User entered '118'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	28 Jan 2021 19:03:33

US3032249

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:53:49

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:40:23
User entered 'mmHg'	System	28 Jan 2021 19:03:33

US3032249

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:53:49

[Diastolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:40:23
DataPoint Verified.		25 Feb 2021 01:49:55
User signature succeeded.	Keith Vrbicky (b) (4)	30 Jan 2021 16:52:32
User entered '66'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	28 Jan 2021 19:03:33

US3032249

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:53:49

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:40:23
User entered 'mmHg'	System	28 Jan 2021 19:03:33

US3032249

Folder: Participant Decision Visit / OL-D1 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 14:53:49

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:40:23
DataPoint Verified.		25 Feb 2021 01:50:26
User signature succeeded.	Keith Vrbicky (b) (4)	30 Jan 2021 16:52:32
User entered 'Yes (Y)'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	28 Jan 2021 19:03:08

US3032249

Folder: Participant Decision Visit / OL-D1 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 14:53:49

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:40:23
DataPoint Verified.		25 Feb 2021 01:50:26
User signature succeeded.	Keith Vrbicky (b) (4)	30 Jan 2021 16:52:32
User entered '28 Jan 2021'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	28 Jan 2021 19:03:08

US3032249

Folder: Participant Decision Visit / OL-D1 (1)

Form: Exposure

Generated On: 09 Jun 2021 14:53:49

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:40:23
DataPoint Verified.		25 Feb 2021 01:50:36
User signature succeeded.	Keith Vrbicky (b) (4)	30 Jan 2021 16:52:32
User entered 'Yes (Y)'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	28 Jan 2021 19:04:34

US3032249

Folder: Participant Decision Visit / OL-D1 (1)

Form: Exposure

Generated On: 09 Jun 2021 14:53:49

[If No, reason not given](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:40:23
DataPoint Verified.		25 Feb 2021 01:50:36
User signature succeeded.	Keith Vrbicky (b) (4)	30 Jan 2021 16:52:32
User entered empty.	(b) (4) Kelsey Kelley (b) (4) (b) (4)	28 Jan 2021 19:04:34

US3032249

Folder: Participant Decision Visit / OL-D1 (1)

Form: Exposure

Generated On: 09 Jun 2021 14:53:49

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)	27 Apr 2021 15:40:23
DataPoint Verified.		25 Feb 2021 01:50:36
User signature succeeded.	Keith Vrbicky (b) (4)	30 Jan 2021 16:52:32
User entered empty.	(b) (4) Kelsey Kelley (b) (4) (b) (4)	28 Jan 2021 19:04:34

US3032249

Folder: Participant Decision Visit / OL-D1 (1)

Form: Exposure

Generated On: 09 Jun 2021 14:53:49

[What was the study treatment? \(Unblinded\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:40:23
User entered 'mRNA-1273'	System	28 Jan 2021 19:04:34
DataPoint set to visible.	System	28 Jan 2021 19:02:34

US3032249

Folder: Participant Decision Visit / OL-D1 (1)

Form: Exposure

Generated On: 09 Jun 2021 14:53:49

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:40:23
DataPoint Verified.	(b) (4), (b) (6)	25 Feb 2021 01:50:36
User signature succeeded.	Keith Vrbicky (b) (4)	30 Jan 2021 16:52:32
User entered '28 Jan 2021'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	28 Jan 2021 19:04:34

US3032249

Folder: Participant Decision Visit / OL-D1 (1)

Form: Exposure

Generated On: 09 Jun 2021 14:53:49

[What was the treatment time? \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:40:23
DataPoint Verified.	(b) (4), (b) (6)	25 Feb 2021 01:50:36
User signature succeeded.	Keith Vrbicky (b) (4)	30 Jan 2021 16:52:32
User entered '11:09'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	28 Jan 2021 19:04:34

US3032249

Folder: Participant Decision Visit / OL-D1 (1)

Form: Exposure

Generated On: 09 Jun 2021 14:53:49

[Treatment Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:40:23
User entered '28 Jan 2021 11:09'	System	28 Jan 2021 19:04:34

US3032249

Folder: Participant Decision Visit / OL-D1 (1)

Form: Exposure

Generated On: 09 Jun 2021 14:53:49

[Which arm was used to give treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:40:23
DataPoint Verified.	(b) (4), (b) (6)	25 Feb 2021 01:50:36
User signature succeeded.	Keith Vrbicky (b) (4)	30 Jan 2021 16:52:32
User entered 'Left Arm (LEFT ARM)'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	28 Jan 2021 19:04:34

US3032249

Folder: Participant Decision Visit / OL-D1 (1)

Form: Exposure

Generated On: 09 Jun 2021 14:53:49

[What was the frequency of the study treatment dosing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:40:23
DataPoint Verified.	(b) (4), (b) (6)	25 Feb 2021 01:50:36
User entered 'ONCE'	System	28 Jan 2021 19:04:34

US3032249

Folder: Participant Decision Visit / OL-D1 (1)

Form: Exposure

Generated On: 09 Jun 2021 14:53:49

[What was the route of administration for the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:40:23
User entered 'INTRAMUSCULAR'	System	28 Jan 2021 19:04:34

US3032249

Folder: Participant Decision Visit / OL-D1 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 14:53:49

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:40:23
DataPoint Verified.		25 Feb 2021 01:50:51
User closed query 'Per GCL Lab Reconciliation: Immunogenicity Assessment: Per GCL, no immunogenicity sample was received for the Patient Decision Visit / OL-D1 on 28JAN2021. Please clarify if sample was shipped and provide the accession number and tracking detail in the query response box, as appropriate. ' (Site from DM).		23 Feb 2021 16:34:46
Query 'Per GCL Lab Reconciliation: Immunogenicity Assessment: Per GCL, no immunogenicity sample was received for the Patient Decision Visit / OL-D1 on 28JAN2021. Please clarify if sample was shipped and provide the accession number and tracking detail in the query response box, as appropriate. ' answered with 'received 10feb' (Site from DM).	Samantha Wieseler (b) (4)	11 Feb 2021 21:57:34
User opened query 'Per GCL Lab Reconciliation: Immunogenicity Assessment: Per GCL, no immunogenicity sample was received for the Patient Decision Visit / OL-D1 on 28JAN2021. Please clarify if sample was shipped and provide the accession number and tracking detail in the query response box, as appropriate. ' (Site from DM).	(b) (4)	
User signature succeeded.	(b) (4), (b) (6)	11 Feb 2021 13:50:10
User entered 'Yes (Y)'	Keith Vrbicky (b) (4)	30 Jan 2021 16:52:32
	(b) (4)	
	Kelsey Kelley (b) (4)	28 Jan 2021 19:02:44
	(b) (4)	

US3032249

Folder: Participant Decision Visit / OL-D1 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 14:53:49

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:40:23
DataPoint Verified.	(b) (4), (b) (6)	25 Feb 2021 01:50:51
User signature succeeded.	Keith Vrbicky (b) (4)	30 Jan 2021 16:52:32
User entered '28 Jan 2021'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	28 Jan 2021 19:02:44

US3032249

Folder: Participant Decision Visit / OL-D1 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 14:53:49

[Collection time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:40:23
DataPoint Verified.	(b) (4), (b) (6)	25 Feb 2021 01:50:51
User signature succeeded.	Keith Vrbicky (b) (4)	30 Jan 2021 16:52:32
User entered '10:14'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	28 Jan 2021 19:02:44

US3032249

Folder: Participant Decision Visit / OL-D1 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 14:53:49

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:40:23
User entered '28 Jan 2021 10:14'	System	28 Jan 2021 19:02:44

US3032249

Folder: Participant Decision Visit / OL-D1 (1)

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 09 Jun 2021 14:53:49

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:40:23
DataPoint Verified.	(b) (4), (b) (6)	25 Feb 2021 01:51:09
User signature succeeded.	Keith Vrbicky (b) (4)	30 Jan 2021 16:52:32
User entered 'Yes (Y)'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	28 Jan 2021 19:02:53

US3032249

Folder: Participant Decision Visit / OL-D1 (1)

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 09 Jun 2021 14:53:49

[Collection date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:40:23
DataPoint Verified.	(b) (4), (b) (6)	25 Feb 2021 01:51:09
User signature succeeded.	Keith Vrbicky (b) (4)	30 Jan 2021 16:52:32
User entered '28 Jan 2021'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	28 Jan 2021 19:02:53

US3032249

Folder: Participant Decision Visit / OL-D1 (1)

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 09 Jun 2021 14:53:49

[Collection time \(00:00 - 23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:40:23
DataPoint Verified.	(b) (4), (b) (6)	25 Feb 2021 01:51:09
User signature succeeded.	Keith Vrbicky (b) (4)	30 Jan 2021 16:52:32
User entered '10:19'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	28 Jan 2021 19:02:53

US3032249

Folder: Participant Decision Visit / OL-D1 (1)

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 09 Jun 2021 14:53:49

[Collection Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:40:23
User entered '28 Jan 2021 10:19'	System	28 Jan 2021 19:02:53

US3032249

Folder: Participant Decision Visit / OL-D1 (1)

Form: Continuing

Generated On: 09 Jun 2021 14:53:49

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:40:23
DataPoint Verified.	(b) (4), (b) (6)	25 Feb 2021 01:51:13
User signature succeeded.	Keith Vrbicky (b) (4)	30 Jan 2021 16:52:32
User entered 'Yes (Y)'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	28 Jan 2021 19:02:56

US3032249

Folder: Participant Decision Visit / OL-D1 (1)

Form: Continuing

Generated On: 09 Jun 2021 14:53:49

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:40:23
User entered 'I'	System	28 Jan 2021 19:02:56

US3032249

Folder: Safety Call OL-D8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 14:53:49

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 04:17:18
User signature succeeded.	Keith Vrbicky (b) (4)	18 Mar 2021 21:21:02
User entered 'Yes (Y)'	Linden DeBoer (b) (4)	15 Mar 2021 23:37:33

US3032249

Folder: Safety Call OL-D8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 14:53:49

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 04:17:18
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:41:55
User closed query 'OL Safety Call Day 8 'Date of Contact or Contact Attempt' is less than 7 days or greater than 10 days after Participant Decision Treatment Date on the Exposure Form. Please review and reconcile, or clarify.' (Site from System).	(b) (4) (b) (4), (b) (6)	24 Mar 2021 01:18:09
Query 'OL Safety Call Day 8 'Date of Contact or Contact Attempt' is less than 7 days or greater than 10 days after Participant Decision Treatment Date on the Exposure Form. Please review and reconcile, or clarify.' answered with 'call completed OOW' (Site from System).	Chelsie Nutsch (b) (4) (b) (4)	19 Mar 2021 19:33:31
User opened query 'OL Safety Call Day 8 'Date of Contact or Contact Attempt' is less than 7 days or greater than 10 days after Participant Decision Treatment Date on the Exposure Form. Please review and reconcile, or clarify.' (Site from System).	System	19 Mar 2021 19:32:53
Signature has been broken.	Chelsie Nutsch (b) (4) (b) (4)	19 Mar 2021 19:32:53
User entered '08 Feb 2021' reason for change: Data Entry Error	Chelsie Nutsch (b) (4) (b) (4)	19 Mar 2021 19:32:53
User signature succeeded.	Keith Vrbicky (b) (4) (b) (4)	18 Mar 2021 21:21:02
User entered '4 Feb 2021'	Linden DeBoer (b) (4) (b) (4)	15 Mar 2021 23:37:33

US3032249

Folder: Safety Call OL-D8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 14:53:49

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 04:17:18
User signature succeeded.	Keith Vrbicky (b) (4)	18 Mar 2021 21:21:02
User entered 'Contact Made (CONTACT MADE)'	Linden DeBoer (b) (4)	15 Mar 2021 23:37:33

US3032249

Folder: Safety Call OL-D8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 14:53:49

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 04:17:18
User signature succeeded.	Keith Vrbicky (b) (4)	18 Mar 2021 21:21:02
User entered empty.	(b) (4)	
	Linden DeBoer (b) (4)	15 Mar 2021 23:37:33
	(b) (4)	

US3032249

Folder: Safety Call OL-D8 (1)

Form: Continuing

Generated On: 09 Jun 2021 14:53:49

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 04:17:18
User signature succeeded.	Keith Vrbicky (b) (4)	18 Mar 2021 21:21:02
User entered 'Yes (Y)'	Linden DeBoer (b) (4)	15 Mar 2021 23:37:40

US3032249

Folder: Safety Call OL-D8 (1)

Form: Continuing

Generated On: 09 Jun 2021 14:53:49

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 04:17:18
User entered 'I'	System	15 Mar 2021 23:37:40

US3032249

Folder: Safety Call OL-D8 (1)

Form: Continuing

Generated On: 09 Jun 2021 14:53:49

[OLD29 Placebo Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 04:17:18
User entered '1'	System	15 Mar 2021 23:37:40
DataPoint set to visible.	System	15 Mar 2021 23:37:40

US3032249

Folder: OL-D29 (1)

Form: Exposure

Generated On: 09 Jun 2021 14:53:49

[What was the study treatment? \(Unblinded\)](#)

Audit	User	Time (GMT)
DataPoint set to visible.	System	15 Mar 2021 23:37:40

US3032249

Folder: Adverse Events

Form: Adverse Events Summary

Generated On: 09 Jun 2021 14:53:49

[Did the participant experience any adverse events?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 06:09:06
DataPoint Verified.	(b) (4), (b) (6)	23 Feb 2021 20:38:14
User signature succeeded.	Keith Vrbicky (b) (4)	12 Feb 2021 19:56:47
User entered 'Yes (Y)'	(b) (4) Linden DeBoer (b) (4) (b) (4)	11 Feb 2021 18:09:16

US3032249

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 14:53:49

[AEID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Feb 2021 20:38:25
User signature succeeded.	Keith Vrbicky (b) (4)	12 Feb 2021 19:56:47
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	12 Feb 2021 13:29:09
User entered 'USA-US032-2021-mRNA-1273-P301000008'	System	12 Feb 2021 13:29:02
User entered 'New'	(b) (4), (b) (6)	12 Feb 2021 13:29:02

US3032249

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 14:53:49

[Adverse event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Feb 2021 20:38:25
User signature succeeded.	Keith Vrbicky (b) (4)	12 Feb 2021 19:56:47
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)	11 Feb 2021 18:19:55
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	11 Feb 2021 18:19:55
Data point term sent to Coder	System	11 Feb 2021 18:19:35
User entered 'Covid-19'	Linden DeBoer (b) (4)	11 Feb 2021 18:18:46

US3032249

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 14:53:49

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Feb 2021 20:38:25
User signature succeeded.	Keith Vrbicky (b) (4)	12 Feb 2021 19:56:47
User entered 'Yes (Y)'	(b) (4)	
	Linden DeBoer (b) (4)	11 Feb 2021 18:18:46
	(b) (4)	

US3032249

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 14:53:49

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Feb 2021 20:38:25
User signature succeeded.	Keith Vrbicky (b) (4)	12 Feb 2021 19:56:47
User entered 'No (N)'	(b) (4) Linden DeBoer (b) (4)	11 Feb 2021 18:18:46
	(b) (4)	

US3032249

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 14:53:49

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Feb 2021 20:38:25
User signature succeeded.	Keith Vrbicky (b) (4)	12 Feb 2021 19:56:47
User entered 'Yes (Y)'	(b) (4) Linden DeBoer (b) (4)	11 Feb 2021 18:18:46
	(b) (4)	

US3032249

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 14:53:49

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Feb 2021 20:38:25
User signature succeeded.	Keith Vrbicky (b) (4)	12 Feb 2021 19:56:47
User entered '2 Feb 2021'	(b) (4)	
	Linden DeBoer (b) (4)	11 Feb 2021 18:18:46
	(b) (4)	

US3032249

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 14:53:49

[Start time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Feb 2021 20:38:25
User signature succeeded.	Keith Vrbicky (b) (4)	12 Feb 2021 19:56:47
User entered empty.	(b) (4)	
	Linden DeBoer (b) (4)	11 Feb 2021 18:18:46
	(b) (4)	

US3032249

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 14:53:49

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	11 Feb 2021 18:18:46

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 14:53:49

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:41:17
	(b) (4)	
DataPoint Un-verified.	Kelsey Kelley (b) (4)	03 Mar 2021 19:43:06
	(b) (4)	
Signature has been broken.	Kelsey Kelley (b) (4)	03 Mar 2021 19:43:06
	(b) (4)	
User entered 'No (N)' reason for change: New Information	Kelsey Kelley (b) (4)	03 Mar 2021 19:43:06
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	23 Feb 2021 20:38:25
User signature succeeded.	Keith Vrbicky (b) (4)	12 Feb 2021 19:56:47
	(b) (4)	
User entered 'Yes (Y)'	Linden DeBoer (b) (4)	11 Feb 2021 18:18:46
	(b) (4)	

US3032249

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 14:53:49

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:41:17
User closed query 'PV Query: Please provide the event end date (recovered, returned to baseline, or, in the investigator's opinion, a new baseline has been achieved), when available.' (Site from Safety).	(b) (4) (b) (4), (b) (6)	04 Mar 2021 14:39:56
Query 'PV Query: Please provide the event end date (recovered, returned to baseline, or, in the investigator's opinion, a new baseline has been achieved), when available.' answered with 'Updated end date' (Site from Safety).	Kelsey Kelley (b) (4) (b) (4)	03 Mar 2021 19:43:23
DataPoint Un-verified.	Kelsey Kelley (b) (4) (b) (4)	03 Mar 2021 19:43:06
Signature has been broken.	Kelsey Kelley (b) (4) (b) (4)	03 Mar 2021 19:43:06
User entered '1 Mar 2021' reason for change: New Information	Kelsey Kelley (b) (4) (b) (4)	03 Mar 2021 19:43:06
DataPoint Verified.	(b) (4), (b) (6)	23 Feb 2021 20:38:25
User opened query 'PV Query: Please provide the event end date (recovered, returned to baseline, or, in the investigator's opinion, a new baseline has been achieved), when available.' (Site from Safety).	(b) (4), (b) (6)	23 Feb 2021 12:06:17
User signature succeeded.	Keith Vrbicky (b) (4) (b) (4)	12 Feb 2021 19:56:47
User entered empty.	Linden DeBoer (b) (4) (b) (4)	11 Feb 2021 18:18:46

US3032249

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 14:53:49

End time (00:00-23:59)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Feb 2021 20:38:25
User closed query 'PV Query: Please provide the event end date (recovered, returned to baseline, or, in the investigator's opinion, a new baseline has been achieved), when available.' (Site from Safety).		22 Feb 2021 22:47:28
Query 'PV Query: Please provide the event end date (recovered, returned to baseline, or, in the investigator's opinion, a new baseline has been achieved), when available.' answered with 'Subject still has symptoms, therefore no end date yet' (Site from Safety).	Kelsey Kelley (b) (4) (b) (4)	20 Feb 2021 14:52:56
User opened query 'PV Query: Please provide the event end date (recovered, returned to baseline, or, in the investigator's opinion, a new baseline has been achieved), when available.' (Site from Safety).	(b) (4), (b) (6)	19 Feb 2021 17:11:07
User signature succeeded.	Keith Vrbicky (b) (4) (b) (4)	12 Feb 2021 19:56:47
User entered empty.	Linden DeBoer (b) (4) (b) (4)	11 Feb 2021 18:18:46

US3032249

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 14:53:49

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	11 Feb 2021 18:18:46

US3032249

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 14:53:49

[Severity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Feb 2021 20:38:25
User signature succeeded.	Keith Vrbicky (b) (4)	12 Feb 2021 19:56:47
User entered 'Grade 3/Severe (Grade 3/Severe)'	Linden DeBoer (b) (4)	11 Feb 2021 18:18:46

US3032249

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 14:53:49

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Feb 2021 20:38:25
User signature succeeded.	Keith Vrbicky (b) (4)	12 Feb 2021 19:56:47
User closed query 'Is the adverse event serious is Yes, but seriousness criteria is missing. Please check at least one criteria from the options below.' (Site from System).	(b) (4) System	11 Feb 2021 18:19:12
User opened query 'Is the adverse event serious is Yes, but seriousness criteria is missing. Please check at least one criteria from the options below.' (Site from System).	System	11 Feb 2021 18:18:46
User entered 'Yes (Y)'	Linden DeBoer (b) (4) (b) (4)	11 Feb 2021 18:18:46

US3032249

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 14:53:49

[Death](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Feb 2021 20:38:25
User signature succeeded.	Keith Vrbicky (b) (4)	12 Feb 2021 19:56:47
User entered '0'	Linden DeBoer (b) (4)	11 Feb 2021 18:18:46

US3032249

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 14:53:49

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Feb 2021 20:38:25
User signature succeeded.	Keith Vrbicky (b) (4)	12 Feb 2021 19:56:47
User entered '0'	(b) (4) Linden DeBoer (b) (4)	11 Feb 2021 18:18:46
	(b) (4)	

US3032249

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 14:53:49

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Feb 2021 20:38:25
User closed query 'Per CDM: Please update the discharge date if the patient is discharged from hospital else clarify.' (Site from DM).	(b) (4), (b) (6)	18 Feb 2021 12:52:53
Query 'Per CDM: Please update the discharge date if the patient is discharged from hospital else clarify.' answered with 'subject is still currently at the hospital' (Site from DM).	Samantha Wieseler (b) (4) (b) (4)	17 Feb 2021 19:52:01
User opened query 'Per CDM: Please update the discharge date if the patient is discharged from hospital else clarify.' (Site from DM).	(b) (4), (b) (6)	15 Feb 2021 18:29:46
User closed query 'Requires inpatient or prolongation of existing Hospitalization is checked, however Hospital Admission Date, Hospital Discharge Date, or Admitted to ICU? is missing. Please review and reconcile.' (Site from System).	(b) (4), (b) (6)	15 Feb 2021 18:28:37
User signature succeeded.	Keith Vrbicky (b) (4) (b) (4)	12 Feb 2021 19:56:47
Query 'Requires inpatient or prolongation of existing Hospitalization is checked, however Hospital Admission Date, Hospital Discharge Date, or Admitted to ICU? is missing. Please review and reconcile.' answered with 'hospital admission date is 09 Feb 2021' (Site from System).	Linden DeBoer (b) (4) (b) (4)	11 Feb 2021 18:19:51
User closed query 'Requires inpatient or prolongation of existing Hospitalization is not checked, but hospitalization data has been provided. Please correct.' (Site from System).		11 Feb 2021 18:19:12
Query 'Requires inpatient or prolongation of existing Hospitalization is not checked, but hospitalization data has been provided. Please correct.' answered by data change (Site from System).		11 Feb 2021 18:19:12
User opened query 'Requires inpatient or prolongation of existing Hospitalization is checked, however Hospital Admission Date, Hospital Discharge Date, or Admitted to ICU? is missing. Please review and reconcile.' (Site from System).	System	11 Feb 2021 18:19:12
User entered '1' reason for change: Data Entry Error	Linden DeBoer (b) (4) (b) (4)	11 Feb 2021 18:19:12

US3032249

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 14:53:49

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User opened query 'Requires inpatient or prolongation of existing Hospitalization is not checked, but hospitalization data has been provided. Please correct.' (Site from System). User entered '0'	System	11 Feb 2021 18:18:46
	Linden DeBoer (b) (4) (b) (4)	11 Feb 2021 18:18:46

US3032249

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 14:53:49

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Feb 2021 20:38:25
User signature succeeded.	Keith Vrbicky (b) (4)	12 Feb 2021 19:56:47
User entered '9 Feb 2021'	Linden DeBoer (b) (4)	11 Feb 2021 18:18:46

US3032249

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 14:53:49

Hospital Discharge Date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:41:17
	(b) (4)	
DataPoint Un-verified.	Samantha Wieseler (b) (4)	26 Mar 2021 14:23:15
	(b) (4)	
Signature has been broken.	Samantha Wieseler (b) (4)	26 Mar 2021 14:23:15
	(b) (4)	
User entered '12 Feb 2021' reason for change: Data Entry Error	Samantha Wieseler (b) (4)	26 Mar 2021 14:23:15
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	23 Feb 2021 20:38:25
User signature succeeded.	Keith Vrbicky (b) (4)	12 Feb 2021 19:56:47
	(b) (4)	
User entered empty.	Linden DeBoer (b) (4)	11 Feb 2021 18:18:46
	(b) (4)	

US3032249

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 14:53:49

[Admitted to ICU?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Feb 2021 20:38:25
User signature succeeded.	Keith Vrbicky (b) (4)	12 Feb 2021 19:56:47
User entered 'No (N)'	Linden DeBoer (b) (4)	11 Feb 2021 18:18:46

US3032249

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 14:53:49

[Number of Days in ICU](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Feb 2021 20:38:25
User signature succeeded.	Keith Vrbicky (b) (4)	12 Feb 2021 19:56:47
User entered empty.	(b) (4)	
	Linden DeBoer (b) (4)	11 Feb 2021 18:18:46
	(b) (4)	

US3032249

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 14:53:49

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Feb 2021 20:38:25
User signature succeeded.	Keith Vrbicky (b) (4)	12 Feb 2021 19:56:47
User entered '0'	Linden DeBoer (b) (4)	11 Feb 2021 18:18:46

US3032249

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 14:53:49

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Feb 2021 20:38:25
User signature succeeded.	Keith Vrbicky (b) (4)	12 Feb 2021 19:56:47
User entered '0'	Linden DeBoer (b) (4)	11 Feb 2021 18:18:46

US3032249

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 14:53:49

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Feb 2021 20:38:25
User signature succeeded.	Keith Vrbicky (b) (4)	12 Feb 2021 19:56:47
User entered '0'	Linden DeBoer (b) (4)	11 Feb 2021 18:18:46

US3032249

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 14:53:49

[Relationship to investigational product](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Feb 2021 20:38:25
User signature succeeded.	Keith Vrbicky (b) (4)	12 Feb 2021 19:56:47
User entered 'Not Related (NOT RELATED)'	Linden DeBoer (b) (4)	11 Feb 2021 18:18:46

US3032249

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 14:53:49

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Feb 2021 20:38:25
User signature succeeded.	Keith Vrbicky (b) (4)	12 Feb 2021 19:56:47
User entered 'Not Related (NOT RELATED)'	(b) (4) Linden DeBoer (b) (4)	11 Feb 2021 18:18:46

US3032249

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 14:53:49

[Action taken with investigational product](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Feb 2021 20:38:25
User signature succeeded.	Keith Vrbicky (b) (4)	12 Feb 2021 19:56:47
User entered 'Dose Delayed (DOSE DELAYED)'	(b) (4) Linden DeBoer (b) (4)	11 Feb 2021 18:18:46
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 14:53:49

[None](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Feb 2021 20:38:25
User signature succeeded.	Keith Vrbicky (b) (4)	12 Feb 2021 19:56:47
User entered '0'	Linden DeBoer (b) (4)	11 Feb 2021 18:18:46

US3032249

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 14:53:49

[Concomitant Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Feb 2021 20:38:25
User signature succeeded.	Keith Vrbicky (b) (4)	12 Feb 2021 19:56:47
User entered 'I'	Linden DeBoer (b) (4)	11 Feb 2021 18:18:46

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 14:53:49

[Concomitant Procedure](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Feb 2021 20:38:25
User signature succeeded.	Keith Vrbicky (b) (4)	12 Feb 2021 19:56:47
User entered '0'	(b) (4) Linden DeBoer (b) (4)	11 Feb 2021 18:18:46
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 14:53:49

[Outcome](#)

Audit	User	Time (GMT)
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:41:17
User closed query 'PV Query: Please provide the final event outcome, when available. Please keep query open until resolution is achieved.' (Site from Safety).	(b) (4) (b) (4), (b) (6)	04 Mar 2021 14:38:43
Query 'PV Query: Please provide the final event outcome, when available. Please keep query open until resolution is achieved.' answered with 'Updated data' (Site from Safety).	Kelsey Kelley (b) (4) (b) (4)	03 Mar 2021 19:43:32
DataPoint Un-verified.	Kelsey Kelley (b) (4) (b) (4)	03 Mar 2021 19:43:06
Signature has been broken.	Kelsey Kelley (b) (4) (b) (4)	03 Mar 2021 19:43:06
User entered 'Recovered/Resolved with Sequelae (RECOVERED/RESOLVED WITH SEQUELAE)' reason for change: Data Entry Error	Kelsey Kelley (b) (4) (b) (4)	03 Mar 2021 19:43:06
DataPoint Verified.	(b) (4), (b) (6)	23 Feb 2021 20:38:25
User opened query 'PV Query: Please provide the final event outcome, when available. Please keep query open until resolution is achieved.' (Site from Safety).		19 Feb 2021 16:58:53
User signature succeeded.	Keith Vrbicky (b) (4) (b) (4)	12 Feb 2021 19:56:47
User entered 'Not Recovered/Not Resolved (NOT RECOVERED/NOT RESOLVED)'	Linden DeBoer (b) (4) (b) (4)	11 Feb 2021 18:18:46

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 14:53:49

If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:

Audit	User	Time (GMT)
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:41:17
	(b) (4)	
User closed query 'Outcome Recovered/Resolved with Sequelae, but specify the sequelae is missing. Please provide.' (Site from System).	System	03 Mar 2021 19:44:10
DataPoint Un-verified.	Kelsey Kelley (b) (4)	03 Mar 2021 19:44:10
	(b) (4)	
Signature has been broken.	Kelsey Kelley (b) (4)	03 Mar 2021 19:44:10
	(b) (4)	
User entered 'Developed bilateral pneumonia and re-hospitalized' reason for change: Data Entry Error	Kelsey Kelley (b) (4)	03 Mar 2021 19:44:10
	(b) (4)	
User opened query 'Outcome Recovered/Resolved with Sequelae, but specify the sequelae is missing. Please provide.' (Site from System).	System	03 Mar 2021 19:43:06
DataPoint Verified.	(b) (4), (b) (6)	23 Feb 2021 20:38:25
	(b) (4)	
User signature succeeded.	Keith Vrbicky (b) (4)	12 Feb 2021 19:56:47
	(b) (4)	
User entered empty.	Linden DeBoer (b) (4)	11 Feb 2021 18:18:46
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 14:53:49

[Narrative](#)

Audit	User	Time (GMT)
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:41:17
User closed query 'PV Query: Please send a hospital discharge summary with patient identifiers redacted and subject ID added to Safety_Moderna@iqvia.com or fax to 866.599.1342 (add protocol and subject ID to cover page). Please leave query unanswered until records are sent or, if unable to obtain, please state so.' (Site from Safety).	(b) (4) (b) (4), (b) (6)	30 Mar 2021 14:36:33
Query 'PV Query: Please send a hospital discharge summary with patient identifiers redacted and subject ID added to Safety_Moderna@iqvia.com or fax to 866.599.1342 (add protocol and subject ID to cover page). Please leave query unanswered until records are sent or, if unable to obtain, please state so.' answered with 'records have been sent' (Site from Safety).	Samantha Wieseler (b) (4) (b) (4)	26 Mar 2021 14:29:48
DataPoint Un-verified.	Kelsey Kelley (b) (4) (b) (4)	25 Mar 2021 22:16:29
Signature has been broken.	Kelsey Kelley (b) (4) (b) (4)	25 Mar 2021 22:16:29

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 14:53:49

[Narrative](#)

Audit	User	Time (GMT)
User entered '09FEB2021 SUBJECT CALLED SITE TO REPORT SHE IS GETTING A BAM INFUSION CURRENTLY. SUBJECT DID CALL THE ER ON 08FEB2021 AND THEY TOLD HER TO FOLLOW UP WITH HER PCP OM 09FEB2021. SHE CALLED HER PCP 09FEB2021 AND GOT A RAPID COVID TEST THAT CONFIRMED SHE WAS COVID POSITIVE AND GOT THE BAM INFUSION ON 09FEB2021. 10FEB2021 ATTEMPTED TO CALL THE SUBJECT TO SEE HOW SHE WAS DOING AND NO ANSWER. 11FEB2021- SITE WAS ABLE TO GET CONTACT WITH THE SUBJECT. SUBJECT STATED SHE HAS BEEN ADMITTED TO THE HOSPITAL ON 09FEB2021 FOR COVID 19 SYMPTOMS. SUBJECT IS STILL CURRENTLY ADMITTED AT THIS TIME. MEDICAL RECORDS RELEASE WILL BE SENT TO PATIENT. WILL UPDATE SAE WHEN MEDICAL RECORDS COME BACK TO THE SITE. SUBJECT DID GET HER FIRST DOSE ON 28JAN2021 UNDER THE EUA UNBLINDING. Update 25Mar2021: Medical records received and reviewed. The following is a summary since her initial hospitalization: the subject initially saw her PCP 09Feb2021 for cough, fever, chills, and increased shortness of breath. BP was 142/76, HR 92, temp 99.9, and o2 95% room air. She was sent to hospital for a BAM infusion. While there, her o2 consistently dropped to low 80s. she had tested positive for covid at PCP visit. She was admitted for observation. Chest x-ray showed infiltrates. She was placed of 2L o2 and given prescribed medications to ease breathing. Due to continued hypoxia she was transferred to inpatient acute care status on 10Feb2021. She was prescribed azithromycin, Rocephin, prednisone, and IV fluids. She improved and was discharged 12Feb2021. She returned home. On 19Feb2021 the subject saw her PCP for hospital follow-up. She continued to experience shortness of breath, fatigue, productive cough. No changes were made that day.' reason for change: New Information	Kelsey Kelley (b) (4) (b) (4)	25 Mar 2021 22:16:29

PRODUCTION RELEASE (v12.003
EAB) (1725)

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 14:53:49

[Narrative](#)

Audit	User	Time (GMT)
User closed query 'PV Query: Please complete the COVID-19 Assessments tab, including results of COVID-19 diagnostic test, symptoms log, and severity assessment.' (Site from Safety).	(b) (4), (b) (6)	04 Mar 2021 14:39:49
Query 'PV Query: Please complete the COVID-19 Assessments tab, including results of COVID-19 diagnostic test, symptoms log, and severity assessment.' answered with 'The subject did not complete the convalescent phase per protocol as she was hospitalized immediately after her initial covid-19 assessment (she sought emergency medical care at the recommendation of the site staff) and had refused the daily phone calls contact during her hospitalization. The covid-19 day 1 illness swab was not completed as the subject did not complete the day 1 illness visit due to hospitalization. ' (Site from Safety).	Chelsie Nutsch (b) (4)	03 Mar 2021 23:28:37
DataPoint Verified.	(b) (4), (b) (6)	23 Feb 2021 20:38:25
User opened query 'PV Query: Please send a hospital discharge summary with patient identifiers redacted and subject ID added to Safety_Moderna@iqvia.com or fax to 866.599.1342 (add protocol and subject ID to cover page). Please leave query unanswered until records are sent or, if unable to obtain, please state so.' (Site from Safety).	(b) (4), (b) (6)	19 Feb 2021 17:14:26
User opened query 'PV Query: Please complete the COVID-19 Assessments tab, including results of COVID-19 diagnostic test, symptoms log, and severity assessment.' (Site from Safety).	(b) (4), (b) (6)	19 Feb 2021 17:14:02
User signature succeeded.	Keith Vrbicky (b) (4)	12 Feb 2021 19:56:47

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 14:53:49

[Narrative](#)

Audit	User	Time (GMT)
User entered '09Feb2021 subject called site to report she is getting a BAM infusion currently. Subject did call the ER on 08Feb2021 and they told her to follow up with her PCP om 09Feb2021. She called her PCP 09Feb2021 and got a rapid COVID test that confirmed she was COVID positive and got the BAM infusion on 09Feb2021. 10Feb2021 Attempted to call the subject to see how she was doing and no answer. 11Feb2021- Site was able to get contact with the subject. Subject stated she has been admitted to the hospital on 09Feb2021 for COVID 19 symptoms. Subject is still currently admitted at this time. Medical Records release will be sent to patient. Will update SAE when medical records come back to the site. Subject did get her first dose on 28Jan2021 under the EUA unblinding.'	Linden DeBoer (b) (4) (b) (4)	11 Feb 2021 18:18:46

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 14:53:49

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered 'I'	System	11 Feb 2021 18:18:46

US3032249

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 14:53:49

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered 'I'	System	11 Feb 2021 18:18:46

US3032249

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 14:53:49

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '0'	System	11 Feb 2021 18:18:46

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 14:53:49

[AEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:41:17
Reviewed for Safety.	(b) (4) (b) (6)	24 Mar 2021 16:04:07
User entered 'USA-US032-2021-mRNA-1273-P301000008'		04 Mar 2021 14:44:38

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 14:53:49

[Adverse event](#)

Audit	User	Time (GMT)
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:41:17
User coded data point as SOC: Infections and infestations, HLGT: Infections - pathogen unspecified, HLT: Lower respiratory tract and lung infections, PT: Pneumonia, LLT: Bilateral pneumonia - version MedDRA\\23.0.	(b) (4) Coder Import (b) (4)	03 Mar 2021 18:07:46
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	03 Mar 2021 18:07:46
Data point term sent to Coder	System	03 Mar 2021 18:07:29
User entered 'Bilateral Pneumonia'	Samantha Wieseler (b) (4) (b) (4)	03 Mar 2021 18:06:55

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 14:53:49

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:41:17
	(b) (4)	
User entered 'Yes (Y)'	Samantha Wieseler (b) (4)	03 Mar 2021 18:06:55
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 14:53:49

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:41:17
	(b) (4)	
User entered 'No (N)'	Samantha Wieseler (b) (4)	03 Mar 2021 18:06:55
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 14:53:49

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:41:17
	(b) (4)	
User entered 'No (N)'	Samantha Wieseler (b) (4)	03 Mar 2021 18:06:55
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 14:53:49

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:41:17
	(b) (4)	
User entered '01 Mar 2021'	Samantha Wieseler (b) (4)	03 Mar 2021 18:06:55
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 14:53:49

[Start time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:41:17
	(b) (4)	
User entered empty.	Samantha Wieseler (b) (4)	03 Mar 2021 18:06:55
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 14:53:49

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	03 Mar 2021 18:06:55

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 14:53:49

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:41:17
	(b) (4)	
User entered 'No (N)' reason for change: Data Entry Error	Kelsey Kelley (b) (4)	23 Mar 2021 15:33:39
	(b) (4)	
User entered 'Yes (Y)'	Samantha Wieseler (b) (4)	03 Mar 2021 18:06:55
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 14:53:49

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:41:17
User closed query 'PV Query: Please provide the event end date (recovered, returned to baseline, or, in the investigator's opinion, a new baseline has been achieved), when available.' (Site from Safety).	(b) (4) (b) (4), (b) (6)	24 Mar 2021 16:04:41
Query 'PV Query: Please provide the event end date (recovered, returned to baseline, or, in the investigator's opinion, a new baseline has been achieved), when available.' answered with 'Updated' (Site from Safety).	Kelsey Kelley (b) (4) (b) (4)	23 Mar 2021 15:34:09
User entered '5 Mar 2021' reason for change: Data Entry Error	Kelsey Kelley (b) (4) (b) (4)	23 Mar 2021 15:33:39
User opened query 'PV Query: Please provide the event end date (recovered, returned to baseline, or, in the investigator's opinion, a new baseline has been achieved), when available.' (Site from Safety).	(b) (4), (b) (6)	11 Mar 2021 14:51:30
User entered empty.	Samantha Wieseler (b) (4) (b) (4)	03 Mar 2021 18:06:55

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 14:53:49

[End time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:41:17
	(b) (4)	
User entered empty.	Samantha Wieseler (b) (4)	03 Mar 2021 18:06:55
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (2)

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[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	03 Mar 2021 18:06:55

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Folder: Adverse Events

Form: Adverse Events (2)

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[Severity](#)

Audit	User	Time (GMT)
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:41:17
User entered 'Grade 3/Severe (Grade 3/Severe)'	(b) (4) Samantha Wieseler (b) (4)	03 Mar 2021 18:06:55

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Folder: Adverse Events

Form: Adverse Events (2)

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[Is the adverse event serious?](#)

Audit	User	Time (GMT)
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:41:17
	(b) (4)	
User entered 'Yes (Y)'	Samantha Wieseler (b) (4)	03 Mar 2021 18:06:55
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 14:53:49

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:41:17
	(b) (4)	
User entered '0'	Samantha Wieseler (b) (4)	03 Mar 2021 18:06:55
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 14:53:49

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:41:17
	(b) (4)	
User entered '0'	Samantha Wieseler (b) (4)	03 Mar 2021 18:06:55
	(b) (4)	

US3032249

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 14:53:49

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:41:17
User closed query 'Per DM Re-query: Per response please update Admitted to ICU and discharge date once it is available, till then keep this query in open state else clarify.' (Site from DM).	(b) (4) (b) (4), (b) (6)	25 Mar 2021 02:50:43
Query 'Per DM Re-query: Per response please update Admitted to ICU and discharge date once it is available, till then keep this query in open state else clarify.' answered with 'Discharge date is updated' (Site from DM).	Kelsey Kelley (b) (4) (b) (4)	23 Mar 2021 16:21:26
User closed query 'Requires inpatient or prolongation of existing Hospitalization is checked, however Hospital Admission Date, Hospital Discharge Date, or Admitted to ICU? is missing. Please review and reconcile.' (Site from System).		09 Mar 2021 19:53:40
Query 'Requires inpatient or prolongation of existing Hospitalization is checked, however Hospital Admission Date, Hospital Discharge Date, or Admitted to ICU? is missing. Please review and reconcile.' answered by data change (Site from System).		09 Mar 2021 19:53:40
User opened query 'Requires inpatient or prolongation of existing Hospitalization is checked, however Hospital Admission Date, Hospital Discharge Date, or Admitted to ICU? is missing. Please review and reconcile.' (Site from System).	System	09 Mar 2021 19:53:14
User opened query 'Per DM Re-query: Per response please update Admitted to ICU and discharge date once it is available, till then keep this query in open state else clarify.' (Site from DM).	(b) (4), (b) (6)	05 Mar 2021 09:10:21
User closed query 'Requires inpatient or prolongation of existing Hospitalization is checked, however Hospital Admission Date, Hospital Discharge Date, or Admitted to ICU? is missing. Please review and reconcile.' (Site from System).		05 Mar 2021 09:08:34
Query 'Requires inpatient or prolongation of existing Hospitalization is checked, however Hospital Admission Date, Hospital Discharge Date, or Admitted to ICU? is missing. Please review and reconcile.' answered with 'subject has not been discharged.' (Site from System).	Samantha Wieseler (b) (4) (b) (4)	03 Mar 2021 18:07:17

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EAB) (1725)

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 14:53:49

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User opened query 'Requires inpatient or prolongation of existing Hospitalization is checked, however Hospital Admission Date, Hospital Discharge Date, or Admitted to ICU? is missing. Please review and reconcile.' (Site from System). User entered 'I'	System	03 Mar 2021 18:06:55
	Samantha Wieseler (b) (4) (b) (4)	03 Mar 2021 18:06:55

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 14:53:49

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:41:17
	(b) (4)	
User entered '01 Mar 2021'	Samantha Wieseler (b) (4)	03 Mar 2021 18:06:55
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 14:53:49

[Hospital Discharge Date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:41:17
	(b) (4)	
User entered '05 Mar 2021' reason for change: New Information	Kelsey Kelley (b) (4)	25 Mar 2021 21:52:03
	(b) (4)	
User entered '06 Mar 2021' reason for change: Data Entry Error	Chelsie Nutsch (b) (4)	09 Mar 2021 19:53:14
	(b) (4)	
User entered empty.	Samantha Wieseler (b) (4)	03 Mar 2021 18:06:55
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 14:53:49

[Admitted to ICU?](#)

Audit	User	Time (GMT)
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:41:17
	(b) (4)	
User entered 'No (N)' reason for change: Data Entry Error	Chelsie Nutsch (b) (4)	09 Mar 2021 19:53:40
	(b) (4)	
User entered empty.	Samantha Wieseler (b) (4)	03 Mar 2021 18:06:55
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 14:53:49

[Number of Days in ICU](#)

Audit	User	Time (GMT)
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:41:17
	(b) (4)	
User entered empty.	Samantha Wieseler (b) (4)	03 Mar 2021 18:06:55
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 14:53:49

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:41:17
	(b) (4)	
User entered '0'	Samantha Wieseler (b) (4)	03 Mar 2021 18:06:55
	(b) (4)	

US3032249

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 14:53:49

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:41:17
	(b) (4)	
User entered '0'	Samantha Wieseler (b) (4)	03 Mar 2021 18:06:55
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 14:53:49

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:41:17
	(b) (4)	
User entered '0'	Samantha Wieseler (b) (4)	03 Mar 2021 18:06:55
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 14:53:49

[Relationship to investigational product](#)

Audit	User	Time (GMT)
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:41:17
User entered 'Not Related (NOT RELATED)'	(b) (4) Samantha Wieseler (b) (4)	03 Mar 2021 18:06:55

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 14:53:49

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:41:17
User entered 'Not Related (NOT RELATED)'	(b) (4) Samantha Wieseler (b) (4)	03 Mar 2021 18:06:55

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 14:53:49

[Action taken with investigational product](#)

Audit	User	Time (GMT)
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:41:17
User entered 'Dose Delayed (DOSE DELAYED)'	(b) (4) Samantha Wieseler (b) (4)	03 Mar 2021 18:06:55

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 14:53:49

[None](#)

Audit	User	Time (GMT)
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:41:17
	(b) (4)	
User entered '0'	Samantha Wieseler (b) (4)	03 Mar 2021 18:06:55
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 14:53:49

[Concomitant Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:41:17
User closed query 'Per DM CLR: Other Action Taken = ConMed. However, there is no recorded ConMed that match this AE within this time frame. Please review and update to record the ConMed treatment as appropriate. Otherwise, clarify.' (Site from DM).	(b) (4) (b) (4), (b) (6)	30 Mar 2021 10:52:21
Query 'Per DM CLR: Other Action Taken = ConMed. However, there is no recorded ConMed that match this AE within this time frame. Please review and update to record the ConMed treatment as appropriate. Otherwise, clarify.' answered with 'conmed page updated' (Site from DM).	Kelsey Kelley (b) (4) (b) (4)	25 Mar 2021 21:40:22
User opened query 'Per DM CLR: Other Action Taken = ConMed. However, there is no recorded ConMed that match this AE within this time frame. Please review and update to record the ConMed treatment as appropriate. Otherwise, clarify.' (Site from DM).	(b) (4), (b) (6)	19 Mar 2021 19:19:51
User entered 'I'	Samantha Wieseler (b) (4) (b) (4)	03 Mar 2021 18:06:55

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 14:53:49

[Concomitant Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:41:17
	(b) (4)	
User entered '0'	Samantha Wieseler (b) (4)	03 Mar 2021 18:06:55
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 14:53:49

[Outcome](#)

Audit	User	Time (GMT)
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:41:17
User closed query 'PV Query: Please provide the final event outcome, when available. Please keep query open until resolution is achieved' (Site from Safety).	(b) (4) (b) (4), (b) (6)	24 Mar 2021 16:04:48
Query 'PV Query: Please provide the final event outcome, when available. Please keep query open until resolution is achieved' answered with 'Updated' (Site from Safety).	Kelsey Kelley (b) (4) (b) (4)	23 Mar 2021 15:34:15
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)' reason for change: Data Entry Error	Kelsey Kelley (b) (4) (b) (4)	23 Mar 2021 15:33:39
User opened query 'PV Query: Please provide the final event outcome, when available. Please keep query open until resolution is achieved' (Site from Safety).	(b) (4), (b) (6)	11 Mar 2021 14:51:53
User entered 'Recovering/Resolving (RECOVERING/RESOLVING)'	Samantha Wieseler (b) (4) (b) (4)	03 Mar 2021 18:06:55

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Folder: Adverse Events

Form: Adverse Events (2)

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[If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:](#)

Audit	User	Time (GMT)
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:41:17
	(b) (4)	
User entered empty.	Samantha Wieseler (b) (4)	03 Mar 2021 18:06:55
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 14:53:49

[Narrative](#)

Audit	User	Time (GMT)
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:41:17
User closed query 'PV Query: Please provide treatment given for the event including medical intervention and/or surgical treatments. Please add any treatment medications to the concomitant medication eCRF (including dates of administration, dose, units, frequency, route and indication). If no treatment was provided, please state so.' (Site from Safety).	(b) (4) (u) (4), (b) (6)	26 Mar 2021 17:24:40
User closed query 'please update Admitted to ICU and discharge date once it is available, till then keep this query in open state else clarify' (Site from Safety).		26 Mar 2021 17:24:36

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 14:53:49

[Narrative](#)

Audit	User	Time (GMT)
User entered 'SUBJECT CALLS TO REPORT SHE HAS BEEN RE-HOSPITALIZED FOR BILATERAL PNEUMONIA. SHE STATES SHE HAS CONTINUED TO FEEL UNWELL SINCE HER INITIAL COVID DIAGNOSIS. SHE NOTED INCREASING SHORTNESS OF BREATH, WEAKNESS, UNCONTROLLED COUGHING, AND O2 SATURATION <90% ON ROOM AIR AT REST. SHE SOUGHT CARE AT THE ER AND WAS ADMITTED. SHE IS ON ANTIBIOTICS AND BREATHING TREATMENTS CURRENTLY. MEDICAL RECORDS HAVE BEEN REQUESTED. SHE REPORTS SHE IS STILL IN THE HOSPITAL BUT "THIS IS THE BEST" SHE HAS FELT SINCE HER ORIGINAL COVID DIAGNOSIS. SHE DID HAVE HER 28 DAY FOLLOW UP SCHEDULED, SO THIS WILL BE RESCHEDULED. WILL CONTINUE TO FOLLOW PATIENTS CONDITION. UPDATE 09MAR2021: SUBJECT REPORTS SHE WAS DISCHARGED 05MAR2021. CONTINUES TO EXPERIENCE WEAKNESS, SHORTNESS OF BREATH, AND PRODUCTIVE COUGH. AWAITING MEDICAL RECORDS. update 25 mar 2021: on 01 Mar 2021 the subject returned to the ER. she was experiencing abrupt increase in shortness of breath, productive cough, posttussive emesis, fevers/sweats, dyspnea with exertion, oxygen 91-93%, lymphadenitis to right axillary lymph node, chest pain, and heaviness. her pro-calcitonin was 1.91, D-dimer elevated at 10,000. a chest x-ray was performed but subject did not tolerate well due to dyspnea. a ct angiogram of chest was performed. it ruled out a pulmonary embolism but did show upper lung lobe infiltrates bilateral. it also showed the right axillary lymph node was swollen. the subjects hospitalization included o2 usage, Levaquin, Zosyn, enoxaparin, and breathing treatments for a diagnosis of bilateral pneumonia. the subject was discharged 05Mar2021 after proving she could walk 300 ft and keep o2 >90% on room air. the subject saw her	Kelsey Kelley (b) (4)	26 Mar 2021 14:51:26

PRODUCTION RELEASE (v12.003
EAB) (1725)

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 14:53:49

[Narrative](#)

Audit	User	Time (GMT)
PCP on 11Mar2021 for hospital follow up. she reports improvement in most symptoms but still has fatigue and night sweats.' reason for change: Data Entry Error		
Query 'please update Admitted to ICU and discharge date once it is available, till then keep this query in open state else clarify' answered with 'Subject was not admitted to ICU. Discharge date was 05Mar2021. ' (Site from Safety).	Kelsey Kelley (b) (4)	25 Mar 2021 21:53:19
User entered 'SUBJECT CALLS TO REPORT SHE HAS BEEN RE-HOSPITALIZED FOR BILATERAL PNEUMONIA. SHE STATES SHE HAS CONTINUED TO FEEL UNWELL SINCE HER INITIAL COVID DIAGNOSIS. SHE NOTED INCREASING SHORTNESS OF BREATH, WEAKNESS, UNCONTROLLED COUGHING, AND O2 SATURATION <90% ON ROOM AIR AT REST. SHE SOUGHT CARE AT THE ER AND WAS ADMITTED. SHE IS ON ANTIBIOTICS AND BREATHING TREATMENTS CURRENTLY. MEDICAL RECORDS HAVE BEEN REQUESTED. SHE REPORTS SHE IS STILL IN THE HOSPITAL BUT "THIS IS THE BEST" SHE HAS FELT SINCE HER ORIGINAL COVID DIAGNOSIS. SHE DID HAVE HER 28 DAY FOLLOW UP SCHEDULED, SO THIS WILL BE RESCHEDULED. WILL CONTINUE TO FOLLOW PATIENTS CONDITION. UPDATE 09MAR2021: SUBJECT REPORTS SHE WAS DISCHARGED 05MAR2021. CONTINUES TO EXPERIENCE WEAKNESS, SHORTNESS OF BREATH, AND PRODUCTIVE COUGH. AWAITING MEDICAL RECORDS.' reason for change: Data Entry Error	Kelsey Kelley (b) (4)	25 Mar 2021 21:52:25
Query 'PV Query: Please provide treatment given for the event including medical intervention and/or surgical treatments. Please add any treatment medications to the concomitant medication eCRF (including dates of administration, dose, units, frequency, route and indication). If no treatment was provided, please state so.' answered with 'Medication and procedure logs updated' (Site from Safety).	Kelsey Kelley (b) (4)	25 Mar 2021 21:47:46

PRODUCTION RELEASE (v12.003
EAB) (1725)

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 14:53:49

[Narrative](#)

Audit	User	Time (GMT)
User opened query 'PV Query: Please provide treatment given for the event including medical intervention and/or surgical treatments. Please add any treatment medications to the concomitant medication eCRF (including dates of administration, dose, units, frequency, route and indication). If no treatment was provided, please state so.' (Site from Safety).	(b) (4), (b) (6)	11 Mar 2021 14:52:28
User opened query 'please update Admitted to ICU and discharge date once it is available, till then keep this query in open state else clarify' (Site from Safety).		11 Mar 2021 14:52:12
User entered 'SUBJECT CALLS TO REPORT SHE HAS BEEN RE-HOSPITALIZED FOR BILATERAL PNEUMONIA. SHE STATES SHE HAS CONTINUED TO FEEL UNWELL SINCE HER INITIAL COVID DIAGNOSIS. SHE NOTED INCREASING SHORTNESS OF BREATH, WEAKNESS, UNCONTROLLED COUGHING, AND O2 SATURATION <90% ON ROOM AIR AT REST. SHE SOUGHT CARE AT THE ER AND WAS ADMITTED. SHE IS ON ANTIBIOTICS AND BREATHING TREATMENTS CURRENTLY. MEDICAL RECORDS HAVE BEEN REQUESTED. SHE REPORTS SHE IS STILL IN THE HOSPITAL BUT "THIS IS THE BEST" SHE HAS FELT SINCE HER ORIGINAL COVID DIAGNOSIS. SHE DID HAVE HER 28 DAY FOLLOW UP SCHEDULED, SO THIS WILL BE RESCHEDULED. WILL CONTINUE TO FOLLOW PATIENTS CONDITION. UPDATE 09MAR2021: SUBJECT REPORTS SHE WAS DISCHARGED 06MAR2021. continues to experience weakness, shortness of breath, and productive cough. AWAITING MEDICAL RECORDS.' reason for change: Data Entry Error	Chelsie Nutsch (b) (4) (b) (4)	09 Mar 2021 19:46:06

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 14:53:49

[Narrative](#)

Audit	User	Time (GMT)
User entered 'SUBJECT CALLS TO REPORT SHE HAS BEEN RE-HOSPITALIZED FOR BILATERAL PNEUMONIA. SHE STATES SHE HAS CONTINUED TO FEEL UNWELL SINCE HER INITIAL COVID DIAGNOSIS. SHE NOTED INCREASING SHORTNESS OF BREATH, WEAKNESS, UNCONTROLLED COUGHING, AND O2 SATURATION <90% ON ROOM AIR AT REST. SHE SOUGHT CARE AT THE ER AND WAS ADMITTED. SHE IS ON ANTIBIOTICS AND BREATHING TREATMENTS CURRENTLY. MEDICAL RECORDS HAVE BEEN REQUESTED. SHE REPORTS SHE IS STILL IN THE HOSPITAL BUT "THIS IS THE BEST" SHE HAS FELT SINCE HER ORIGINAL COVID DIAGNOSIS. SHE DID HAVE HER 28 DAY FOLLOW UP SCHEDULED, SO THIS WILL BE RESCHEDULED. WILL CONTINUE TO FOLLOW PATIENTS CONDITION. update 09mar2021: subject reports she was discharged 06mar2021. awaiting medical records.' reason for change: Data Entry Error	Chelsie Nutsch (b) (4) (b) (4)	09 Mar 2021 19:45:26
User entered 'Subject calls to report she has been re-hospitalized for bilateral pneumonia. She states she has continued to feel unwell since her initial covid diagnosis. She noted increasing shortness of breath, weakness, uncontrolled coughing, and O2 saturation <90% on room air at rest. She sought care at the ER and was admitted. She is on antibiotics and breathing treatments currently. Medical records have been requested. She reports she is still in the hospital but "this is the best" she has felt since her original covid diagnosis. She did have her 28 day follow up scheduled, so this will be rescheduled. Will continue to follow patients condition.'	Samantha Wieseler (b) (4) (b) (4)	03 Mar 2021 18:06:55

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 14:53:49

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '1'	System	03 Mar 2021 18:06:55

US3032249

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 14:53:49

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered 'I'	System	03 Mar 2021 18:06:55

US3032249

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 14:53:49

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '0'	System	09 Mar 2021 19:53:40

US3032249

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 14:53:49

[AEID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:42:22

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 14:53:49

[Adverse event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:42:22
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:41:17
User coded data point as SOC: Respiratory, thoracic and mediastinal disorders, HLGT: Bronchial disorders (excl neoplasms), HLT: Bronchospasm and obstruction, PT: Asthma, LLT: Asthma aggravated - version MedDRA\\23.0.	Coder Import (b) (4)	03 Mar 2021 20:02:43
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	03 Mar 2021 20:02:43
Data point term sent to Coder	System	03 Mar 2021 19:46:59
User entered 'worsening of asthma'	Kelsey Kelley (b) (4)	03 Mar 2021 19:46:35

US3032249

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 14:53:49

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:42:22
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:41:17
User entered 'Yes (Y)'	(b) (4) Kelsey Kelley (b) (4)	03 Mar 2021 19:46:35

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 14:53:49

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:42:22
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:41:17
User entered 'No (N)'	(b) (4) Kelsey Kelley (b) (4)	03 Mar 2021 19:46:35

US3032249

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 14:53:49

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:42:22
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:41:17
User entered 'No (N)'	(b) (4) Kelsey Kelley (b) (4)	03 Mar 2021 19:46:35

US3032249

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 14:53:49

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:42:22
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:41:17
User entered '23 Dec 2020'	(b) (4) Kelsey Kelley (b) (4)	03 Mar 2021 19:46:35
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 14:53:49

[Start time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:42:22
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:41:17
User entered empty.	(b) (4) Kelsey Kelley (b) (4)	03 Mar 2021 19:46:35

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 14:53:49

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:42:22
User entered empty.	System	03 Mar 2021 19:46:35

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 14:53:49

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:42:22
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:41:17
User entered 'No (N)'	(b) (4) Kelsey Kelley (b) (4)	03 Mar 2021 19:46:35

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 14:53:49

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:42:22
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:41:17
User entered '28 Jan 2021'	(b) (4) Kelsey Kelley (b) (4)	03 Mar 2021 19:46:35
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 14:53:49

[End time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:42:22
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:41:17
User entered empty.	(b) (4) Kelsey Kelley (b) (4)	03 Mar 2021 19:46:35

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 14:53:49

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:42:22
User entered empty.	System	03 Mar 2021 19:46:35

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 14:53:49

[Severity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:42:22
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:41:17
User entered 'Grade 2/Moderate (Grade 2/Moderate)'	(b) (4) Kelsey Kelley (b) (4)	03 Mar 2021 19:46:35
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 14:53:49

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:42:22
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:41:17
User entered 'No (N)'	(b) (4) Kelsey Kelley (b) (4)	03 Mar 2021 19:46:35
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 14:53:49

[Death](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:42:22
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:41:17
User entered '0'	(b) (4) Kelsey Kelley (b) (4)	03 Mar 2021 19:46:35

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 14:53:49

[Life threatening](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:42:22
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:41:17
User entered '0'	(b) (4) Kelsey Kelley (b) (4)	03 Mar 2021 19:46:35

US3032249

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 14:53:49

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:42:22
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:41:17
User entered '0'	(b) (4) Kelsey Kelley (b) (4)	03 Mar 2021 19:46:35

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 14:53:49

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:42:22
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:41:17
User entered empty.	(b) (4) Kelsey Kelley (b) (4)	03 Mar 2021 19:46:35

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 14:53:49

Hospital Discharge Date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:42:22
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:41:17
User entered empty.	(b) (4) Kelsey Kelley (b) (4)	03 Mar 2021 19:46:35

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 14:53:49

[Admitted to ICU?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:42:22
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:41:17
User entered empty.	(b) (4) Kelsey Kelley (b) (4)	03 Mar 2021 19:46:35

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 14:53:49

[Number of Days in ICU](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:42:22
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:41:17
User entered empty.	(b) (4) Kelsey Kelley (b) (4)	03 Mar 2021 19:46:35

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 14:53:49

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:42:22
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:41:17
User entered '0'	(b) (4) Kelsey Kelley (b) (4)	03 Mar 2021 19:46:35

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Folder: Adverse Events

Form: Adverse Events (3)

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[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:42:22
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:41:17
User entered '0'	(b) (4) Kelsey Kelley (b) (4)	03 Mar 2021 19:46:35

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Folder: Adverse Events

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[Other medically important event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:42:22
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:41:17
User entered '0'	(b) (4) Kelsey Kelley (b) (4)	03 Mar 2021 19:46:35

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Folder: Adverse Events

Form: Adverse Events (3)

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[Relationship to investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:42:22
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:41:17
User entered 'Not Related (NOT RELATED)'	(b) (4) Kelsey Kelley (b) (4)	03 Mar 2021 19:46:35

US3032249

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 14:53:49

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:42:22
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:41:17
User entered 'Not Related (NOT RELATED)'	(b) (4) Kelsey Kelley (b) (4)	03 Mar 2021 19:46:35

US3032249

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 14:53:49

Action taken with investigational product

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:42:22
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:41:17
User closed query 'Per CDM CLR re-query: Per response however the OL-1 visit data is not entered yet kindly review and amend as appropriate.' (Site from DM).	(b) (4) (b) (4), (b) (6)	02 Apr 2021 20:50:34
Query 'Per CDM CLR re-query: Per response however the OL-1 visit data is not entered yet kindly review and amend as appropriate.' answered with 'updated' (Site from DM).	Samantha Wieseler (b) (4) (b) (4)	31 Mar 2021 13:04:50
User entered 'Not Applicable (NOT APPLICABLE)' reason for change: Data Entry Error	Samantha Wieseler (b) (4) (b) (4)	31 Mar 2021 13:04:31
User opened query 'Per CDM CLR re-query: Per response however the OL-1 visit data is not entered yet kindly review and amend as appropriate.' (Site from DM).	(b) (4), (b) (6)	31 Mar 2021 12:06:18
User closed query ' Per CDM: Per CCGs, if the Adverse event started during a time period when study dose was not given, "Not applicable" should be selected for "Action taken with investigational product". Please review and update as appropriate. ' (Site from DM).		31 Mar 2021 12:06:18
Query ' Per CDM: Per CCGs, if the Adverse event started during a time period when study dose was not given, "Not applicable" should be selected for "Action taken with investigational product". Please review and update as appropriate. ' answered with 'AE reported to site during OL-1 visit. Given OK by PI to vaccinate, therefore "none" is correct as entered' (Site from DM).	Kelsey Kelley (b) (4) (b) (4)	25 Mar 2021 21:49:52
User opened query ' Per CDM: Per CCGs, if the Adverse event started during a time period when study dose was not given, "Not applicable" should be selected for "Action taken with investigational product". Please review and update as appropriate. ' (Site from DM).	(b) (4), (b) (6)	15 Mar 2021 14:12:14
User entered 'None (NONE)'	Kelsey Kelley (b) (4) (b) (4)	03 Mar 2021 19:46:35

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Folder: Adverse Events

Form: Adverse Events (3)

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[None](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:42:22
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:41:17
User entered '0'	(b) (4) Kelsey Kelley (b) (4)	03 Mar 2021 19:46:35

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 14:53:49

[Concomitant Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:42:22
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:41:17
User entered 'I'	(b) (4) Kelsey Kelley (b) (4)	03 Mar 2021 19:46:35

US3032249

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 14:53:49

[Concomitant Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:42:22
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:41:17
User entered '0'	(b) (4) Kelsey Kelley (b) (4)	03 Mar 2021 19:46:35

US3032249

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 14:53:49

[Outcome](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:42:22
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:41:17
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)'	(b) (4) Kelsey Kelley (b) (4)	03 Mar 2021 19:46:35

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Folder: Adverse Events

Form: Adverse Events (3)

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[If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:42:22
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:41:17
User entered empty.	(b) (4) Kelsey Kelley (b) (4)	03 Mar 2021 19:46:35
	(b) (4)	

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[Narrative](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:42:22
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:41:17
User entered empty.	(b) (4) Kelsey Kelley (b) (4)	03 Mar 2021 19:46:35

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Folder: Adverse Events

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[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:42:22
User entered '0'	System	03 Mar 2021 19:46:35

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 14:53:49

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:42:22
User entered 'I'	System	03 Mar 2021 19:46:35

US3032249

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 14:53:49

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:42:22

US3032249

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 14:53:49

[AEID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:42:27

US3032249

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 14:53:49

[Adverse event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:42:27
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:41:17
User coded data point as SOC: Gastrointestinal disorders, HLGT: Gastrointestinal haemorrhages NEC, HLT: Non-site specific gastrointestinal haemorrhages, PT: Haematochezia, LLT: Hematochezia - version MedDRA\\23.0.	Coder Import (b) (4)	23 Mar 2021 15:37:58
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	23 Mar 2021 15:37:58
Data point term sent to Coder	System	23 Mar 2021 15:35:48
User entered 'hematochezia'	Kelsey Kelley (b) (4)	23 Mar 2021 15:35:35

US3032249

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 14:53:49

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:42:27
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:41:17
User entered 'No (N)'	(b) (4) Kelsey Kelley (b) (4)	23 Mar 2021 15:35:35

US3032249

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 14:53:49

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:42:27
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:41:17
User entered 'No (N)'	(b) (4) Kelsey Kelley (b) (4)	23 Mar 2021 15:35:35

US3032249

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 14:53:49

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:42:27
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:41:17
User entered 'No (N)'	(b) (4) Kelsey Kelley (b) (4)	23 Mar 2021 15:35:35

US3032249

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 14:53:49

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:42:27
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:41:17
User entered '17 Mar 2021'	(b) (4) Kelsey Kelley (b) (4)	23 Mar 2021 15:35:35
	(b) (4)	

US3032249

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 14:53:49

[Start time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:42:27
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:41:17
User entered empty.	(b) (4) Kelsey Kelley (b) (4)	23 Mar 2021 15:35:35

US3032249

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 14:53:49

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:42:27
User entered empty.	System	23 Mar 2021 15:35:35

US3032249

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 14:53:49

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:42:27
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:41:17
User entered 'No (N)' reason for change: Data Entry Error	(b) (4)	25 Mar 2021 21:50:18
User entered 'Yes (Y)'	Kelsey Kelley (b) (4)	23 Mar 2021 15:35:35
	(b) (4)	

US3032249

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 14:53:49

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:42:27
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:41:17
User closed query 'Outcome is not Recovered/Resolved, Recovered/Resolved with sequelae or Fatal, but End Date is provided. Please correct.' (Site from System).	(b) (4)	25 Mar 2021 21:50:24
Query 'Outcome is not Recovered/Resolved, Recovered/Resolved with sequelae or Fatal, but End Date is provided. Please correct.' answered by data change (Site from System).	System	25 Mar 2021 21:50:24
User opened query 'Outcome is not Recovered/Resolved, Recovered/Resolved with sequelae or Fatal, but End Date is provided. Please correct.' (Site from System).	System	25 Mar 2021 21:50:18
User entered '19 Mar 2021' reason for change: Data Entry Error	Kelsey Kelley (b) (4)	25 Mar 2021 21:50:18
User entered empty.	(b) (4)	23 Mar 2021 15:35:35
	Kelsey Kelley (b) (4)	
	(b) (4)	

US3032249

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 14:53:49

End time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:42:27
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:41:17
User entered empty.	(b) (4) Kelsey Kelley (b) (4)	23 Mar 2021 15:35:35

US3032249

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 14:53:49

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:42:27
User entered empty.	System	23 Mar 2021 15:35:35

US3032249

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 14:53:49

[Severity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:42:27
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:41:17
User entered 'Grade 2/Moderate (Grade 2/Moderate)'	(b) (4) Kelsey Kelley (b) (4)	23 Mar 2021 15:35:35
	(b) (4)	

US3032249

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 14:53:49

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:42:27
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:41:17
User entered 'No (N)'	(b) (4) Kelsey Kelley (b) (4)	23 Mar 2021 15:35:35

US3032249

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 14:53:49

[Death](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:42:27
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:41:17
User entered '0'	(b) (4) Kelsey Kelley (b) (4)	23 Mar 2021 15:35:35

US3032249

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 14:53:49

[Life threatening](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:42:27
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:41:17
User entered '0'	(b) (4) Kelsey Kelley (b) (4)	23 Mar 2021 15:35:35

US3032249

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 14:53:49

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:42:27
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:41:17
User entered '0'	Kelsey Kelley (b) (4)	23 Mar 2021 15:35:35

US3032249

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 14:53:49

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:42:27
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:41:17
User entered empty.	(b) (4) Kelsey Kelley (b) (4)	23 Mar 2021 15:35:35

US3032249

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 14:53:49

Hospital Discharge Date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:42:27
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:41:17
User entered empty.	(b) (4) Kelsey Kelley (b) (4)	23 Mar 2021 15:35:35

US3032249

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 14:53:49

[Admitted to ICU?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:42:27
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:41:17
User entered empty.	(b) (4) Kelsey Kelley (b) (4)	23 Mar 2021 15:35:35

US3032249

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 14:53:49

[Number of Days in ICU](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:42:27
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:41:17
User entered empty.	(b) (4) Kelsey Kelley (b) (4)	23 Mar 2021 15:35:35

US3032249

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 14:53:49

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:42:27
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:41:17
User entered '0'	(b) (4) Kelsey Kelley (b) (4)	23 Mar 2021 15:35:35

US3032249

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 14:53:49

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:42:27
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:41:17
User entered '0'	(b) (4) Kelsey Kelley (b) (4)	23 Mar 2021 15:35:35

US3032249

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 14:53:49

[Other medically important event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:42:27
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:41:17
User entered '0'	(b) (4) Kelsey Kelley (b) (4)	23 Mar 2021 15:35:35

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 14:53:49

[Relationship to investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:42:27
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:41:17
User entered 'Not Related (NOT RELATED)'	(b) (4) Kelsey Kelley (b) (4)	23 Mar 2021 15:35:35

US3032249

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 14:53:49

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:42:27
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:41:17
User entered 'Not Related (NOT RELATED)'	(b) (4) Kelsey Kelley (b) (4)	23 Mar 2021 15:35:35

US3032249

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 14:53:49

[Action taken with investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:42:27
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:41:17
User entered 'Dose Delayed (DOSE DELAYED)'	(b) (4) Kelsey Kelley (b) (4)	23 Mar 2021 15:35:35
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 14:53:49

[None](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:42:27
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:41:17
User entered 'I'	(b) (4) Kelsey Kelley (b) (4)	23 Mar 2021 15:35:35

US3032249

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 14:53:49

[Concomitant Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:42:27
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:41:17
User entered '0'	(b) (4) Kelsey Kelley (b) (4)	23 Mar 2021 15:35:35

US3032249

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 14:53:49

[Concomitant Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:42:27
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:41:17
User entered '0'	(b) (4) Kelsey Kelley (b) (4)	23 Mar 2021 15:35:35

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 14:53:49

[Outcome](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:42:27
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:41:17
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)' reason for change: Data Entry Error	(b) (4)	
	Kelsey Kelley (b) (4)	25 Mar 2021 21:50:24
User entered 'Not Recovered/Not Resolved (NOT RECOVERED/NOT RESOLVED)'	(b) (4)	
	Kelsey Kelley (b) (4)	23 Mar 2021 15:35:35
	(b) (4)	

US3032249

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 14:53:49

[If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:42:27
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:41:17
User entered empty.	(b) (4) Kelsey Kelley (b) (4)	23 Mar 2021 15:35:35

US3032249

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 14:53:49

[Narrative](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:42:27
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:41:17
User entered empty.	(b) (4) Kelsey Kelley (b) (4)	23 Mar 2021 15:35:35

US3032249

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 14:53:49

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:42:27
User entered '0'	System	23 Mar 2021 15:35:35

US3032249

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 14:53:49

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:42:27
User entered '0'	System	23 Mar 2021 15:35:35

US3032249

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 14:53:49

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:42:27

US3032249

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 14:53:49

[Adverse event](#)

Audit	User	Time (GMT)
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:41:17
User coded data point as SOC: Gastrointestinal disorders, HLT: Gastrointestinal vascular conditions, HLT: Haemorrhoids and gastrointestinal varices (excl oesophageal), PT: Haemorrhoids, LLT: Hemorrhoids - version MedDRA\\23.0.	(b) (4) (b) (4) Coder Import (b) (4)	23 Mar 2021 15:38:38
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	23 Mar 2021 15:38:38
Data point term sent to Coder	System	23 Mar 2021 15:37:59
User entered 'hemorrhoids'	Kelsey Kelley (b) (4) (b) (4)	23 Mar 2021 15:37:03

US3032249

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 14:53:49

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:41:17
	(b) (4)	
User entered 'Yes (Y)'	Kelsey Kelley (b) (4)	23 Mar 2021 15:37:03
	(b) (4)	

US3032249

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 14:53:49

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:41:17
	(b) (4)	
User entered 'No (N)'	Kelsey Kelley (b) (4)	23 Mar 2021 15:37:03
	(b) (4)	

US3032249

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 14:53:49

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:41:17
User entered 'No (N)'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	23 Mar 2021 15:37:03

US3032249

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 14:53:49

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:41:17
	(b) (4)	
User entered '19 Mar 2021'	Kelsey Kelley (b) (4)	23 Mar 2021 15:37:03
	(b) (4)	

US3032249

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 14:53:49

[Start time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:41:17
	(b) (4)	
User entered empty.	Kelsey Kelley (b) (4)	23 Mar 2021 15:37:03
	(b) (4)	

US3032249

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 14:53:49

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	23 Mar 2021 15:37:03

US3032249

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 14:53:49

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:41:17
	(b) (4)	
User entered 'Yes (Y)'	Kelsey Kelley (b) (4)	23 Mar 2021 15:37:03
	(b) (4)	

US3032249

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 14:53:49

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:41:17
	(b) (4)	
User entered empty.	Kelsey Kelley (b) (4)	23 Mar 2021 15:37:03
	(b) (4)	

US3032249

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 14:53:49

[End time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:41:17
	(b) (4)	
User entered empty.	Kelsey Kelley (b) (4)	23 Mar 2021 15:37:03
	(b) (4)	

US3032249

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 14:53:49

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	23 Mar 2021 15:37:03

US3032249

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 14:53:49

[Severity](#)

Audit	User	Time (GMT)
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:41:17
User entered 'Grade 1/Mild (Grade 1/Mild)'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	23 Mar 2021 15:37:03

US3032249

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 14:53:49

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:41:17
	(b) (4)	
User entered 'No (N)'	Kelsey Kelley (b) (4)	23 Mar 2021 15:37:03
	(b) (4)	

US3032249

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 14:53:49

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:41:17
	(b) (4)	
User entered '0'	Kelsey Kelley (b) (4)	23 Mar 2021 15:37:03
	(b) (4)	

US3032249

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 14:53:49

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:41:17
	(b) (4)	
User entered '0'	Kelsey Kelley (b) (4)	23 Mar 2021 15:37:03
	(b) (4)	

US3032249

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 14:53:49

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:41:17
	(b) (4)	
User entered '0'	Kelsey Kelley (b) (4)	23 Mar 2021 15:37:03
	(b) (4)	

US3032249

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 14:53:49

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:41:17
	(b) (4)	
User entered empty.	Kelsey Kelley (b) (4)	23 Mar 2021 15:37:03
	(b) (4)	

US3032249

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 14:53:49

[Hospital Discharge Date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:41:17
	(b) (4)	
User entered empty.	Kelsey Kelley (b) (4)	23 Mar 2021 15:37:03
	(b) (4)	

US3032249

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 14:53:49

[Admitted to ICU?](#)

Audit	User	Time (GMT)
User signature succeeded.	Keith Vrbicky (b) (4) (b) (4)	06 Apr 2021 15:41:17
User entered empty.	Kelsey Kelley (b) (4) (b) (4)	23 Mar 2021 15:37:03

US3032249

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 14:53:49

[Number of Days in ICU](#)

Audit	User	Time (GMT)
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:41:17
User entered empty.	(b) (4) Kelsey Kelley (b) (4) (b) (4)	23 Mar 2021 15:37:03

US3032249

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 14:53:49

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:41:17
	(b) (4)	
User entered '0'	Kelsey Kelley (b) (4)	23 Mar 2021 15:37:03
	(b) (4)	

US3032249

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 14:53:49

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:41:17
	(b) (4)	
User entered '0'	Kelsey Kelley (b) (4)	23 Mar 2021 15:37:03
	(b) (4)	

US3032249

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 14:53:49

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:41:17
	(b) (4)	
User entered '0'	Kelsey Kelley (b) (4)	23 Mar 2021 15:37:03
	(b) (4)	

US3032249

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 14:53:49

[Relationship to investigational product](#)

Audit	User	Time (GMT)
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:41:17
User entered 'Not Related (NOT RELATED)'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	23 Mar 2021 15:37:03

US3032249

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 14:53:49

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:41:17
User entered 'Not Related (NOT RELATED)'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	23 Mar 2021 15:37:03

US3032249

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 14:53:49

[Action taken with investigational product](#)

Audit	User	Time (GMT)
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:41:17
User entered 'Not Applicable (NOT APPLICABLE)'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	23 Mar 2021 15:37:03

US3032249

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 14:53:49

[None](#)

Audit	User	Time (GMT)
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:41:17
User entered '1' reason for change: Data Entry Error	(b) (4)	
	Kelsey Kelley (b) (4)	05 Apr 2021 20:27:51
	(b) (4)	
User entered '0'	Kelsey Kelley (b) (4)	23 Mar 2021 15:37:03
	(b) (4)	

US3032249

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 14:53:49

[Concomitant Medication](#)

Audit	User	Time (GMT)
User closed query 'Per DM CLR: Other Action Taken = Concomitant Medication, however there is no Concomitant Medication recorded that matches this AE during this timeframe. Please review and add a Con Medication as appropriate or update action taken. ' (Site from DM).	(b) (4), (b) (6)	07 Apr 2021 11:21:46
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:41:17
Query 'Per DM CLR: Other Action Taken = Concomitant Medication, however there is no Concomitant Medication recorded that matches this AE during this timeframe. Please review and add a Con Medication as appropriate or update action taken. ' answered with 'Action of ConMed entered in error. Subject did not take medication for this AE. Corrected data.' (Site from DM).	(b) (4)	
User entered '0' reason for change: Data Entry Error	Kelsey Kelley (b) (4)	05 Apr 2021 20:28:20
User opened query 'Per DM CLR: Other Action Taken = Concomitant Medication, however there is no Concomitant Medication recorded that matches this AE during this timeframe. Please review and add a Con Medication as appropriate or update action taken. ' (Site from DM).	(b) (4)	
User entered '1'	Kelsey Kelley (b) (4)	05 Apr 2021 02:37:30
	(b) (4), (b) (6)	
	Kelsey Kelley (b) (4)	23 Mar 2021 15:37:03
	(b) (4)	

US3032249

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 14:53:49

[Concomitant Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:41:17
	(b) (4)	
User entered '0'	Kelsey Kelley (b) (4)	23 Mar 2021 15:37:03
	(b) (4)	

US3032249

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 14:53:49

[Outcome](#)

Audit	User	Time (GMT)
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:41:17
User entered 'Recovering/Resolving (RECOVERING/RESOLVING)'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	23 Mar 2021 15:37:03

US3032249

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 14:53:49

[If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:](#)

Audit	User	Time (GMT)
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:41:17
	(b) (4)	
User entered empty.	Kelsey Kelley (b) (4)	23 Mar 2021 15:37:03
	(b) (4)	

US3032249

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 14:53:49

[Narrative](#)

Audit	User	Time (GMT)
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:41:17
	(b) (4)	
User entered empty.	Kelsey Kelley (b) (4)	23 Mar 2021 15:37:03
	(b) (4)	

US3032249

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 14:53:49

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '0'	System	23 Mar 2021 15:37:03

US3032249

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 14:53:49

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered 'I'	System	23 Mar 2021 15:37:03

US3032249

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 14:53:49

[AEID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:30:55

US3032249

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 14:53:49

[Adverse event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:30:55
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:41:17
User coded data point as SOC: Respiratory, thoracic and mediastinal disorders, HLG: Respiratory disorders NEC, HLT: Breathing abnormalities, PT: Dyspnoea, LLT: Dyspnea - version MedDRA\\23.0.	Coder Import (b) (4)	26 Mar 2021 10:14:42
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4)	26 Mar 2021 10:14:42
Data point term sent to Coder	System	25 Mar 2021 20:57:26
User entered 'Dyspnea due to covid-19'	Kelsey Kelley (b) (4)	25 Mar 2021 20:57:07

US3032249

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 14:53:49

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:30:55
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:41:17
User entered 'Yes (Y)'	(b) (4) Kelsey Kelley (b) (4)	25 Mar 2021 20:57:07

US3032249

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 14:53:49

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:30:55
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:41:17
User entered 'No (N)'	(b) (4) Kelsey Kelley (b) (4)	25 Mar 2021 20:57:07

US3032249

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 14:53:49

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:30:55
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:41:17
User entered 'No (N)'	(b) (4) Kelsey Kelley (b) (4)	25 Mar 2021 20:57:07

US3032249

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 14:53:49

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:30:55
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:41:17
User entered '1 Mar 2021'	(b) (4) Kelsey Kelley (b) (4)	25 Mar 2021 20:57:07

US3032249

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 14:53:49

[Start time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:30:55
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:41:17
User entered empty.	(b) (4) Kelsey Kelley (b) (4)	25 Mar 2021 20:57:07

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Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 14:53:49

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:30:55
User entered empty.	System	25 Mar 2021 20:57:07

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Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 14:53:49

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:30:55
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:41:17
User entered 'No (N)'	(b) (4) Kelsey Kelley (b) (4)	25 Mar 2021 20:57:07

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Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 14:53:49

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:30:55
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:41:17
User entered '5 Mar 2021'	(b) (4) Kelsey Kelley (b) (4)	25 Mar 2021 20:57:07
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 14:53:49

[End time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:30:55
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:41:17
User entered empty.	(b) (4) Kelsey Kelley (b) (4)	25 Mar 2021 20:57:07

US3032249

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 14:53:49

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:30:55
User entered empty.	System	25 Mar 2021 20:57:07

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Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 14:53:49

[Severity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:30:55
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:41:17
User entered 'Grade 3/Severe (Grade 3/Severe)'	(b) (4) Kelsey Kelley (b) (4)	25 Mar 2021 20:57:07

US3032249

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 14:53:49

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:30:55
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:41:17
User entered 'No (N)'	(b) (4) Kelsey Kelley (b) (4)	25 Mar 2021 20:57:07

US3032249

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 14:53:49

[Death](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:30:55
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:41:17
User entered '0'	(b) (4) Kelsey Kelley (b) (4)	25 Mar 2021 20:57:07

US3032249

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 14:53:49

[Life threatening](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:30:55
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:41:17
User entered '0'	(b) (4) Kelsey Kelley (b) (4)	25 Mar 2021 20:57:07

US3032249

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 14:53:49

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:30:55
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:41:17
User entered '0'	Kelsey Kelley (b) (4)	25 Mar 2021 20:57:07

US3032249

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 14:53:49

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:30:55
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:41:17
User entered empty.	(b) (4) Kelsey Kelley (b) (4)	25 Mar 2021 20:57:07

US3032249

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 14:53:49

Hospital Discharge Date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:30:55
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:41:17
User entered empty.	(b) (4) Kelsey Kelley (b) (4)	25 Mar 2021 20:57:07

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Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 14:53:49

[Admitted to ICU?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:30:55
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:41:17
User entered empty.	(b) (4) Kelsey Kelley (b) (4)	25 Mar 2021 20:57:07

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Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 14:53:49

[Number of Days in ICU](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:30:55
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:41:17
User entered empty.	(b) (4) Kelsey Kelley (b) (4)	25 Mar 2021 20:57:07

US3032249

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 14:53:49

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:30:55
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:41:17
User entered '0'	(b) (4) Kelsey Kelley (b) (4)	25 Mar 2021 20:57:07

US3032249

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 14:53:49

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:30:55
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:41:17
User entered '0'	(b) (4) Kelsey Kelley (b) (4)	25 Mar 2021 20:57:07

US3032249

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 14:53:49

[Other medically important event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:30:55
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:41:17
User entered '0'	(b) (4) Kelsey Kelley (b) (4)	25 Mar 2021 20:57:07

US3032249

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 14:53:49

[Relationship to investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:30:55
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:41:17
User entered 'Not Related (NOT RELATED)'	(b) (4) Kelsey Kelley (b) (4)	25 Mar 2021 20:57:07

US3032249

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 14:53:49

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:30:55
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:41:17
User entered 'Not Related (NOT RELATED)'	(b) (4) Kelsey Kelley (b) (4)	25 Mar 2021 20:57:07

US3032249

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 14:53:49

[Action taken with investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:30:55
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:41:17
User entered 'Not Applicable (NOT APPLICABLE)'	(b) (4) Kelsey Kelley (b) (4)	25 Mar 2021 20:57:07

US3032249

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 14:53:49

[None](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:30:55
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:41:17
User entered 'I'	(b) (4) Kelsey Kelley (b) (4)	25 Mar 2021 20:57:07

US3032249

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 14:53:49

[Concomitant Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:30:55
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:41:17
User entered '0'	(b) (4) Kelsey Kelley (b) (4)	25 Mar 2021 20:57:07

US3032249

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 14:53:49

[Concomitant Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:30:55
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:41:17
User entered '0'	(b) (4) Kelsey Kelley (b) (4)	25 Mar 2021 20:57:07

US3032249

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 14:53:49

[Outcome](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:30:55
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:41:17
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)'	(b) (4) Kelsey Kelley (b) (4)	25 Mar 2021 20:57:07

US3032249

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 14:53:49

[If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:30:55
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:41:17
User entered empty.	(b) (4) Kelsey Kelley (b) (4)	25 Mar 2021 20:57:07
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 14:53:49

[Narrative](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:30:55
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:41:17
User entered empty.	(b) (4) Kelsey Kelley (b) (4)	25 Mar 2021 20:57:07

US3032249

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 14:53:49

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:30:55
User entered '0'	System	25 Mar 2021 20:57:07

US3032249

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 14:53:49

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:30:55
User entered '1'	System	25 Mar 2021 20:57:07

US3032249

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 14:53:49

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:30:55

US3032249

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 14:53:49

[AEID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:42:34

US3032249

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 14:53:49

[Adverse event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:42:34
User coded data point as SOC: Reproductive system and breast disorders, HLG: Reproductive tract disorders NEC, HLT: Reproductive tract disorders NEC (excl neoplasms), PT: Perineal disorder, LLT: Perineal disorder - version MedDRA\\23.0.	Coder Import (b) (4)	08 Apr 2021 08:47:54
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4)	08 Apr 2021 08:47:54
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:41:17
Data point term sent to Coder	(b) (4) System	25 Mar 2021 20:58:27
User entered 'perineal irritation in female'	Kelsey Kelley (b) (4)	25 Mar 2021 20:58:05
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 14:53:49

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:42:34
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:41:17
User entered 'Yes (Y)'	(b) (4) Kelsey Kelley (b) (4)	25 Mar 2021 20:58:05

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Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 14:53:49

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:42:34
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:41:17
User entered 'No (N)'	(b) (4) Kelsey Kelley (b) (4)	25 Mar 2021 20:58:05

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Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 14:53:49

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:42:34
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:41:17
User entered 'No (N)'	(b) (4) Kelsey Kelley (b) (4)	25 Mar 2021 20:58:05

US3032249

Folder: Adverse Events

Form: Adverse Events (7)

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[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:42:34
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:41:17
User entered '19 Mar 2021'	(b) (4) Kelsey Kelley (b) (4)	25 Mar 2021 20:58:05
	(b) (4)	

US3032249

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 14:53:49

[Start time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:42:34
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:41:17
User entered empty.	(b) (4) Kelsey Kelley (b) (4)	25 Mar 2021 20:58:05

US3032249

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 14:53:49

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:42:34
User entered empty.	System	25 Mar 2021 20:58:05

US3032249

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 14:53:49

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:42:34
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:41:17
User entered 'No (N)'	(b) (4) Kelsey Kelley (b) (4)	25 Mar 2021 20:58:05

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Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 14:53:49

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:42:34
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:41:17
User entered '22 Mar 2021'	(b) (4) Kelsey Kelley (b) (4)	25 Mar 2021 20:58:05
	(b) (4)	

US3032249

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 14:53:49

[End time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:42:34
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:41:17
User entered empty.	(b) (4) Kelsey Kelley (b) (4)	25 Mar 2021 20:58:05

US3032249

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 14:53:49

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:42:34
User entered empty.	System	25 Mar 2021 20:58:05

US3032249

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 14:53:49

[Severity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:42:34
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:41:17
User entered 'Grade 1/Mild (Grade 1/Mild)'	Kelsey Kelley (b) (4)	25 Mar 2021 20:58:05

US3032249

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 14:53:49

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:42:34
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:41:17
User entered 'No (N)'	(b) (4) Kelsey Kelley (b) (4)	25 Mar 2021 20:58:05

US3032249

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 14:53:49

[Death](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:42:34
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:41:17
User entered '0'	(b) (4) Kelsey Kelley (b) (4)	25 Mar 2021 20:58:05

US3032249

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 14:53:49

[Life threatening](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:42:34
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:41:17
User entered '0'	(b) (4) Kelsey Kelley (b) (4)	25 Mar 2021 20:58:05

US3032249

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 14:53:49

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:42:34
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:41:17
User entered '0'	Kelsey Kelley (b) (4)	25 Mar 2021 20:58:05

US3032249

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 14:53:49

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:42:34
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:41:17
User entered empty.	(b) (4) Kelsey Kelley (b) (4)	25 Mar 2021 20:58:05

US3032249

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 14:53:49

Hospital Discharge Date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:42:34
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:41:17
User entered empty.	(b) (4) Kelsey Kelley (b) (4)	25 Mar 2021 20:58:05

US3032249

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 14:53:49

[Admitted to ICU?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:42:34
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:41:17
User entered empty.	(b) (4) Kelsey Kelley (b) (4)	25 Mar 2021 20:58:05

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Folder: Adverse Events

Form: Adverse Events (7)

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[Number of Days in ICU](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:42:34
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:41:17
User entered empty.	(b) (4) Kelsey Kelley (b) (4)	25 Mar 2021 20:58:05

US3032249

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 14:53:49

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:42:34
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:41:17
User entered '0'	(b) (4) Kelsey Kelley (b) (4)	25 Mar 2021 20:58:05

US3032249

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 14:53:49

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:42:34
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:41:17
User entered '0'	Kelsey Kelley (b) (4)	25 Mar 2021 20:58:05

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Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 14:53:49

[Other medically important event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:42:34
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:41:17
User entered '0'	(b) (4) Kelsey Kelley (b) (4)	25 Mar 2021 20:58:05

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Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 14:53:49

[Relationship to investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:42:34
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:41:17
User entered 'Not Related (NOT RELATED)'	(b) (4) Kelsey Kelley (b) (4)	25 Mar 2021 20:58:05

US3032249

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 14:53:49

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:42:34
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:41:17
User entered 'Not Related (NOT RELATED)'	(b) (4) Kelsey Kelley (b) (4)	25 Mar 2021 20:58:05

US3032249

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 14:53:49

[Action taken with investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:42:34
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:41:17
User entered 'Not Applicable (NOT APPLICABLE)'	(b) (4) Kelsey Kelley (b) (4)	25 Mar 2021 20:58:05

US3032249

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 14:53:49

[None](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:42:34
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:41:17
User entered '0'	(b) (4) Kelsey Kelley (b) (4)	25 Mar 2021 20:58:05

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Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 14:53:49

[Concomitant Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:42:34
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:41:17
User entered 'I'	(b) (4) Kelsey Kelley (b) (4)	25 Mar 2021 20:58:05

US3032249

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 14:53:49

[Concomitant Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:42:34
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:41:17
User entered '0'	(b) (4) Kelsey Kelley (b) (4)	25 Mar 2021 20:58:05

US3032249

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 14:53:49

[Outcome](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:42:34
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:41:17
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)'	Kelsey Kelley (b) (4)	25 Mar 2021 20:58:05

US3032249

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 14:53:49

[If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:42:34
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:41:17
User entered empty.	(b) (4) Kelsey Kelley (b) (4)	25 Mar 2021 20:58:05

US3032249

Folder: Adverse Events

Form: Adverse Events (7)

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[Narrative](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:42:34
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:41:17
User entered empty.	(b) (4) Kelsey Kelley (b) (4)	25 Mar 2021 20:58:05

US3032249

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 14:53:49

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:42:34
User entered '0'	System	25 Mar 2021 20:58:05

US3032249

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 14:53:49

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:42:34
User entered '1'	System	25 Mar 2021 20:58:05

US3032249

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 14:53:49

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:42:34

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Generated On: 09 Jun 2021 14:53:49

[Were any prior/concomitant medications and/or vaccinations taken?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 06:09:06
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:50:49
User entered 'Yes (Y)'	Kelsey Kelley (b) (4)	21 Sep 2020 17:19:04

US3032249

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 14:53:49

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:50:49
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: DRUGS FOR ACID RELATED DISORDERS, ATC: DRUGS FOR PEPTIC ULCER AND GASTRO-OESOPHAGEAL REFLUX DISEASE (GORD), ATC: PROTON PUMP INHIBITORS, PRODUCT: OMEPRAZOLE - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4)	21 Sep 2020 17:26:46
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	21 Sep 2020 17:26:46
Data point term sent to Coder	System	21 Sep 2020 17:25:31
User entered 'omeprazole'	Kelsey Kelley (b) (4)	21 Sep 2020 17:25:20

US3032249

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 14:53:49

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:50:49
	(b) (4)	
User entered 'No (N)'	Kelsey Kelley (b) (4)	21 Sep 2020 17:25:20
	(b) (4)	

US3032249

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 14:53:49

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:50:49
User entered 'medical history: acid reflux'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	21 Sep 2020 17:25:20

US3032249

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 14:53:49

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:50:49
User entered '40'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	21 Sep 2020 17:25:20

US3032249

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 14:53:49

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:50:49
	(b) (4)	
User entered 'mg (mg)'	Kelsey Kelley (b) (4)	21 Sep 2020 17:25:20
	(b) (4)	

US3032249

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 14:53:49

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:50:49
	(b) (4)	
User entered empty.	Kelsey Kelley (b) (4)	21 Sep 2020 17:25:20
	(b) (4)	

US3032249

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 14:53:49

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:50:49
User entered 'once daily (QD)'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	21 Sep 2020 17:25:20

US3032249

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 14:53:49

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:50:49
	(b) (4)	
User entered empty.	Kelsey Kelley (b) (4)	21 Sep 2020 17:25:20
	(b) (4)	

US3032249

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 14:53:49

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:50:49
User entered 'Oral (ORAL)'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	21 Sep 2020 17:25:20

US3032249

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 14:53:49

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:50:49
	(b) (4)	
User entered empty.	Kelsey Kelley (b) (4)	21 Sep 2020 17:25:20
	(b) (4)	

US3032249

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 14:53:49

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:50:49
	(b) (4)	
User entered 'un UNK 2017'	Kelsey Kelley (b) (4)	21 Sep 2020 17:25:20
	(b) (4)	

US3032249

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 14:53:49

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:50:49
	(b) (4)	
User entered '0'	Kelsey Kelley (b) (4)	21 Sep 2020 17:25:20
	(b) (4)	

US3032249

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 14:53:49

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:50:49
	(b) (4)	
User entered 'Yes (Y)'	Kelsey Kelley (b) (4)	21 Sep 2020 17:25:20
	(b) (4)	

US3032249

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 14:53:49

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:50:49
	(b) (4)	
User entered empty.	Kelsey Kelley (b) (4)	21 Sep 2020 17:25:20
	(b) (4)	

US3032249

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 14:53:49

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:50:49
	(b) (4)	
User entered 'No (N)'	Kelsey Kelley (b) (4)	21 Sep 2020 17:25:20
	(b) (4)	

US3032249

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 14:53:49

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	21 Sep 2020 17:25:20

US3032249

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 14:53:49

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	21 Sep 2020 17:25:20

US3032249

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 14:53:49

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	21 Sep 2020 17:25:20

US3032249

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 14:53:49

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:50:49
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: AGENTS ACTING ON THE RENIN-ANGIOTENSIN SYSTEM, ATC: ANGIOTENSIN II RECEPTOR BLOCKERS (ARBS), COMBINATIONS, ATC: ANGIOTENSIN II RECEPTOR BLOCKERS (ARBS) AND DIURETICS, PRODUCT: HYDROCHLOROTHIAZIDE;OLMESARTAN - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4) (b) (4)	25 Sep 2020 11:38:50
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	25 Sep 2020 11:38:50
Data point term sent to Coder	System	21 Sep 2020 17:27:36
User entered 'olmesartan hctz'	Kelsey Kelley (b) (4) (b) (4)	21 Sep 2020 17:26:57

US3032249

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 14:53:49

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:50:49
	(b) (4)	
User entered 'No (N)'	Kelsey Kelley (b) (4)	21 Sep 2020 17:26:57
	(b) (4)	

US3032249

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 14:53:49

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:50:49
User entered 'medical history: hypertension'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	21 Sep 2020 17:26:57

US3032249

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 14:53:49

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Keith Vrbicky (b) (4)	22 Oct 2020 14:56:35
User closed query 'Per DM CLR: Please review the recorded combination dose for this medication, as it seems this is not the standard combination dose. Please correct the dosage (i.e. 40/12.5) or provide explanation for alternate dosage. ' (Site from DM). Query 'Per DM CLR: Please review the recorded combination dose for this medication, as it seems this is not the standard combination dose. Please correct the dosage (i.e. 40/12.5) or provide explanation for alternate dosage. ' answered with 'data updated' (Site from DM).	(b) (4) (b) (4), (b) (6)	20 Oct 2020 13:55:36
Signature has been broken.	Linden DeBoer (b) (4)	09 Oct 2020 15:49:02
User entered '40/12.5' reason for change: Data Entry Error	(b) (4)	09 Oct 2020 15:48:53
User opened query 'Per DM CLR: Please review the recorded combination dose for this medication, as it seems this is not the standard combination dose. Please correct the dosage (i.e. 40/12.5) or provide explanation for alternate dosage. ' (Site from DM). User signature succeeded.	Linden DeBoer (b) (4)	09 Oct 2020 15:48:53
	(b) (4)	
	(b) (4), (b) (6)	08 Oct 2020 07:23:43
	Keith Vrbicky (b) (4)	28 Sep 2020 17:50:49
	(b) (4)	
User entered '40-125'	Kelsey Kelley (b) (4)	21 Sep 2020 17:26:57
	(b) (4)	

US3032249

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 14:53:49

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:50:49
	(b) (4)	
User entered 'mg (mg)'	Kelsey Kelley (b) (4)	21 Sep 2020 17:26:57
	(b) (4)	

US3032249

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 14:53:49

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:50:49
	(b) (4)	
User entered empty.	Kelsey Kelley (b) (4)	21 Sep 2020 17:26:57
	(b) (4)	

US3032249

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 14:53:49

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:50:49
User entered 'once daily (QD)'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	21 Sep 2020 17:26:57

US3032249

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 14:53:49

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:50:49
User entered empty.	(b) (4) Kelsey Kelley (b) (4) (b) (4)	21 Sep 2020 17:26:57

US3032249

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 14:53:49

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:50:49
	(b) (4)	
User entered 'Oral (ORAL)'	Kelsey Kelley (b) (4)	21 Sep 2020 17:26:57
	(b) (4)	

US3032249

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 14:53:49

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:50:49
	(b) (4)	
User entered empty.	Kelsey Kelley (b) (4)	21 Sep 2020 17:26:57
	(b) (4)	

US3032249

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 14:53:49

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:50:49
	(b) (4)	
User entered 'un UNK 2017'	Kelsey Kelley (b) (4)	21 Sep 2020 17:26:57
	(b) (4)	

US3032249

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 14:53:49

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:50:49
	(b) (4)	
User entered '0'	Kelsey Kelley (b) (4)	21 Sep 2020 17:26:57
	(b) (4)	

US3032249

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 14:53:49

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:50:49
	(b) (4)	
User entered 'Yes (Y)'	Kelsey Kelley (b) (4)	21 Sep 2020 17:26:57
	(b) (4)	

US3032249

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 14:53:49

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:50:49
	(b) (4)	
User entered empty.	Kelsey Kelley (b) (4)	21 Sep 2020 17:26:57
	(b) (4)	

US3032249

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 14:53:49

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:50:49
	(b) (4)	
User entered 'No (N)'	Kelsey Kelley (b) (4)	21 Sep 2020 17:26:57
	(b) (4)	

US3032249

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 14:53:49

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	21 Sep 2020 17:26:57

US3032249

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 14:53:49

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	21 Sep 2020 17:26:57

US3032249

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 14:53:49

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	21 Sep 2020 17:26:57

US3032249

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 14:53:49

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:50:49
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: DIURETICS, ATC: HIGH-CEILING DIURETICS, ATC: SULFONAMIDES, PLAIN, PRODUCT: FUROSEMIDE - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4)	28 Sep 2020 15:56:40
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	28 Sep 2020 15:56:40
Data point term sent to Coder Coding entries removed.	System Kelsey Kelley (b) (4)	28 Sep 2020 15:55:39 28 Sep 2020 15:54:40
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: DIURETICS, ATC: HIGH-CEILING DIURETICS, ATC: SULFONAMIDES, PLAIN, PRODUCT: FUROSEMIDE - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4)	21 Sep 2020 17:28:43
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	21 Sep 2020 17:28:43
Data point term sent to Coder User entered 'furosemide'	System Kelsey Kelley (b) (4)	21 Sep 2020 17:27:37 21 Sep 2020 17:27:35

US3032249

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 14:53:49

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:50:49
	(b) (4)	
User entered 'No (N)'	Kelsey Kelley (b) (4)	21 Sep 2020 17:27:35
	(b) (4)	

US3032249

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 14:53:49

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:50:49
User entered 'MEDICAL HISTORY: bilateral lower leg EDEMA' reason for change: Data Entry Error	(b) (4) Kelsey Kelley (b) (4)	28 Sep 2020 15:54:40
User entered 'medical history: edema'	(b) (4) Kelsey Kelley (b) (4)	21 Sep 2020 17:27:35

US3032249

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 14:53:49

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:50:49
User entered '40'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	21 Sep 2020 17:27:35

US3032249

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 14:53:49

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:50:49
	(b) (4)	
User entered 'mg (mg)'	Kelsey Kelley (b) (4)	21 Sep 2020 17:27:35
	(b) (4)	

US3032249

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 14:53:49

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:50:49
	(b) (4)	
User entered empty.	Kelsey Kelley (b) (4)	21 Sep 2020 17:27:35
	(b) (4)	

US3032249

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 14:53:49

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:50:49
User entered 'once daily (QD)'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	21 Sep 2020 17:27:35

US3032249

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 14:53:49

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:50:49
User entered empty.	(b) (4) Kelsey Kelley (b) (4) (b) (4)	21 Sep 2020 17:27:35

US3032249

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 14:53:49

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:50:49
User entered 'Oral (ORAL)'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	21 Sep 2020 17:27:35

US3032249

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 14:53:49

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:50:49
	(b) (4)	
User entered empty.	Kelsey Kelley (b) (4)	21 Sep 2020 17:27:35
	(b) (4)	

US3032249

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 14:53:49

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:50:49
	(b) (4)	
User entered 'un UNK 2018'	Kelsey Kelley (b) (4)	21 Sep 2020 17:27:35
	(b) (4)	

US3032249

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 14:53:49

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:50:49
	(b) (4)	
User entered '0'	Kelsey Kelley (b) (4)	21 Sep 2020 17:27:35
	(b) (4)	

US3032249

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 14:53:49

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:50:49
	(b) (4)	
User entered 'Yes (Y)'	Kelsey Kelley (b) (4)	21 Sep 2020 17:27:35
	(b) (4)	

US3032249

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 14:53:49

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:50:49
	(b) (4)	
User entered empty.	Kelsey Kelley (b) (4)	21 Sep 2020 17:27:35
	(b) (4)	

US3032249

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 14:53:49

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:50:49
	(b) (4)	
User entered 'No (N)'	Kelsey Kelley (b) (4)	21 Sep 2020 17:27:35
	(b) (4)	

US3032249

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 14:53:49

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	21 Sep 2020 17:27:35

US3032249

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 14:53:49

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	21 Sep 2020 17:27:35

US3032249

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 14:53:49

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	21 Sep 2020 17:27:35

US3032249

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 14:53:49

Name of Medication

Audit	User	Time (GMT)
User signature succeeded.	Keith Vrbicky (b) (4)	05 Oct 2020 16:18:54
User coded data point as ATC: GENITO URINARY SYSTEM AND SEX HORMONES, ATC: UROLOGICALS, ATC: UROLOGICALS, ATC: DRUGS FOR URINARY FREQUENCY AND INCONTINENCE, PRODUCT: OXYBUTYNIN - version WHODrug-Global-B3\202003.	(b) (4) Coder Import (b) (4)	04 Oct 2020 05:44:30
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\202003.	Coder Import (b) (4)	04 Oct 2020 05:44:30
Data point term sent to Coder	System	30 Sep 2020 22:29:36
User closed query 'CDM Coding: This medication cannot be referred in the standard coding dictionary. Please verify the spelling of this medication. If spelling is correct, please enter the active ingredients in parentheses following the drug name and make your change to the reported term. Thank you.' (Site from System).	System	30 Sep 2020 22:29:35
Query 'CDM Coding: This medication cannot be referred in the standard coding dictionary. Please verify the spelling of this medication. If spelling is correct, please enter the active ingredients in parentheses following the drug name and make your change to the reported term. Thank you.' answered with 'updated' (Site from System).	Samantha Wieseler (b) (4)	30 Sep 2020 22:29:35
Data point term sent to Coder	System	30 Sep 2020 22:29:35
Signature has been broken.	Samantha Wieseler (b) (4)	30 Sep 2020 22:29:29
User entered 'OXBUTYNin ER' reason for change: Data Entry Error	Samantha Wieseler (b) (4)	30 Sep 2020 22:29:29
User opened query 'CDM Coding: This medication cannot be referred in the standard coding dictionary. Please verify the spelling of this medication. If spelling is correct, please enter the active ingredients in parentheses following the drug name and make your change to the reported term. Thank you.' (Site from System).	Coder Import (b) (4)	29 Sep 2020 07:30:43
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:50:49
Data point term sent to Coder	System	21 Sep 2020 17:31:48

US3032249

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 14:53:49

[Name of Medication](#)

Audit	User	Time (GMT)
User entered 'oxbutyniol er'	Kelsey Kelley (b) (4) (b) (4)	21 Sep 2020 17:31:11

US3032249

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 14:53:49

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:50:49
	(b) (4)	
User entered 'No (N)'	Kelsey Kelley (b) (4)	21 Sep 2020 17:31:11
	(b) (4)	

US3032249

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 14:53:49

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:50:49
User entered 'medical history: overactive bladder'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	21 Sep 2020 17:31:11

US3032249

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 14:53:49

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:50:49
	(b) (4)	
User entered '10'	Kelsey Kelley (b) (4)	21 Sep 2020 17:31:11
	(b) (4)	

US3032249

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 14:53:49

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:50:49
	(b) (4)	
User entered 'mg (mg)'	Kelsey Kelley (b) (4)	21 Sep 2020 17:31:11
	(b) (4)	

US3032249

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 14:53:49

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:50:49
	(b) (4)	
User entered empty.	Kelsey Kelley (b) (4)	21 Sep 2020 17:31:11
	(b) (4)	

US3032249

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 14:53:49

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:50:49
User entered 'once daily (QD)'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	21 Sep 2020 17:31:11

US3032249

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 14:53:49

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:50:49
User entered empty.	(b) (4) Kelsey Kelley (b) (4) (b) (4)	21 Sep 2020 17:31:11

US3032249

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 14:53:49

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:50:49
User entered 'Oral (ORAL)'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	21 Sep 2020 17:31:11

US3032249

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 14:53:49

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:50:49
	(b) (4)	
User entered empty.	Kelsey Kelley (b) (4)	21 Sep 2020 17:31:11
	(b) (4)	

US3032249

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 14:53:49

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:50:49
	(b) (4)	
User entered 'un UNK 2019'	Kelsey Kelley (b) (4)	21 Sep 2020 17:31:11
	(b) (4)	

US3032249

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 14:53:49

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:50:49
	(b) (4)	
User entered '0'	Kelsey Kelley (b) (4)	21 Sep 2020 17:31:11
	(b) (4)	

US3032249

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 14:53:49

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:50:49
User entered 'Yes (Y)'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	21 Sep 2020 17:31:11

US3032249

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 14:53:49

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:50:49
	(b) (4)	
User entered empty.	Kelsey Kelley (b) (4)	21 Sep 2020 17:31:11
	(b) (4)	

US3032249

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 14:53:49

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:50:49
	(b) (4)	
User entered 'No (N)'	Kelsey Kelley (b) (4)	21 Sep 2020 17:31:11
	(b) (4)	

US3032249

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 14:53:49

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	21 Sep 2020 17:31:11

US3032249

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 14:53:49

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	21 Sep 2020 17:31:11

US3032249

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 14:53:49

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	21 Sep 2020 17:31:11

US3032249

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 14:53:49

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:50:49
User coded data point as ATC: RESPIRATORY SYSTEM, ATC: DRUGS FOR OBSTRUCTIVE AIRWAY DISEASES, ATC: OTHER DRUGS FOR OBSTRUCTIVE AIRWAY DISEASES, INHALANTS, ATC: GLUCOCORTICOIDS, PRODUCT: FLUTICASONE - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4)	22 Sep 2020 05:15:56
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	22 Sep 2020 05:15:56
Data point term sent to Coder	System	21 Sep 2020 17:32:51
User entered 'fluticasone spray'	Kelsey Kelley (b) (4) (b) (4)	21 Sep 2020 17:31:53

US3032249

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 14:53:49

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:50:49
	(b) (4)	
User entered 'No (N)'	Kelsey Kelley (b) (4)	21 Sep 2020 17:31:53
	(b) (4)	

US3032249

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 14:53:49

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:50:49
User entered 'medical history: seasonal allergies'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	21 Sep 2020 17:31:53

US3032249

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 14:53:49

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:50:49
User entered '50'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	21 Sep 2020 17:31:53

US3032249

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 14:53:49

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:50:49
	(b) (4)	
User entered 'ug (ug)'	Kelsey Kelley (b) (4)	21 Sep 2020 17:31:53
	(b) (4)	

US3032249

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 14:53:49

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:50:49
	(b) (4)	
User entered empty.	Kelsey Kelley (b) (4)	21 Sep 2020 17:31:53
	(b) (4)	

US3032249

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 14:53:49

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:50:49
User entered 'once daily (QD)'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	21 Sep 2020 17:31:53

US3032249

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 14:53:49

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:50:49
	(b) (4)	
User entered empty.	Kelsey Kelley (b) (4)	21 Sep 2020 17:31:53
	(b) (4)	

US3032249

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 14:53:49

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:50:49
	(b) (4)	
User entered 'Respiratory (Inhalation) (RESPIRATORY (INHALATION))'	Kelsey Kelley (b) (4)	21 Sep 2020 17:31:53
	(b) (4)	

US3032249

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 14:53:49

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:50:49
	(b) (4)	
User entered empty.	Kelsey Kelley (b) (4)	21 Sep 2020 17:31:53
	(b) (4)	

US3032249

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 14:53:49

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:50:49
	(b) (4)	
User entered 'un UNK 2008'	Kelsey Kelley (b) (4)	21 Sep 2020 17:31:53
	(b) (4)	

US3032249

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 14:53:49

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:50:49
	(b) (4)	
User entered '0'	Kelsey Kelley (b) (4)	21 Sep 2020 17:31:53
	(b) (4)	

US3032249

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 14:53:49

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:50:49
	(b) (4)	
User entered 'Yes (Y)'	Kelsey Kelley (b) (4)	21 Sep 2020 17:31:53
	(b) (4)	

US3032249

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 14:53:49

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:50:49
	(b) (4)	
User entered empty.	Kelsey Kelley (b) (4)	21 Sep 2020 17:31:53
	(b) (4)	

US3032249

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 14:53:49

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:50:49
	(b) (4)	
User entered 'No (N)'	Kelsey Kelley (b) (4)	21 Sep 2020 17:31:53
	(b) (4)	

US3032249

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 14:53:49

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	21 Sep 2020 17:31:53

US3032249

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 14:53:49

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	21 Sep 2020 17:31:53

US3032249

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 14:53:49

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	21 Sep 2020 17:31:53

US3032249

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 14:53:49

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:50:49
User coded data point as ATC: RESPIRATORY SYSTEM, ATC: ANTIHISTAMINES FOR SYSTEMIC USE, ATC: ANTIHISTAMINES FOR SYSTEMIC USE, ATC: OTHER ANTIHISTAMINES FOR SYSTEMIC USE, PRODUCT: FEXOFENADINE - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4)	21 Sep 2020 17:33:40
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	21 Sep 2020 17:33:40
Data point term sent to Coder	System	21 Sep 2020 17:32:52
User entered 'fexofenadine'	Kelsey Kelley (b) (4) (b) (4)	21 Sep 2020 17:32:21

US3032249

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 14:53:49

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:50:49
	(b) (4)	
User entered 'No (N)'	Kelsey Kelley (b) (4)	21 Sep 2020 17:32:21
	(b) (4)	

US3032249

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 14:53:49

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:50:49
User entered 'medical history: seasonal allergies'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	21 Sep 2020 17:32:21

US3032249

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 14:53:49

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:50:49
	(b) (4)	
User entered '180'	Kelsey Kelley (b) (4)	21 Sep 2020 17:32:21
	(b) (4)	

US3032249

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 14:53:49

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:50:49
	(b) (4)	
User entered 'mg (mg)'	Kelsey Kelley (b) (4)	21 Sep 2020 17:32:21
	(b) (4)	

US3032249

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 14:53:49

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:50:49
	(b) (4)	
User entered empty.	Kelsey Kelley (b) (4)	21 Sep 2020 17:32:21
	(b) (4)	

US3032249

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 14:53:49

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:50:49
	(b) (4)	
User entered 'once daily (QD)'	Kelsey Kelley (b) (4)	21 Sep 2020 17:32:21
	(b) (4)	

US3032249

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 14:53:49

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:50:49
	(b) (4)	
User entered empty.	Kelsey Kelley (b) (4)	21 Sep 2020 17:32:21
	(b) (4)	

US3032249

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 14:53:49

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:50:49
	(b) (4)	
User entered 'Oral (ORAL)'	Kelsey Kelley (b) (4)	21 Sep 2020 17:32:21
	(b) (4)	

US3032249

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 14:53:49

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:50:49
	(b) (4)	
User entered empty.	Kelsey Kelley (b) (4)	21 Sep 2020 17:32:21
	(b) (4)	

US3032249

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 14:53:49

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:50:49
	(b) (4)	
User entered 'un UNK 2009'	Kelsey Kelley (b) (4)	21 Sep 2020 17:32:21
	(b) (4)	

US3032249

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 14:53:49

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:50:49
	(b) (4)	
User entered '0'	Kelsey Kelley (b) (4)	21 Sep 2020 17:32:21
	(b) (4)	

US3032249

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 14:53:49

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:50:49
	(b) (4)	
User entered 'Yes (Y)'	Kelsey Kelley (b) (4)	21 Sep 2020 17:32:21
	(b) (4)	

US3032249

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 14:53:49

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:50:49
	(b) (4)	
User entered empty.	Kelsey Kelley (b) (4)	21 Sep 2020 17:32:21
	(b) (4)	

US3032249

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 14:53:49

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:50:49
	(b) (4)	
User entered 'No (N)'	Kelsey Kelley (b) (4)	21 Sep 2020 17:32:21
	(b) (4)	

US3032249

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 14:53:49

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	21 Sep 2020 17:32:21

US3032249

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 14:53:49

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	21 Sep 2020 17:32:21

US3032249

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 14:53:49

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	21 Sep 2020 17:32:21

US3032249

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 14:53:49

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:50:49
User coded data point as ATC: MUSCULO-SKELETAL SYSTEM, ATC: ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, ATC: ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, NON-STERIODS, ATC: OTHER ANTIINFLAMMATORY AND ANTIRHEUMATIC AGENTS, NON-STERIODS, PRODUCT: CHONDROITIN;GLUCOSAMINE - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4) (b) (4)	22 Sep 2020 01:11:48
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	22 Sep 2020 01:11:48
Data point term sent to Coder	System	21 Sep 2020 17:33:54
User entered 'glucosamine chondroitin'	Kelsey Kelley (b) (4) (b) (4)	21 Sep 2020 17:33:15

US3032249

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 14:53:49

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:50:49
	(b) (4)	
User entered 'No (N)'	Kelsey Kelley (b) (4)	21 Sep 2020 17:33:15
	(b) (4)	

US3032249

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 14:53:49

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:50:49
User entered 'medical history: osteoarthritis'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	21 Sep 2020 17:33:15

US3032249

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 14:53:49

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Keith Vrbicky (b) (4)	08 Dec 2020 19:48:23
User closed query 'Per DM CLR: Please note, this is a combination drug; however, only one component has been reported in the dose field. Please update the dose to include both components as applicable (e.g., 500/125). ' (Site from DM).	(b) (4) (b) (4), (b) (6)	04 Dec 2020 11:29:49
Query 'Per DM CLR: Please note, this is a combination drug; however, only one component has been reported in the dose field. Please update the dose to include both components as applicable (e.g., 500/125). ' answered with 'data updated' (Site from DM).	Kelsey Kelley (b) (4) (b) (4)	03 Dec 2020 16:02:55
Signature has been broken.	Kelsey Kelley (b) (4) (b) (4)	03 Dec 2020 16:02:40
User entered '1500/1200' reason for change: Data Entry Error	Kelsey Kelley (b) (4) (b) (4)	03 Dec 2020 16:02:40
User opened query 'Per DM CLR: Please note, this is a combination drug; however, only one component has been reported in the dose field. Please update the dose to include both components as applicable (e.g., 500/125). ' (Site from DM).	(b) (4), (b) (6)	03 Dec 2020 10:08:11
User signature succeeded.	Keith Vrbicky (b) (4) (b) (4)	28 Sep 2020 17:50:49
User entered '1500'	Kelsey Kelley (b) (4) (b) (4)	21 Sep 2020 17:33:15

US3032249

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 14:53:49

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:50:49
	(b) (4)	
User entered 'mg (mg)'	Kelsey Kelley (b) (4)	21 Sep 2020 17:33:15
	(b) (4)	

US3032249

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 14:53:49

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:50:49
	(b) (4)	
User entered empty.	Kelsey Kelley (b) (4)	21 Sep 2020 17:33:15
	(b) (4)	

US3032249

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 14:53:49

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:50:49
User entered 'once daily (QD)'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	21 Sep 2020 17:33:15

US3032249

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 14:53:49

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:50:49
User entered empty.	(b) (4) Kelsey Kelley (b) (4) (b) (4)	21 Sep 2020 17:33:15

US3032249

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 14:53:49

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:50:49
User entered 'Oral (ORAL)'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	21 Sep 2020 17:33:15

US3032249

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 14:53:49

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:50:49
	(b) (4)	
User entered empty.	Kelsey Kelley (b) (4)	21 Sep 2020 17:33:15
	(b) (4)	

US3032249

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 14:53:49

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Keith Vrbicky (b) (4)	24 Nov 2020 20:29:25
Signature has been broken.	(b) (4) (u) (4), (b) (6)	23 Nov 2020 20:55:56
User entered 'UN UNK 2015' reason for change: Data Entry Error		23 Nov 2020 20:55:56
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:50:49
User entered 'un Jul 2020'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	21 Sep 2020 17:33:15

US3032249

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 14:53:49

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:50:49
	(b) (4)	
User entered '0'	Kelsey Kelley (b) (4)	21 Sep 2020 17:33:15
	(b) (4)	

US3032249

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 14:53:49

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:50:49
User entered 'Yes (Y)'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	21 Sep 2020 17:33:15

US3032249

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 14:53:49

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:50:49
	(b) (4)	
User entered empty.	Kelsey Kelley (b) (4)	21 Sep 2020 17:33:15
	(b) (4)	

US3032249

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 14:53:49

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:50:49
	(b) (4)	
User entered 'No (N)'	Kelsey Kelley (b) (4)	21 Sep 2020 17:33:15
	(b) (4)	

US3032249

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 14:53:49

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	21 Sep 2020 17:33:15

US3032249

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 14:53:49

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	21 Sep 2020 17:33:15

US3032249

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 14:53:49

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	21 Sep 2020 17:33:15

US3032249

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 14:53:49

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:50:49
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: DRUGS FOR FUNCTIONAL GASTROINTESTINAL DISORDERS, ATC: PROPULSIVES, ATC: PROPULSIVES, PRODUCT: METOCLOPRAMIDE - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4)	22 Sep 2020 05:35:51
User coded data point as Term Coded data point by User (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	22 Sep 2020 05:35:51
Data point term sent to Coder	System	21 Sep 2020 17:38:08
User entered 'metoclopramide'	Kelsey Kelley (b) (4) (b) (4)	21 Sep 2020 17:37:25

US3032249

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 14:53:49

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:50:49
	(b) (4)	
User entered 'No (N)'	Kelsey Kelley (b) (4)	21 Sep 2020 17:37:25
	(b) (4)	

US3032249

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 14:53:49

[Indication](#)

Audit	User	Time (GMT)
User closed query 'Per DM CLR: Please note that there is no Medical History that matches this Con Med indication during this time frame (JUL 2020). Please review Con Med use and add a medical condition and all applicable details to the medical history eCRF as appropriate.' (Site from DM).	(b) (4), (b) (6)	20 Oct 2020 13:56:23
Query 'Per DM CLR: Please note that there is no Medical History that matches this Con Med indication during this time frame (JUL 2020). Please review Con Med use and add a medical condition and all applicable details to the medical history eCRF as appropriate.' answered with 'line 6 of MH' (Site from DM).	Linden DeBoer (b) (4)	09 Oct 2020 15:50:22
User opened query 'Per DM CLR: Please note that there is no Medical History that matches this Con Med indication during this time frame (JUL 2020). Please review Con Med use and add a medical condition and all applicable details to the medical history eCRF as appropriate.' (Site from DM).	(b) (4), (b) (6)	08 Oct 2020 07:23:07
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:50:49
User entered 'medical history: gastroparesis'	Kelsey Kelley (b) (4)	21 Sep 2020 17:37:25

US3032249

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 14:53:49

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:50:49
User entered '5'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	21 Sep 2020 17:37:25

US3032249

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 14:53:49

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:50:49
	(b) (4)	
User entered 'mg (mg)'	Kelsey Kelley (b) (4)	21 Sep 2020 17:37:25
	(b) (4)	

US3032249

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 14:53:49

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:50:49
	(b) (4)	
User entered empty.	Kelsey Kelley (b) (4)	21 Sep 2020 17:37:25
	(b) (4)	

US3032249

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 14:53:49

[Frequency](#)

Audit	User	Time (GMT)
Query 'Per CDM: Please select the frequency from one of the option present here for example once daily or twice daily and delete it from other.' canceled (Site from DM).	(b) (4), (b) (6)	28 Dec 2020 11:54:56
User opened query 'Per CDM: Please select the frequency from one of the option present here for example once daily or twice daily and delete it from other.' (Site from DM).		28 Dec 2020 11:07:11
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:50:49
User entered 'other (OTHER)'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	21 Sep 2020 17:37:25

US3032249

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 14:53:49

If frequency is Other, specify

Audit	User	Time (GMT)
User closed query 'Per CDM: Please review "Other Frequency" as there are option for example "once daily or twice daily" in the listed choices for frequency. Please review and select an appropriate option from the list provided in the CRF and amend as appropriate. ' (Site from DM).	(b) (4), (b) (6)	29 Dec 2020 06:43:08
Query 'Per CDM: Please review "Other Frequency" as there are option for example "once daily or twice daily" in the listed choices for frequency. Please review and select an appropriate option from the list provided in the CRF and amend as appropriate. ' answered with 'Medication is dependent on how many times subject eats per day which can vary' (Site from DM).	Kelsey Kelley (b) (4) (b) (4)	28 Dec 2020 15:01:19
User opened query 'Per CDM: Please review "Other Frequency" as there are option for example "once daily or twice daily" in the listed choices for frequency. Please review and select an appropriate option from the list provided in the CRF and amend as appropriate. ' (Site from DM).	(b) (4), (b) (6)	28 Dec 2020 11:57:49
User signature succeeded.	Keith Vrbicky (b) (4) (b) (4)	28 Sep 2020 17:50:49
User entered 'before meals'	Kelsey Kelley (b) (4) (b) (4)	21 Sep 2020 17:37:25

US3032249

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 14:53:49

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:50:49
User entered 'Oral (ORAL)'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	21 Sep 2020 17:37:25

US3032249

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 14:53:49

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:50:49
User entered empty.	(b) (4) Kelsey Kelley (b) (4) (b) (4)	21 Sep 2020 17:37:25

US3032249

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 14:53:49

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:50:49
	(b) (4)	
User entered 'un Jul 2020'	Kelsey Kelley (b) (4)	21 Sep 2020 17:37:25
	(b) (4)	

US3032249

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 14:53:49

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:50:49
	(b) (4)	
User entered '0'	Kelsey Kelley (b) (4)	21 Sep 2020 17:37:25
	(b) (4)	

US3032249

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 14:53:49

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:50:49
	(b) (4)	
User entered 'Yes (Y)'	Kelsey Kelley (b) (4)	21 Sep 2020 17:37:25
	(b) (4)	

US3032249

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 14:53:49

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:50:49
	(b) (4)	
User entered empty.	Kelsey Kelley (b) (4)	21 Sep 2020 17:37:25
	(b) (4)	

US3032249

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 14:53:49

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:50:49
	(b) (4)	
User entered 'No (N)'	Kelsey Kelley (b) (4)	21 Sep 2020 17:37:25
	(b) (4)	

US3032249

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 14:53:49

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	21 Sep 2020 17:37:25

US3032249

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 14:53:49

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	21 Sep 2020 17:37:25

US3032249

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 14:53:49

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	21 Sep 2020 17:37:25

US3032249

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 14:53:49

Name of Medication

Audit	User	Time (GMT)
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:50:49
User coded data point as ATC: RESPIRATORY SYSTEM, ATC: DRUGS FOR OBSTRUCTIVE AIRWAY DISEASES, ATC: OTHER SYSTEMIC DRUGS FOR OBSTRUCTIVE AIRWAY DISEASES, ATC: LEUKOTRIENE RECEPTOR ANTAGONISTS, PRODUCT: MONTELUKAST - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4)	21 Sep 2020 17:39:52
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	21 Sep 2020 17:39:52
Data point term sent to Coder	System	21 Sep 2020 17:38:13
User entered 'montelukast'	Kelsey Kelley (b) (4) (b) (4)	21 Sep 2020 17:37:49

US3032249

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 14:53:49

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:50:49
	(b) (4)	
User entered 'No (N)'	Kelsey Kelley (b) (4)	21 Sep 2020 17:37:49
	(b) (4)	

US3032249

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 14:53:49

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:50:49
User entered 'medical history: seasonal allergies'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	21 Sep 2020 17:37:49

US3032249

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 14:53:49

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:50:49
	(b) (4)	
User entered '10'	Kelsey Kelley (b) (4)	21 Sep 2020 17:37:49
	(b) (4)	

US3032249

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 14:53:49

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:50:49
	(b) (4)	
User entered 'mg (mg)'	Kelsey Kelley (b) (4)	21 Sep 2020 17:37:49
	(b) (4)	

US3032249

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 14:53:49

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:50:49
	(b) (4)	
User entered empty.	Kelsey Kelley (b) (4)	21 Sep 2020 17:37:49
	(b) (4)	

US3032249

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 14:53:49

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:50:49
User entered 'once daily (QD)'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	21 Sep 2020 17:37:49

US3032249

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 14:53:49

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:50:49
	(b) (4)	
User entered empty.	Kelsey Kelley (b) (4)	21 Sep 2020 17:37:49
	(b) (4)	

US3032249

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 14:53:49

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:50:49
User entered 'Oral (ORAL)'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	21 Sep 2020 17:37:49

US3032249

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 14:53:49

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:50:49
	(b) (4)	
User entered empty.	Kelsey Kelley (b) (4)	21 Sep 2020 17:37:49
	(b) (4)	

US3032249

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 14:53:49

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:50:49
User entered 'un UNK 2015'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	21 Sep 2020 17:37:49

US3032249

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 14:53:49

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:50:49
	(b) (4)	
User entered '0'	Kelsey Kelley (b) (4)	21 Sep 2020 17:37:49
	(b) (4)	

US3032249

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 14:53:49

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:50:49
	(b) (4)	
User entered 'Yes (Y)'	Kelsey Kelley (b) (4)	21 Sep 2020 17:37:49
	(b) (4)	

US3032249

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 14:53:49

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:50:49
	(b) (4)	
User entered empty.	Kelsey Kelley (b) (4)	21 Sep 2020 17:37:49
	(b) (4)	

US3032249

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 14:53:49

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:50:49
User entered 'No (N)'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	21 Sep 2020 17:37:49

US3032249

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 14:53:49

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	21 Sep 2020 17:37:49

US3032249

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 14:53:49

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	21 Sep 2020 17:37:49

US3032249

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 14:53:49

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	21 Sep 2020 17:37:49

US3032249

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 14:53:49

Name of Medication

Audit	User		Time (GMT)
User coded data point as ATC: RESPIRATORY SYSTEM, ATC: DRUGS FOR OBSTRUCTIVE AIRWAY DISEASES, ATC: ADRENERGICS, INHALANTS, ATC: ADRENERGICS IN COMBINATIONS WITH ANTICHOLINERGICS INCL. TRIPLE COMBINATIONS WITH CORTICOSTEROIDS, PRODUCT: FLUTICASONE FUROATE;UMECLIDINIUM BROMIDE;VILANTEROL TRIFENATATE, PRODUCTSYNONYM: TRELEGY - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	(b) (4)	29 Sep 2020 02:41:50
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	(b) (4)	29 Sep 2020 02:41:50
User signature succeeded.	Keith Vrbicky (b) (4)	(b) (4)	28 Sep 2020 17:50:49
Data point term sent to Coder	System		28 Sep 2020 15:21:16
Coding entries removed.	Kelsey Kelley (b) (4)	(b) (4)	28 Sep 2020 15:21:11
User entered 'TRELEGY INHALER (fluticasone furoate/umeclidinium bromide/vilanterol trifenate)' reason for change: Data Entry Error	Kelsey Kelley (b) (4)	(b) (4)	28 Sep 2020 15:21:11
User coded data point as ATC: RESPIRATORY SYSTEM, ATC: DRUGS FOR OBSTRUCTIVE AIRWAY DISEASES, ATC: ADRENERGICS, INHALANTS, ATC: ADRENERGICS IN COMBINATIONS WITH ANTICHOLINERGICS INCL. TRIPLE COMBINATIONS WITH CORTICOSTEROIDS, PRODUCT: FLUTICASONE FUROATE;UMECLIDINIUM BROMIDE;VILANTEROL TRIFENATATE, PRODUCTSYNONYM: TRELEGY - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	(b) (4)	27 Sep 2020 10:32:42
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	(b) (4)	27 Sep 2020 10:32:42
Data point term sent to Coder	System		21 Sep 2020 17:39:15
User entered 'trelegly inhaler'	Kelsey Kelley (b) (4)	(b) (4)	21 Sep 2020 17:38:20

US3032249

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 14:53:49

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:50:49
	(b) (4)	
User entered 'No (N)'	Kelsey Kelley (b) (4)	21 Sep 2020 17:38:20
	(b) (4)	

US3032249

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 14:53:49

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:50:49
User entered 'medical history: copd & asthma'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	21 Sep 2020 17:38:20

US3032249

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 14:53:49

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:50:49
	(b) (4)	
User closed query 'Data is required. Please complete.' (Site from System).	System	28 Sep 2020 15:21:11
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	28 Sep 2020 15:21:11
User entered '100/62.5/25' reason for change: Data Entry Error	Kelsey Kelley (b) (4)	28 Sep 2020 15:21:11
	(b) (4)	
User opened query 'Data is required. Please complete.' (Site from System).	System	21 Sep 2020 17:38:20
User entered empty.	Kelsey Kelley (b) (4)	21 Sep 2020 17:38:20
	(b) (4)	

US3032249

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 14:53:49

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:50:49
	(b) (4)	
User closed query 'Data is required. Please complete.' (Site from System).	System	28 Sep 2020 15:21:11
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	28 Sep 2020 15:21:11
User entered 'ug (ug)' reason for change: Data Entry Error	Kelsey Kelley (b) (4)	28 Sep 2020 15:21:11
	(b) (4)	
User opened query 'Data is required. Please complete.' (Site from System).	System	21 Sep 2020 17:38:20
User entered empty.	Kelsey Kelley (b) (4)	21 Sep 2020 17:38:20
	(b) (4)	

US3032249

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 14:53:49

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:50:49
	(b) (4)	
User entered empty.	Kelsey Kelley (b) (4)	21 Sep 2020 17:38:20
	(b) (4)	

US3032249

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 14:53:49

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:50:49
	(b) (4)	
User closed query 'Data is required. Please complete.' (Site from System).	System	28 Sep 2020 15:21:11
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	28 Sep 2020 15:21:11
User entered 'once daily (QD)' reason for change: Data Entry Error	Kelsey Kelley (b) (4)	28 Sep 2020 15:21:11
	(b) (4)	
User opened query 'Data is required. Please complete.' (Site from System).	System	21 Sep 2020 17:38:20
User entered empty.	Kelsey Kelley (b) (4)	21 Sep 2020 17:38:20
	(b) (4)	

US3032249

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 14:53:49

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:50:49
	(b) (4)	
User entered empty.	Kelsey Kelley (b) (4)	21 Sep 2020 17:38:20
	(b) (4)	

US3032249

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 14:53:49

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:50:49
User entered 'Respiratory (Inhalation) (RESPIRATORY (INHALATION))'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	21 Sep 2020 17:38:20

US3032249

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 14:53:49

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:50:49
	(b) (4)	
User entered empty.	Kelsey Kelley (b) (4)	21 Sep 2020 17:38:20
	(b) (4)	

US3032249

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 14:53:49

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User closed query 'Per CDM Please note the indication start date (COPD) is UNK UNK 2015 and the medication date does not match . Kindly correct or Clarify. Thanks ' (Site from DM).	(b) (4), (b) (6)	05 Oct 2020 08:01:38
Query 'Per CDM Please note the indication start date (COPD) is UNK UNK 2015 and the medication date does not match . Kindly correct or Clarify. Thanks ' answered with 'medication was started after the diagnosis of COPD' (Site from DM).	Samantha Wieseler (b) (4)	01 Oct 2020 22:17:57
User opened query 'Per CDM Please note the indication start date (COPD) is UNK UNK 2015 and the medication date does not match . Kindly correct or Clarify. Thanks ' (Site from DM).	(b) (4), (b) (6)	30 Sep 2020 10:25:02
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:50:49
User entered 'un UNK 2017'	(b) (4) Kelsey Kelley (b) (4)	21 Sep 2020 17:38:20

US3032249

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 14:53:49

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:50:49
	(b) (4)	
User entered '0'	Kelsey Kelley (b) (4)	21 Sep 2020 17:38:20
	(b) (4)	

US3032249

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 14:53:49

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:50:49
	(b) (4)	
User entered 'Yes (Y)'	Kelsey Kelley (b) (4)	21 Sep 2020 17:38:20
	(b) (4)	

US3032249

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 14:53:49

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:50:49
	(b) (4)	
User entered empty.	Kelsey Kelley (b) (4)	21 Sep 2020 17:38:20
	(b) (4)	

US3032249

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 14:53:49

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:50:49
	(b) (4)	
User entered 'No (N)'	Kelsey Kelley (b) (4)	21 Sep 2020 17:38:20
	(b) (4)	

US3032249

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 14:53:49

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	28 Sep 2020 15:21:11
User entered empty.	System	21 Sep 2020 17:38:20

US3032249

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 14:53:49

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	28 Sep 2020 15:21:11
User entered empty.	System	21 Sep 2020 17:38:20

US3032249

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 14:53:49

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	28 Sep 2020 15:21:11
User entered empty.	System	21 Sep 2020 17:38:20

US3032249

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 14:53:49

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Keith Vrbicky (b) (4)	30 Jan 2021 16:52:32
User coded data point as ATC: RESPIRATORY SYSTEM, ATC: DRUGS FOR OBSTRUCTIVE AIRWAY DISEASES, ATC: OTHER SYSTEMIC DRUGS FOR OBSTRUCTIVE AIRWAY DISEASES, ATC: OTHER SYSTEMIC DRUGS FOR OBSTRUCTIVE AIRWAY DISEASES, PRODUCT: DUPILUMAB - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4)	29 Jan 2021 09:45:15
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	29 Jan 2021 09:45:15
Data point term sent to Coder	System	28 Jan 2021 19:01:58
User entered 'dupilumab'	Kelsey Kelley (b) (4) (b) (4)	28 Jan 2021 19:01:10

US3032249

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 14:53:49

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Keith Vrbicky (b) (4)	30 Jan 2021 16:52:32
User entered 'No (N)'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	28 Jan 2021 19:01:10

US3032249

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 14:53:49

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Keith Vrbicky (b) (4)	30 Jan 2021 16:52:32
User entered 'asthma'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	28 Jan 2021 19:01:10

US3032249

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 14:53:49

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Keith Vrbicky (b) (4)	30 Jan 2021 16:52:32
User entered '300'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	28 Jan 2021 19:01:10

US3032249

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 14:53:49

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Keith Vrbicky (b) (4)	30 Jan 2021 16:52:32
	(b) (4)	
User entered 'mg (mg)'	Kelsey Kelley (b) (4)	28 Jan 2021 19:01:10
	(b) (4)	

US3032249

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 14:53:49

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Keith Vrbicky (b) (4)	30 Jan 2021 16:52:32
User entered empty.	(b) (4) Kelsey Kelley (b) (4) (b) (4)	28 Jan 2021 19:01:10

US3032249

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 14:53:49

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Keith Vrbicky (b) (4)	30 Jan 2021 16:52:32
User entered 'other (OTHER)'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	28 Jan 2021 19:01:10

US3032249

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 14:53:49

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Keith Vrbicky (b) (4)	30 Jan 2021 16:52:32
	(b) (4)	
User entered 'every 2 weeks'	Kelsey Kelley (b) (4)	28 Jan 2021 19:01:10
	(b) (4)	

US3032249

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 14:53:49

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Keith Vrbicky (b) (4)	30 Jan 2021 16:52:32
User entered 'Subcutaneous (SUBCUTANEOUS)'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	28 Jan 2021 19:01:10

US3032249

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 14:53:49

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Keith Vrbicky (b) (4)	30 Jan 2021 16:52:32
	(b) (4)	
User entered empty.	Kelsey Kelley (b) (4)	28 Jan 2021 19:01:10
	(b) (4)	

US3032249

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 14:53:49

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Keith Vrbicky (b) (4)	30 Jan 2021 16:52:32
	(b) (4)	
User entered 'un Jan 2021'	Kelsey Kelley (b) (4)	28 Jan 2021 19:01:10
	(b) (4)	

US3032249

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 14:53:49

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Keith Vrbicky (b) (4)	30 Jan 2021 16:52:32
	(b) (4)	
User entered '0'	Kelsey Kelley (b) (4)	28 Jan 2021 19:01:10
	(b) (4)	

US3032249

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 14:53:49

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Keith Vrbicky (b) (4)	30 Jan 2021 16:52:32
	(b) (4)	
User entered 'Yes (Y)'	Kelsey Kelley (b) (4)	28 Jan 2021 19:01:10
	(b) (4)	

US3032249

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 14:53:49

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Keith Vrbicky (b) (4)	30 Jan 2021 16:52:32
	(b) (4)	
User entered empty.	Kelsey Kelley (b) (4)	28 Jan 2021 19:01:10
	(b) (4)	

US3032249

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 14:53:49

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Keith Vrbicky (b) (4)	30 Jan 2021 16:52:32
User entered 'No (N)'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	28 Jan 2021 19:01:10

US3032249

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 14:53:49

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	28 Jan 2021 19:01:10

US3032249

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 14:53:49

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	28 Jan 2021 19:01:10

US3032249

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 14:53:49

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	28 Jan 2021 19:01:10

US3032249

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 14:53:49

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:27:23
User signature succeeded.	Keith Vrbicky (b) (4)	12 Feb 2021 19:56:47
User coded data point as ATC: ANTIINFECTIVES FOR SYSTEMIC USE, ATC: ANTIVIRALS FOR SYSTEMIC USE, ATC: DIRECT ACTING ANTIVIRALS, ATC: OTHER ANTIVIRALS, PRODUCT: OTHER ANTIVIRALS - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4)	11 Feb 2021 18:22:55
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	11 Feb 2021 18:22:55
Data point term sent to Coder	System	11 Feb 2021 18:22:37
User entered 'Bamlanivimab'	Linden DeBoer (b) (4)	11 Feb 2021 18:22:15
	(b) (4)	

US3032249

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 14:53:49

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:27:23
User signature succeeded.	Keith Vrbicky (b) (4)	12 Feb 2021 19:56:47
User entered 'No (N)'	Linden DeBoer (b) (4)	11 Feb 2021 18:22:15

US3032249

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 14:53:49

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:27:23
User signature succeeded.	Keith Vrbicky (b) (4)	12 Feb 2021 19:56:47
User entered 'COVID-19'	Linden DeBoer (b) (4)	11 Feb 2021 18:22:15

US3032249

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 14:53:49

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:27:23
User signature succeeded.	Keith Vrbicky (b) (4)	12 Feb 2021 19:56:47
User entered '700'	Linden DeBoer (b) (4)	11 Feb 2021 18:22:15

US3032249

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 14:53:49

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:27:23
User signature succeeded.	Keith Vrbicky (b) (4)	12 Feb 2021 19:56:47
User entered 'mg (mg)'	Linden DeBoer (b) (4)	11 Feb 2021 18:22:15

US3032249

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 14:53:49

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:27:23
User signature succeeded.	Keith Vrbicky (b) (4)	12 Feb 2021 19:56:47
User entered empty.	Linden DeBoer (b) (4)	11 Feb 2021 18:22:15

US3032249

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 14:53:49

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:27:23
User signature succeeded.	Keith Vrbicky (b) (4)	12 Feb 2021 19:56:47
User entered 'once (ONCE)'	Linden DeBoer (b) (4)	11 Feb 2021 18:22:15

US3032249

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 14:53:49

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:27:23
User signature succeeded.	Keith Vrbicky (b) (4)	12 Feb 2021 19:56:47
User entered empty.	Linden DeBoer (b) (4)	11 Feb 2021 18:22:15

US3032249

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 14:53:49

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:27:23
User signature succeeded.	Keith Vrbicky (b) (4)	12 Feb 2021 19:56:47
User entered 'Intravenous Bolus (INTRAVENOUS BOLUS)'	Linden DeBoer (b) (4)	11 Feb 2021 18:22:15

US3032249

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 14:53:49

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:27:23
User signature succeeded.	Keith Vrbicky (b) (4)	12 Feb 2021 19:56:47
User entered empty.	Linden DeBoer (b) (4)	11 Feb 2021 18:22:15

US3032249

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 14:53:49

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:27:23
User signature succeeded.	Keith Vrbicky (b) (4)	12 Feb 2021 19:56:47
User entered '9 Feb 2021'	Linden DeBoer (b) (4)	11 Feb 2021 18:22:15

US3032249

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 14:53:49

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:27:23
User signature succeeded.	Keith Vrbicky (b) (4)	12 Feb 2021 19:56:47
User entered '0'	Linden DeBoer (b) (4)	11 Feb 2021 18:22:15

US3032249

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 14:53:49

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:27:23
User signature succeeded.	Keith Vrbicky (b) (4)	12 Feb 2021 19:56:47
User entered 'No (N)'	Linden DeBoer (b) (4)	11 Feb 2021 18:22:15

US3032249

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 14:53:49

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:27:23
User signature succeeded.	Keith Vrbicky (b) (4)	12 Feb 2021 19:56:47
User entered '9 Feb 2021'	Linden DeBoer (b) (4)	11 Feb 2021 18:22:15

US3032249

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 14:53:49

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:27:23
User signature succeeded.	Keith Vrbicky (b) (4)	12 Feb 2021 19:56:47
User entered 'No (N)'	Linden DeBoer (b) (4)	11 Feb 2021 18:22:15

US3032249

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 14:53:49

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:27:23
User entered empty.	System	11 Feb 2021 18:22:15

US3032249

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 14:53:49

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:27:23
User entered empty.	System	11 Feb 2021 18:22:15

US3032249

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 14:53:49

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:27:23
User entered empty.	System	11 Feb 2021 18:22:15

US3032249

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 14:53:49

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:41:17
User coded data point as ATC: RESPIRATORY SYSTEM, ATC: DRUGS FOR OBSTRUCTIVE AIRWAY DISEASES, ATC: ADRENERGICS, INHALANTS, ATC: SELECTIVE BETA-2-ADRENORECEPTOR AGONISTS, PRODUCT: SALBUTAMOL, PRODUCTSYNONYM: ALBUTEROL [SALBUTAMOL] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	23 Mar 2021 15:54:37
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	23 Mar 2021 15:54:37
Data point term sent to Coder	System	23 Mar 2021 15:38:00
User entered 'albuterol'	Kelsey Kelley (b) (4)	23 Mar 2021 15:37:50

US3032249

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 14:53:49

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:41:17
	(b) (4)	
User entered 'No (N)'	Kelsey Kelley (b) (4)	23 Mar 2021 15:37:50
	(b) (4)	

US3032249

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 14:53:49

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:41:17
User entered 'bilateral pneumonia'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	23 Mar 2021 15:37:50

US3032249

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 14:53:49

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:41:17
User entered '9'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	23 Mar 2021 15:37:50

US3032249

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 14:53:49

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:41:17
	(b) (4)	
User entered 'ug (ug)'	Kelsey Kelley (b) (4)	23 Mar 2021 15:37:50
	(b) (4)	

US3032249

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 14:53:49

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:41:17
	(b) (4)	
User entered empty.	Kelsey Kelley (b) (4)	23 Mar 2021 15:37:50
	(b) (4)	

US3032249

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 14:53:49

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:41:17
	(b) (4)	
User entered 'three times daily (TID)'	Kelsey Kelley (b) (4)	23 Mar 2021 15:37:50
	(b) (4)	

US3032249

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 14:53:49

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:41:17
	(b) (4)	
User entered empty.	Kelsey Kelley (b) (4)	23 Mar 2021 15:37:50
	(b) (4)	

US3032249

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 14:53:49

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:41:17
User entered 'Respiratory (Inhalation) (RESPIRATORY (INHALATION))'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	23 Mar 2021 15:37:50

US3032249

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 14:53:49

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:41:17
	(b) (4)	
User entered empty.	Kelsey Kelley (b) (4)	23 Mar 2021 15:37:50
	(b) (4)	

US3032249

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 14:53:49

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:41:17
User entered '5 Mar 2021'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	23 Mar 2021 15:37:50

US3032249

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 14:53:49

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:41:17
User entered '0'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	23 Mar 2021 15:37:50

US3032249

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 14:53:49

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:41:17
	(b) (4)	
User entered 'Yes (Y)'	Kelsey Kelley (b) (4)	23 Mar 2021 15:37:50
	(b) (4)	

US3032249

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 14:53:49

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:41:17
	(b) (4)	
User entered empty.	Kelsey Kelley (b) (4)	23 Mar 2021 15:37:50
	(b) (4)	

US3032249

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 14:53:49

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:41:17
User entered 'No (N)'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	23 Mar 2021 15:37:50

US3032249

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 14:53:49

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '3'	System	23 Mar 2021 15:37:50

US3032249

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 14:53:49

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	23 Mar 2021 15:37:50

US3032249

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 14:53:49

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	23 Mar 2021 15:37:50

US3032249

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 14:53:49

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:27:26
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:41:17
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: OTHER ANALGESICS AND ANTIPYRETICS, ATC: ANILIDES, PRODUCT: PARACETAMOL, PRODUCTSYNONYM: ACETAMINOPHEN - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	25 Mar 2021 21:03:30
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	25 Mar 2021 21:03:30
Data point term sent to Coder	System	25 Mar 2021 21:02:31
User entered 'acetaminophen'	Kelsey Kelley (b) (4)	25 Mar 2021 21:02:20

US3032249

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 14:53:49

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:27:26
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:41:17
User entered 'No (N)'	(b) (4) Kelsey Kelley (b) (4)	25 Mar 2021 21:02:20

US3032249

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 14:53:49

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:27:26
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:41:17
User entered 'covid-19'	Kelsey Kelley (b) (4)	25 Mar 2021 21:02:20

US3032249

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 14:53:49

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:27:26
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:41:17
User entered '650'	(b) (4) Kelsey Kelley (b) (4)	25 Mar 2021 21:02:20

US3032249

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 14:53:49

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:27:26
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:41:17
User entered 'mg (mg)'	(b) (4) Kelsey Kelley (b) (4)	25 Mar 2021 21:02:20

US3032249

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 14:53:49

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:27:26
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:41:17
User entered empty.	(b) (4) Kelsey Kelley (b) (4)	25 Mar 2021 21:02:20

US3032249

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 14:53:49

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:27:26
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:41:17
User entered 'as needed (PRN)'	(b) (4) Kelsey Kelley (b) (4)	25 Mar 2021 21:02:20

US3032249

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 14:53:49

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:27:26
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:41:17
User entered empty.	(b) (4) Kelsey Kelley (b) (4)	25 Mar 2021 21:02:20

US3032249

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 14:53:49

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:27:26
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:41:17
User entered 'Oral (ORAL)'	(b) (4) Kelsey Kelley (b) (4)	25 Mar 2021 21:02:20

US3032249

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 14:53:49

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:27:26
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:41:17
User entered empty.	(b) (4) Kelsey Kelley (b) (4)	25 Mar 2021 21:02:20

US3032249

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 14:53:49

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:27:26
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:41:17
User entered '9 Feb 2021'	(b) (4) Kelsey Kelley (b) (4)	25 Mar 2021 21:02:20

US3032249

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 14:53:49

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:27:26
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:41:17
User entered '0'	(b) (4) Kelsey Kelley (b) (4)	25 Mar 2021 21:02:20

US3032249

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 14:53:49

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:27:26
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:41:17
User entered 'No (N)'	(b) (4) Kelsey Kelley (b) (4)	25 Mar 2021 21:02:20

US3032249

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 14:53:49

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:27:26
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:41:17
User entered '12 Feb 2021'	(b) (4) Kelsey Kelley (b) (4)	25 Mar 2021 21:02:20
	(b) (4)	

US3032249

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 14:53:49

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:27:26
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:41:17
User entered 'No (N)'	(b) (4) Kelsey Kelley (b) (4)	25 Mar 2021 21:02:20

US3032249

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 14:53:49

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:27:26
User entered empty.	System	25 Mar 2021 21:02:20

US3032249

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 14:53:49

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:27:26
User entered empty.	System	25 Mar 2021 21:02:20

US3032249

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 14:53:49

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:27:26
User entered empty.	System	25 Mar 2021 21:02:20

US3032249

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 14:53:49

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:27:31
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:41:17
User coded data point as ATC: RESPIRATORY SYSTEM, ATC: DRUGS FOR OBSTRUCTIVE AIRWAY DISEASES, ATC: ADRENERGICS, INHALANTS, ATC: SELECTIVE BETA-2-ADRENORECEPTOR AGONISTS, PRODUCT: SALBUTAMOL, PRODUCTSYNONYM: ALBUTEROL [SALBUTAMOL] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	25 Mar 2021 21:04:30
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	25 Mar 2021 21:04:30
Data point term sent to Coder	System	25 Mar 2021 21:03:32
User entered 'albuterol'	Kelsey Kelley (b) (4)	25 Mar 2021 21:02:51

US3032249

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 14:53:49

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:27:31
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:41:17
User entered 'No (N)'	(b) (4) Kelsey Kelley (b) (4)	25 Mar 2021 21:02:51

US3032249

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 14:53:49

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:27:31
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:41:17
User entered 'covid-19'	Kelsey Kelley (b) (4)	25 Mar 2021 21:02:51

US3032249

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 14:53:49

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:27:31
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:41:17
User entered '2.5'	(b) (4) Kelsey Kelley (b) (4)	25 Mar 2021 21:02:51

US3032249

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 14:53:49

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:27:31
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:41:17
User entered 'mg (mg)'	(b) (4) Kelsey Kelley (b) (4)	25 Mar 2021 21:02:51

US3032249

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 14:53:49

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:27:31
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:41:17
User entered empty.	(b) (4) Kelsey Kelley (b) (4)	25 Mar 2021 21:02:51

US3032249

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 14:53:49

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:27:31
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:41:17
User entered 'as needed (PRN)'	(b) (4) Kelsey Kelley (b) (4)	25 Mar 2021 21:02:51

US3032249

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 14:53:49

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:27:31
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:41:17
User entered empty.	(b) (4) Kelsey Kelley (b) (4)	25 Mar 2021 21:02:51

US3032249

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 14:53:49

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:27:31
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:41:17
User entered 'Respiratory (Inhalation) (RESPIRATORY (INHALATION))'	Kelsey Kelley (b) (4)	25 Mar 2021 21:02:51

US3032249

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 14:53:49

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:27:31
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:41:17
User entered empty.	(b) (4) Kelsey Kelley (b) (4)	25 Mar 2021 21:02:51

US3032249

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 14:53:49

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:27:31
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:41:17
User entered '9 Feb 2021'	(b) (4) Kelsey Kelley (b) (4)	25 Mar 2021 21:02:51

US3032249

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 14:53:49

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:27:31
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:41:17
User entered '0'	(b) (4) Kelsey Kelley (b) (4)	25 Mar 2021 21:02:51

US3032249

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 14:53:49

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:27:31
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:41:17
User entered 'No (N)'	(b) (4) Kelsey Kelley (b) (4)	25 Mar 2021 21:02:51

US3032249

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 14:53:49

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:27:31
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:41:17
User entered '12 Feb 2021'	(b) (4) Kelsey Kelley (b) (4)	25 Mar 2021 21:02:51
	(b) (4)	

US3032249

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 14:53:49

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:27:31
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:41:17
User entered 'No (N)'	(b) (4) Kelsey Kelley (b) (4)	25 Mar 2021 21:02:51

US3032249

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 14:53:49

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:27:31
User entered empty.	System	25 Mar 2021 21:02:51

US3032249

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 14:53:49

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:27:31
User entered empty.	System	25 Mar 2021 21:02:51

US3032249

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 14:53:49

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:27:31
User entered empty.	System	25 Mar 2021 21:02:51

US3032249

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 14:53:49

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:27:35
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:41:17
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: DRUGS FOR ACID RELATED DISORDERS, ATC: DRUGS FOR PEPTIC ULCER AND GASTRO-OESOPHAGEAL REFLUX DISEASE (GORD), ATC: PROTON PUMP INHIBITORS, PRODUCT: PANTOPRAZOLE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	26 Mar 2021 10:44:51
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	26 Mar 2021 10:44:51
Data point term sent to Coder	System	25 Mar 2021 21:04:33
User entered 'pantoprazole'	Kelsey Kelley (b) (4)	25 Mar 2021 21:03:45

US3032249

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 14:53:49

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:27:35
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:41:17
User entered 'No (N)'	(b) (4) Kelsey Kelley (b) (4)	25 Mar 2021 21:03:45

US3032249

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 14:53:49

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:27:35
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:41:17
User entered 'covid-19'	Kelsey Kelley (b) (4)	25 Mar 2021 21:03:45

US3032249

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 14:53:49

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:27:35
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:41:17
User entered '40'	Kelsey Kelley (b) (4)	25 Mar 2021 21:03:45

US3032249

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 14:53:49

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:27:35
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:41:17
User entered 'mg (mg)'	(b) (4) Kelsey Kelley (b) (4)	25 Mar 2021 21:03:45

US3032249

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 14:53:49

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:27:35
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:41:17
User entered empty.	(b) (4) Kelsey Kelley (b) (4)	25 Mar 2021 21:03:45

US3032249

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 14:53:49

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:27:35
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:41:17
User entered 'once daily (QD)'	Kelsey Kelley (b) (4)	25 Mar 2021 21:03:45

US3032249

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 14:53:49

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:27:35
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:41:17
User entered empty.	(b) (4) Kelsey Kelley (b) (4)	25 Mar 2021 21:03:45

US3032249

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 14:53:49

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:27:35
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:41:17
User entered 'Oral (ORAL)'	(b) (4) Kelsey Kelley (b) (4)	25 Mar 2021 21:03:45

US3032249

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 14:53:49

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:27:35
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:41:17
User entered empty.	(b) (4) Kelsey Kelley (b) (4)	25 Mar 2021 21:03:45

US3032249

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 14:53:49

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:27:35
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:41:17
User entered '9 Feb 2021'	(b) (4) Kelsey Kelley (b) (4)	25 Mar 2021 21:03:45

US3032249

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 14:53:49

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:27:35
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:41:17
User entered '0'	(b) (4) Kelsey Kelley (b) (4)	25 Mar 2021 21:03:45

US3032249

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 14:53:49

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:27:35
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:41:17
User entered 'No (N)'	(b) (4) Kelsey Kelley (b) (4)	25 Mar 2021 21:03:45

US3032249

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 14:53:49

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:27:35
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:41:17
User entered '12 Feb 2021'	(b) (4) Kelsey Kelley (b) (4)	25 Mar 2021 21:03:45
	(b) (4)	

US3032249

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 14:53:49

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:27:35
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:41:17
User entered 'No (N)'	(b) (4) Kelsey Kelley (b) (4)	25 Mar 2021 21:03:45

US3032249

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 14:53:49

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:27:35
User entered '1'	System	25 Mar 2021 21:03:45

US3032249

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 14:53:49

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:27:35
User entered '1'	System	25 Mar 2021 21:03:45

US3032249

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 14:53:49

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:27:35
User entered '804 (804)'	System	25 Mar 2021 21:03:45

US3032249

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 14:53:49

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:28:13
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:41:17
User coded data point as ATC: SYSTEMIC HORMONAL PREPARATIONS, EXCL. SEX HORMONES AND INSULINS, ATC: CORTICOSTEROIDS FOR SYSTEMIC USE, ATC: CORTICOSTEROIDS FOR SYSTEMIC USE, PLAIN, ATC: GLUCOCORTICOID, PRODUCT: PREDNISONE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	25 Mar 2021 21:05:33
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	25 Mar 2021 21:05:33
Data point term sent to Coder	System	25 Mar 2021 21:04:32
User entered 'prednisone'	Kelsey Kelley (b) (4)	25 Mar 2021 21:04:14

US3032249

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 14:53:49

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:28:13
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:41:17
User entered 'No (N)'	(b) (4) Kelsey Kelley (b) (4)	25 Mar 2021 21:04:14

US3032249

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 14:53:49

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:28:13
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:41:17
User entered 'covid-19'	Kelsey Kelley (b) (4)	25 Mar 2021 21:04:14

US3032249

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 14:53:49

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:28:13
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:41:17
User entered '10'	Kelsey Kelley (b) (4)	25 Mar 2021 21:04:14

US3032249

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 14:53:49

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:28:13
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:41:17
User entered 'mg (mg)'	(b) (4) Kelsey Kelley (b) (4)	25 Mar 2021 21:04:14

US3032249

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 14:53:49

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:28:13
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:41:17
User entered empty.	Kelsey Kelley (b) (4)	25 Mar 2021 21:04:14

US3032249

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 14:53:49

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:28:13
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:41:17
User entered 'once daily (QD)'	Kelsey Kelley (b) (4)	25 Mar 2021 21:04:14

US3032249

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 14:53:49

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:28:13
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:41:17
User entered empty.	(b) (4) Kelsey Kelley (b) (4)	25 Mar 2021 21:04:14

US3032249

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 14:53:49

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:28:13
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:41:17
User entered 'Oral (ORAL)'	Kelsey Kelley (b) (4)	25 Mar 2021 21:04:14

US3032249

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 14:53:49

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:28:13
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:41:17
User entered empty.	Kelsey Kelley (b) (4)	25 Mar 2021 21:04:14

US3032249

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 14:53:49

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:28:13
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:41:17
User entered '9 Feb 2021'	(b) (4) Kelsey Kelley (b) (4)	25 Mar 2021 21:04:14

US3032249

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 14:53:49

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:28:13
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:41:17
User entered '0'	Kelsey Kelley (b) (4)	25 Mar 2021 21:04:14

US3032249

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 14:53:49

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:28:13
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:41:17
User entered 'No (N)'	(b) (4) Kelsey Kelley (b) (4)	25 Mar 2021 21:04:14

US3032249

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 14:53:49

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:28:13
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:41:17
User entered '12 Feb 2021'	(b) (4) Kelsey Kelley (b) (4)	25 Mar 2021 21:04:14
	(b) (4)	

US3032249

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 14:53:49

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:28:13
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:41:17
User entered 'No (N)'	Kelsey Kelley (b) (4)	25 Mar 2021 21:04:14

US3032249

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 14:53:49

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:28:13
User entered '1'	System	25 Mar 2021 21:04:14

US3032249

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 14:53:49

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:28:13
User entered '1'	System	25 Mar 2021 21:04:14

US3032249

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 14:53:49

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:28:13
User entered '804 (804)'	System	25 Mar 2021 21:04:14

US3032249

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 14:53:49

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:27:38
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:41:17
User coded data point as ATC: RESPIRATORY SYSTEM, ATC: COUGH AND COLD PREPARATIONS, ATC: COUGH SUPPRESSANTS, EXCL. COMBINATIONS WITH EXPECTORANTS, ATC: OPIUM ALKALOIDS AND DERIVATIVES, PRODUCT: CODEINE PHOSPHATE;PROMETHAZINE HYDROCHLORIDE, PRODUCTSYNONYM: PROMETHAZINE WITH CODEINE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	25 Mar 2021 21:06:30
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	25 Mar 2021 21:06:30
Data point term sent to Coder	System	25 Mar 2021 21:05:33
User entered 'promethazine with codeine'	Kelsey Kelley (b) (4)	25 Mar 2021 21:04:48

US3032249

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 14:53:49

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:27:38
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:41:17
User entered 'No (N)'	(b) (4) Kelsey Kelley (b) (4)	25 Mar 2021 21:04:48

US3032249

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 14:53:49

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:27:38
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:41:17
User entered 'covid-19'	Kelsey Kelley (b) (4)	25 Mar 2021 21:04:48

US3032249

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 14:53:49

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:27:38
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:41:17
User entered '6.25/10'	Kelsey Kelley (b) (4)	25 Mar 2021 21:04:48

US3032249

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 14:53:49

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:27:38
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:41:17
User entered 'mg (mg)'	(b) (4) Kelsey Kelley (b) (4)	25 Mar 2021 21:04:48

US3032249

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 14:53:49

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:27:38
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:41:17
User entered empty.	(b) (4) Kelsey Kelley (b) (4)	25 Mar 2021 21:04:48

US3032249

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 14:53:49

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:27:38
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:41:17
User entered 'as needed (PRN)'	Kelsey Kelley (b) (4)	25 Mar 2021 21:04:48

US3032249

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 14:53:49

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:27:38
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:41:17
User entered empty.	(b) (4) Kelsey Kelley (b) (4)	25 Mar 2021 21:04:48

US3032249

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 14:53:49

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:27:38
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:41:17
User entered 'Oral (ORAL)'	Kelsey Kelley (b) (4)	25 Mar 2021 21:04:48

US3032249

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 14:53:49

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:27:38
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:41:17
User entered empty.	(b) (4) Kelsey Kelley (b) (4)	25 Mar 2021 21:04:48

US3032249

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 14:53:49

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:27:38
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:41:17
User entered '9 Feb 2021'	(b) (4) Kelsey Kelley (b) (4)	25 Mar 2021 21:04:48

US3032249

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 14:53:49

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:27:38
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:41:17
User entered '0'	(b) (4) Kelsey Kelley (b) (4)	25 Mar 2021 21:04:48

US3032249

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 14:53:49

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:27:38
User closed query 'Per DM CLR: Please review if a stop date should be recorded as the corresponding AE has resolved. If yes, please update CM stop date as applicable. Otherwise, provide clarification for continued use of medication. ' (Site from DM).		07 Apr 2021 10:59:46
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:41:17
Query 'Per DM CLR: Please review if a stop date should be recorded as the corresponding AE has resolved. If yes, please update CM stop date as applicable. Otherwise, provide clarification for continued use of medication. ' answered with 'Data updated. Subject did continue to use medication for nighttime comfort, but stopped 24mar2021. thank you' (Site from DM).	(b) (4)	
User entered 'No (N)' reason for change: Data Entry Error	Chelsie Nutsch (b) (4)	06 Apr 2021 13:59:17
User opened query 'Per DM CLR: Please review if a stop date should be recorded as the corresponding AE has resolved. If yes, please update CM stop date as applicable. Otherwise, provide clarification for continued use of medication. ' (Site from DM).	(b) (4)	
User entered 'Yes (Y)'	Chelsie Nutsch (b) (4)	06 Apr 2021 13:58:40
	(b) (4)	
	(b) (4), (b) (6)	04 Apr 2021 12:56:53
	Kelsey Kelley (b) (4)	25 Mar 2021 21:04:48
	(b) (4)	

US3032249

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 14:53:49

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:27:38
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:41:17
User entered '24 Mar 2021' reason for change: Data Entry Error	(b) (4)	06 Apr 2021 13:58:40
User entered empty.	Chelsie Nutsch (b) (4)	06 Apr 2021 13:58:40
	(b) (4)	
	Kelsey Kelley (b) (4)	25 Mar 2021 21:04:48
	(b) (4)	

US3032249

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 14:53:49

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:27:38
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:41:17
User entered 'No (N)'	(b) (4) Kelsey Kelley (b) (4)	25 Mar 2021 21:04:48

US3032249

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 14:53:49

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:27:38
User entered empty.	System	25 Mar 2021 21:04:48

US3032249

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 14:53:49

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:27:38
User entered empty.	System	25 Mar 2021 21:04:48

US3032249

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 14:53:49

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:27:38
User entered empty.	System	25 Mar 2021 21:04:48

US3032249

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 14:53:49

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:27:42
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:41:17
User coded data point as ATC: ANTIINFECTIVES FOR SYSTEMIC USE, ATC: ANTIBACTERIALS FOR SYSTEMIC USE, ATC: OTHER BETA-LACTAM ANTIBACTERIALS, ATC: THIRD-GENERATION CEPHALOSPORINS, PRODUCT: CEFTRIAXONE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	29 Mar 2021 07:12:21
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	29 Mar 2021 07:12:21
Data point term sent to Coder	System	25 Mar 2021 21:09:36
User entered 'ceftriaxone'	Kelsey Kelley (b) (4)	25 Mar 2021 21:09:35

US3032249

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 14:53:49

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:27:42
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:41:17
User entered 'No (N)'	(b) (4) Kelsey Kelley (b) (4)	25 Mar 2021 21:09:35

US3032249

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 14:53:49

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:27:42
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:41:17
User entered 'covid-19'	Kelsey Kelley (b) (4)	25 Mar 2021 21:09:35

US3032249

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 14:53:49

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:27:42
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:41:17
User entered 'I'	(b) (4) Kelsey Kelley (b) (4)	25 Mar 2021 21:09:35

US3032249

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 14:53:49

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:27:42
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:41:17
User entered 'g (g)'	(b) (4) Kelsey Kelley (b) (4)	25 Mar 2021 21:09:35

US3032249

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 14:53:49

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:27:42
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:41:17
User entered empty.	(b) (4) Kelsey Kelley (b) (4)	25 Mar 2021 21:09:35

US3032249

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 14:53:49

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:27:42
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:41:17
User entered 'once daily (QD)'	Kelsey Kelley (b) (4)	25 Mar 2021 21:09:35

US3032249

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 14:53:49

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:27:42
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:41:17
User entered empty.	(b) (4) Kelsey Kelley (b) (4)	25 Mar 2021 21:09:35

US3032249

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 14:53:49

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:27:42
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:41:17
User entered 'Intravenous (INTRAVENOUS)'	Kelsey Kelley (b) (4)	25 Mar 2021 21:09:35

US3032249

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 14:53:49

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:27:42
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:41:17
User entered empty.	(b) (4) Kelsey Kelley (b) (4)	25 Mar 2021 21:09:35

US3032249

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 14:53:49

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:27:42
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:41:17
User entered '9 Feb 2021'	(b) (4) Kelsey Kelley (b) (4)	25 Mar 2021 21:09:35

US3032249

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 14:53:49

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:27:42
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:41:17
User entered '0'	(b) (4) Kelsey Kelley (b) (4)	25 Mar 2021 21:09:35

US3032249

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 14:53:49

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:27:42
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:41:17
User entered 'No (N)'	(b) (4) Kelsey Kelley (b) (4)	25 Mar 2021 21:09:35

US3032249

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 14:53:49

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:27:42
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:41:17
User entered '12 Feb 2021'	(b) (4) Kelsey Kelley (b) (4)	25 Mar 2021 21:09:35
	(b) (4)	

US3032249

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 14:53:49

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:27:42
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:41:17
User entered 'No (N)'	(b) (4) Kelsey Kelley (b) (4)	25 Mar 2021 21:09:35

US3032249

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 14:53:49

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:27:42
User entered '1'	System	25 Mar 2021 21:09:35

US3032249

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 14:53:49

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:27:42
User entered '1'	System	25 Mar 2021 21:09:35

US3032249

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 14:53:49

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:27:42
User entered '804 (804)'	System	25 Mar 2021 21:09:35

US3032249

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 09 Jun 2021 14:53:49

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:28:06
User coded data point as ATC: BLOOD AND BLOOD FORMING ORGANS, ATC: BLOOD SUBSTITUTES AND PERFUSION SOLUTIONS, ATC: I.V. SOLUTIONS, ATC: SOLUTIONS AFFECTING THE ELECTROLYTE BALANCE, PRODUCT: SODIUM CHLORIDE, PRODUCTSYNONYM: SODIUM CHLORIDE 0.9% - version WHODrug-Global-B3\202003.	Coder Import (b) (4)	18 Apr 2021 13:36:43
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\202003.	Coder Import (b) (4)	18 Apr 2021 13:36:43
User coded data point as ATC: BLOOD AND BLOOD FORMING ORGANS, ATC: BLOOD SUBSTITUTES AND PERFUSION SOLUTIONS, ATC: I.V. SOLUTION ADDITIVES, ATC: ELECTROLYTE SOLUTIONS, PRODUCT: SODIUM CHLORIDE - version WHODrug-Global-B3\202003.	Coder Import (b) (4)	07 Apr 2021 12:38:51
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\202003.	Coder Import (b) (4)	07 Apr 2021 12:38:51
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:41:17
Data point term sent to Coder	System	06 Apr 2021 13:59:52
Coding entries removed.	Chelsie Nutsch (b) (4)	06 Apr 2021 13:59:51
User entered 'SODIUM CHLORIDE 0.9%' reason for change: Data Entry Error	Chelsie Nutsch (b) (4)	06 Apr 2021 13:59:51
User coded data point as ATC: BLOOD AND BLOOD FORMING ORGANS, ATC: BLOOD SUBSTITUTES AND PERFUSION SOLUTIONS, ATC: I.V. SOLUTION ADDITIVES, ATC: ELECTROLYTE SOLUTIONS, PRODUCT: SODIUM CHLORIDE - version WHODrug-Global-B3\202003.	Coder Import (b) (4)	25 Mar 2021 21:11:30
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\202003.	Coder Import (b) (4)	25 Mar 2021 21:11:30
Data point term sent to Coder	System	25 Mar 2021 21:10:36

US3032249

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 09 Jun 2021 14:53:49

[Name of Medication](#)

Audit	User	Time (GMT)
User entered 'sodium chloride'	Kelsey Kelley (b) (4) (b) (4)	25 Mar 2021 21:10:22

US3032249

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 09 Jun 2021 14:53:49

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:28:06
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:41:17
User entered 'No (N)'	(b) (4) Kelsey Kelley (b) (4)	25 Mar 2021 21:10:22

US3032249

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 09 Jun 2021 14:53:49

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:28:06
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:41:17
User entered 'covid-19'	Kelsey Kelley (b) (4)	25 Mar 2021 21:10:22

US3032249

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 09 Jun 2021 14:53:49

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:28:06
User closed query 'Per DM CLR: Please provide the strength of this IV Fluid in the medication name, and consider recording the actual dose given instead (eg. 1000 ml). Review and amend as appropriate. ' (Site from DM).		09 Apr 2021 11:49:03
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:41:17
	(b) (4)	
Query 'Per DM CLR: Please provide the strength of this IV Fluid in the medication name, and consider recording the actual dose given instead (eg. 1000 ml). Review and amend as appropriate. ' answered with 'data updated. thank you ' (Site from DM).	Chelsie Nutsch (b) (4)	06 Apr 2021 13:59:59
	(b) (4)	
User entered '100' reason for change: Data Entry Error	Chelsie Nutsch (b) (4)	06 Apr 2021 13:59:51
	(b) (4)	
User opened query 'Per DM CLR: Please provide the strength of this IV Fluid in the medication name, and consider recording the actual dose given instead (eg. 1000 ml). Review and amend as appropriate. ' (Site from DM).	(b) (4), (b) (6)	04 Apr 2021 12:57:20
User entered '0.9'	Kelsey Kelley (b) (4)	25 Mar 2021 21:10:22
	(b) (4)	

US3032249

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 09 Jun 2021 14:53:49

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:28:06
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:41:17
User entered 'mL (mL)' reason for change: Data Entry Error	(b) (4)	
	Chelsie Nutsch (b) (4)	06 Apr 2021 13:59:51
User entered 'Other (OTHER)'	(b) (4)	
	Kelsey Kelley (b) (4)	25 Mar 2021 21:10:22
	(b) (4)	

US3032249

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 09 Jun 2021 14:53:49

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:28:06
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:41:17
User entered empty; reason for change Data Entry Error	(b) (4)	
	Chelsie Nutsch (b) (4)	06 Apr 2021 13:59:51
User entered '%'	(b) (4)	
	Kelsey Kelley (b) (4)	25 Mar 2021 21:10:22
	(b) (4)	

US3032249

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 09 Jun 2021 14:53:49

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:28:06
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:41:17
User entered 'other (OTHER)'	Kelsey Kelley (b) (4)	25 Mar 2021 21:10:22

US3032249

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 09 Jun 2021 14:53:49

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:28:06
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:41:17
User entered 'continuous'	(b) (4) Kelsey Kelley (b) (4)	25 Mar 2021 21:10:22

US3032249

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 09 Jun 2021 14:53:49

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:28:06
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:41:17
User entered 'Intravenous (INTRAVENOUS)'	Kelsey Kelley (b) (4)	25 Mar 2021 21:10:22

US3032249

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 09 Jun 2021 14:53:49

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:28:06
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:41:17
User entered empty.	(b) (4) Kelsey Kelley (b) (4)	25 Mar 2021 21:10:22

US3032249

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 09 Jun 2021 14:53:49

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:28:06
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:41:17
User entered '9 Feb 2021'	(b) (4) Kelsey Kelley (b) (4)	25 Mar 2021 21:10:22

US3032249

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 09 Jun 2021 14:53:49

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:28:06
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:41:17
User entered '0'	(b) (4) Kelsey Kelley (b) (4)	25 Mar 2021 21:10:22

US3032249

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 09 Jun 2021 14:53:49

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:28:06
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:41:17
User entered 'No (N)'	(b) (4) Kelsey Kelley (b) (4)	25 Mar 2021 21:10:22

US3032249

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 09 Jun 2021 14:53:49

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:28:06
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:41:17
User entered '12 Feb 2021'	Kelsey Kelley (b) (4)	25 Mar 2021 21:10:22

US3032249

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 09 Jun 2021 14:53:49

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:28:06
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:41:17
User entered 'No (N)'	(b) (4) Kelsey Kelley (b) (4)	25 Mar 2021 21:10:22

US3032249

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 09 Jun 2021 14:53:49

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:28:06
User entered empty.	System	25 Mar 2021 21:10:22

US3032249

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 09 Jun 2021 14:53:49

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:28:06
User entered empty.	System	25 Mar 2021 21:10:22

US3032249

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 09 Jun 2021 14:53:49

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:28:06
User entered empty.	System	25 Mar 2021 21:10:22

US3032249

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 09 Jun 2021 14:53:49

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:27:46
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:41:17
User coded data point as ATC: ANTIINFECTIVES FOR SYSTEMIC USE, ATC: ANTIBACTERIALS FOR SYSTEMIC USE, ATC: MACROLIDES, LINCOSAMIDES AND STREPTOGRAMINS, ATC: MACROLIDES, PRODUCT: AZITHROMYCIN - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	25 Mar 2021 21:27:30
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	25 Mar 2021 21:27:30
Data point term sent to Coder	System	25 Mar 2021 21:11:37
User entered 'azithromycin'	Kelsey Kelley (b) (4)	25 Mar 2021 21:10:53

US3032249

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 09 Jun 2021 14:53:49

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:27:46
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:41:17
User entered 'No (N)'	(b) (4) Kelsey Kelley (b) (4)	25 Mar 2021 21:10:53

US3032249

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 09 Jun 2021 14:53:49

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:27:46
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:41:17
User entered 'covid-19'	Kelsey Kelley (b) (4)	25 Mar 2021 21:10:53

US3032249

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 09 Jun 2021 14:53:49

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:27:46
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:41:17
User entered '500'	Kelsey Kelley (b) (4)	25 Mar 2021 21:10:53

US3032249

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 09 Jun 2021 14:53:49

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:27:46
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:41:17
User entered 'mg (mg)'	(b) (4) Kelsey Kelley (b) (4)	25 Mar 2021 21:10:53

US3032249

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 09 Jun 2021 14:53:49

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:27:46
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:41:17
User entered empty.	Kelsey Kelley (b) (4)	25 Mar 2021 21:10:53

US3032249

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 09 Jun 2021 14:53:49

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:27:46
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:41:17
User entered 'once daily (QD)'	Kelsey Kelley (b) (4)	25 Mar 2021 21:10:53

US3032249

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 09 Jun 2021 14:53:49

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:27:46
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:41:17
User entered empty.	(b) (4) Kelsey Kelley (b) (4)	25 Mar 2021 21:10:53

US3032249

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 09 Jun 2021 14:53:49

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:27:46
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:41:17
User entered 'Oral (ORAL)'	Kelsey Kelley (b) (4)	25 Mar 2021 21:10:53

US3032249

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 09 Jun 2021 14:53:49

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:27:46
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:41:17
User entered empty.	Kelsey Kelley (b) (4)	25 Mar 2021 21:10:53

US3032249

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 09 Jun 2021 14:53:49

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:27:46
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:41:17
User entered '10 Feb 2021'	(b) (4) Kelsey Kelley (b) (4)	25 Mar 2021 21:10:53
	(b) (4)	

US3032249

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 09 Jun 2021 14:53:49

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:27:46
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:41:17
User entered '0'	(b) (4) Kelsey Kelley (b) (4)	25 Mar 2021 21:10:53

US3032249

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 09 Jun 2021 14:53:49

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:27:46
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:41:17
User entered 'No (N)'	(b) (4) Kelsey Kelley (b) (4)	25 Mar 2021 21:10:53

US3032249

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 09 Jun 2021 14:53:49

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:27:46
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:41:17
User entered '12 Feb 2021'	Kelsey Kelley (b) (4)	25 Mar 2021 21:10:53

US3032249

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 09 Jun 2021 14:53:49

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:27:46
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:41:17
User entered 'No (N)'	Kelsey Kelley (b) (4)	25 Mar 2021 21:10:53

US3032249

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 09 Jun 2021 14:53:49

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:27:46
User entered '1'	System	25 Mar 2021 21:10:53

US3032249

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 09 Jun 2021 14:53:49

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:27:46
User entered '1'	System	25 Mar 2021 21:10:53

US3032249

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 09 Jun 2021 14:53:49

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:27:46
User entered '804 (804)'	System	25 Mar 2021 21:10:53

US3032249

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 09 Jun 2021 14:53:49

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:27:51
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:41:17
User coded data point as ATC: RESPIRATORY SYSTEM, ATC: DRUGS FOR OBSTRUCTIVE AIRWAY DISEASES, ATC: OTHER DRUGS FOR OBSTRUCTIVE AIRWAY DISEASES, INHALANTS, ATC: GLUCOCORTICOIDS, PRODUCT: BUDESONIDE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	29 Mar 2021 06:09:56
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	29 Mar 2021 06:09:56
Data point term sent to Coder	System	25 Mar 2021 21:11:37
User entered 'budesonide'	Kelsey Kelley (b) (4)	25 Mar 2021 21:11:17

US3032249

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 09 Jun 2021 14:53:49

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:27:51
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:41:17
User entered 'No (N)'	(b) (4) Kelsey Kelley (b) (4)	25 Mar 2021 21:11:17

US3032249

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 09 Jun 2021 14:53:49

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:27:51
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:41:17
User entered 'covid-19'	(b) (4) Kelsey Kelley (b) (4)	25 Mar 2021 21:11:17

US3032249

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 09 Jun 2021 14:53:49

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:27:51
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:41:17
User entered '0.5'	(b) (4) Kelsey Kelley (b) (4)	25 Mar 2021 21:11:17

US3032249

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 09 Jun 2021 14:53:49

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:27:51
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:41:17
User entered 'mg (mg)'	(b) (4) Kelsey Kelley (b) (4)	25 Mar 2021 21:11:17

US3032249

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 09 Jun 2021 14:53:49

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:27:51
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:41:17
User entered empty.	(b) (4) Kelsey Kelley (b) (4)	25 Mar 2021 21:11:17

US3032249

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 09 Jun 2021 14:53:49

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:27:51
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:41:17
User entered 'twice daily (BID)'	(b) (4) Kelsey Kelley (b) (4)	25 Mar 2021 21:11:17

US3032249

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 09 Jun 2021 14:53:49

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:27:51
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:41:17
User entered empty.	(b) (4) Kelsey Kelley (b) (4)	25 Mar 2021 21:11:17

US3032249

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 09 Jun 2021 14:53:49

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:27:51
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:41:17
User entered 'Respiratory (Inhalation) (RESPIRATORY (INHALATION))'	Kelsey Kelley (b) (4)	25 Mar 2021 21:11:17

US3032249

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 09 Jun 2021 14:53:49

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:27:51
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:41:17
User entered empty.	(b) (4) Kelsey Kelley (b) (4)	25 Mar 2021 21:11:17

US3032249

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 09 Jun 2021 14:53:49

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:27:51
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:41:17
User entered '09 Feb 2021'	(b) (4) Kelsey Kelley (b) (4)	25 Mar 2021 21:11:17
	(b) (4)	

US3032249

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 09 Jun 2021 14:53:49

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:27:51
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:41:17
User entered '0'	(b) (4) Kelsey Kelley (b) (4)	25 Mar 2021 21:11:17

US3032249

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 09 Jun 2021 14:53:49

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:27:51
User closed query 'Per DM CLR: Please review if a stop date should be recorded as the corresponding AE has resolved. If yes, please update CM stop date as applicable. Otherwise, provide clarification for continued use of medication. ' (Site from DM).	(b) (4), (b) (6)	07 Apr 2021 11:05:55
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:41:17
Query 'Per DM CLR: Please review if a stop date should be recorded as the corresponding AE has resolved. If yes, please update CM stop date as applicable. Otherwise, provide clarification for continued use of medication. ' answered with 'data updated. thank you' (Site from DM).	(b) (4) Chelsie Nutsch (b) (4)	06 Apr 2021 13:57:47
User entered 'No (N)' reason for change: Data Entry Error	Chelsie Nutsch (b) (4)	06 Apr 2021 13:57:38
User opened query 'Per DM CLR: Please review if a stop date should be recorded as the corresponding AE has resolved. If yes, please update CM stop date as applicable. Otherwise, provide clarification for continued use of medication. ' (Site from DM).	(b) (4), (b) (6)	04 Apr 2021 12:57:37
User entered 'Yes (Y)'	Kelsey Kelley (b) (4)	25 Mar 2021 21:11:17

US3032249

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 09 Jun 2021 14:53:49

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:27:51
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:41:17
User entered '12 Feb 2021' reason for change: Data Entry Error	(b) (4)	06 Apr 2021 13:57:38
User entered empty.	Chelsie Nutsch (b) (4)	06 Apr 2021 13:57:38
	(b) (4)	
	Kelsey Kelley (b) (4)	25 Mar 2021 21:11:17
	(b) (4)	

US3032249

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 09 Jun 2021 14:53:49

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:27:51
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:41:17
User entered 'No (N)'	(b) (4) Kelsey Kelley (b) (4)	25 Mar 2021 21:11:17

US3032249

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 09 Jun 2021 14:53:49

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:27:51
User entered '2'	System	25 Mar 2021 21:11:17

US3032249

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 09 Jun 2021 14:53:49

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:27:51
User entered '1'	System	25 Mar 2021 21:11:17

US3032249

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 09 Jun 2021 14:53:49

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:27:51
User entered '804 (804)'	System	25 Mar 2021 21:11:17

US3032249

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 09 Jun 2021 14:53:49

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:27:54
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:41:17
User coded data point as ATC: RESPIRATORY SYSTEM, ATC: DRUGS FOR OBSTRUCTIVE AIRWAY DISEASES, ATC: ADRENERGICS, INHALANTS, ATC: SELECTIVE BETA-2-ADRENORECEPTOR AGONISTS, PRODUCT: FORMOTEROL - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4)	30 Mar 2021 14:18:25
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	30 Mar 2021 14:18:25
Data point term sent to Coder	System	25 Mar 2021 21:12:38
User entered 'formoterol'	Kelsey Kelley (b) (4)	25 Mar 2021 21:12:23

US3032249

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 09 Jun 2021 14:53:49

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:27:54
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:41:17
User entered 'No (N)'	(b) (4) Kelsey Kelley (b) (4)	25 Mar 2021 21:12:23

US3032249

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 09 Jun 2021 14:53:49

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:27:54
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:41:17
User entered 'covid-19'	(b) (4) Kelsey Kelley (b) (4)	25 Mar 2021 21:12:23

US3032249

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 09 Jun 2021 14:53:49

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:27:54
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:41:17
User entered '20'	Kelsey Kelley (b) (4)	25 Mar 2021 21:12:23

US3032249

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 09 Jun 2021 14:53:49

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:27:54
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:41:17
User entered 'ug (ug)'	(b) (4) Kelsey Kelley (b) (4)	25 Mar 2021 21:12:23
	(b) (4)	

US3032249

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 09 Jun 2021 14:53:49

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:27:54
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:41:17
User entered empty.	(b) (4) Kelsey Kelley (b) (4)	25 Mar 2021 21:12:23

US3032249

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 09 Jun 2021 14:53:49

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:27:54
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:41:17
User entered 'twice daily (BID)'	(b) (4) Kelsey Kelley (b) (4)	25 Mar 2021 21:12:23

US3032249

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 09 Jun 2021 14:53:49

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:27:54
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:41:17
User entered empty.	(b) (4) Kelsey Kelley (b) (4)	25 Mar 2021 21:12:23

US3032249

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 09 Jun 2021 14:53:49

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:27:54
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:41:17
User entered 'Respiratory (Inhalation) (RESPIRATORY (INHALATION))'	Kelsey Kelley (b) (4)	25 Mar 2021 21:12:23

US3032249

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 09 Jun 2021 14:53:49

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:27:54
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:41:17
User entered empty.	(b) (4) Kelsey Kelley (b) (4)	25 Mar 2021 21:12:23

US3032249

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 09 Jun 2021 14:53:49

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:27:54
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:41:17
User entered '9 Feb 2021'	(b) (4) Kelsey Kelley (b) (4)	25 Mar 2021 21:12:23

US3032249

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 09 Jun 2021 14:53:49

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:27:54
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:41:17
User entered '0'	(b) (4) Kelsey Kelley (b) (4)	25 Mar 2021 21:12:23

US3032249

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 09 Jun 2021 14:53:49

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:27:54
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:41:17
User entered 'No (N)'	(b) (4) Kelsey Kelley (b) (4)	25 Mar 2021 21:12:23

US3032249

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 09 Jun 2021 14:53:49

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:27:54
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:41:17
User entered '12 Feb 2021'	(b) (4) Kelsey Kelley (b) (4)	25 Mar 2021 21:12:23
	(b) (4)	

US3032249

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 09 Jun 2021 14:53:49

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:27:54
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:41:17
User entered 'No (N)'	(b) (4) Kelsey Kelley (b) (4)	25 Mar 2021 21:12:23

US3032249

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 09 Jun 2021 14:53:49

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:27:54
User entered '2'	System	25 Mar 2021 21:12:23

US3032249

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 09 Jun 2021 14:53:49

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:27:54
User entered '1'	System	25 Mar 2021 21:12:23

US3032249

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 09 Jun 2021 14:53:49

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:27:54
User entered '804 (804)'	System	25 Mar 2021 21:12:23

US3032249

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 09 Jun 2021 14:53:49

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:28:02
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:41:17
User coded data point as ATC: BLOOD AND BLOOD FORMING ORGANS, ATC: ANTITHROMBOTIC AGENTS, ATC: ANTITHROMBOTIC AGENTS, ATC: HEPARIN GROUP, PRODUCT: ENOXAPARIN - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4)	25 Mar 2021 21:14:30
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	25 Mar 2021 21:14:30
Data point term sent to Coder	System	25 Mar 2021 21:13:39
User entered 'enoxaparin'	Kelsey Kelley (b) (4)	25 Mar 2021 21:13:06

US3032249

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 09 Jun 2021 14:53:49

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:28:02
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:41:17
User entered 'No (N)'	(b) (4) Kelsey Kelley (b) (4)	25 Mar 2021 21:13:06

US3032249

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 09 Jun 2021 14:53:49

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:28:02
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:41:17
User entered 'covid-19'	Kelsey Kelley (b) (4)	25 Mar 2021 21:13:06

US3032249

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 09 Jun 2021 14:53:49

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:28:02
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:41:17
User entered '30'	Kelsey Kelley (b) (4)	25 Mar 2021 21:13:06

US3032249

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 09 Jun 2021 14:53:49

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:28:02
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:41:17
User entered 'mg (mg)'	(b) (4) Kelsey Kelley (b) (4)	25 Mar 2021 21:13:06

US3032249

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 09 Jun 2021 14:53:49

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:28:02
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:41:17
User entered empty.	(b) (4) Kelsey Kelley (b) (4)	25 Mar 2021 21:13:06

US3032249

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 09 Jun 2021 14:53:49

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:28:02
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:41:17
User entered 'twice daily (BID)'	Kelsey Kelley (b) (4)	25 Mar 2021 21:13:06

US3032249

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 09 Jun 2021 14:53:49

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:28:02
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:41:17
User entered empty.	(b) (4) Kelsey Kelley (b) (4)	25 Mar 2021 21:13:06

US3032249

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 09 Jun 2021 14:53:49

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:28:02
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:41:17
User entered 'Subcutaneous (SUBCUTANEOUS)'	Kelsey Kelley (b) (4)	25 Mar 2021 21:13:06

US3032249

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 09 Jun 2021 14:53:49

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:28:02
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:41:17
User entered empty.	Kelsey Kelley (b) (4)	25 Mar 2021 21:13:06

US3032249

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 09 Jun 2021 14:53:49

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:28:02
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:41:17
User entered '9 Feb 2021'	(b) (4) Kelsey Kelley (b) (4)	25 Mar 2021 21:13:06

US3032249

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 09 Jun 2021 14:53:49

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:28:02
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:41:17
User entered '0'	(b) (4) Kelsey Kelley (b) (4)	25 Mar 2021 21:13:06

US3032249

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 09 Jun 2021 14:53:49

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:28:02
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:41:17
User entered 'No (N)'	(b) (4) Kelsey Kelley (b) (4)	25 Mar 2021 21:13:06

US3032249

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 09 Jun 2021 14:53:49

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:28:02
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:41:17
User entered '12 Feb 2021'	(b) (4) Kelsey Kelley (b) (4)	25 Mar 2021 21:13:06
	(b) (4)	

US3032249

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 09 Jun 2021 14:53:49

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:28:02
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:41:17
User entered 'No (N)'	(b) (4) Kelsey Kelley (b) (4)	25 Mar 2021 21:13:06

US3032249

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 09 Jun 2021 14:53:49

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:28:02
User entered '2'	System	25 Mar 2021 21:13:06

US3032249

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 09 Jun 2021 14:53:49

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:28:02
User entered '1'	System	25 Mar 2021 21:13:06

US3032249

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 09 Jun 2021 14:53:49

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:28:02
User entered '804 (804)'	System	25 Mar 2021 21:13:06

US3032249

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 09 Jun 2021 14:53:49

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:27:58
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:41:17
User coded data point as ATC: VARIOUS, ATC: ALL OTHER THERAPEUTIC PRODUCTS, ATC: ALL OTHER THERAPEUTIC PRODUCTS, ATC: MEDICAL GASES, PRODUCT: OXYGEN - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	25 Mar 2021 21:30:30
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	25 Mar 2021 21:30:30
Data point term sent to Coder	System	25 Mar 2021 21:14:40
User entered 'Oxygen'	Kelsey Kelley (b) (4)	25 Mar 2021 21:13:59

US3032249

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 09 Jun 2021 14:53:49

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:27:58
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:41:17
User entered 'No (N)'	(b) (4) Kelsey Kelley (b) (4)	25 Mar 2021 21:13:59

US3032249

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 09 Jun 2021 14:53:49

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:27:58
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:41:17
User entered 'covid-19'	Kelsey Kelley (b) (4)	25 Mar 2021 21:13:59

US3032249

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 09 Jun 2021 14:53:49

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:27:58
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:41:17
User entered '2'	(b) (4) Kelsey Kelley (b) (4)	25 Mar 2021 21:13:59

US3032249

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 09 Jun 2021 14:53:49

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:27:58
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:41:17
User entered 'Other (OTHER)'	(b) (4) Kelsey Kelley (b) (4)	25 Mar 2021 21:13:59

US3032249

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 09 Jun 2021 14:53:49

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:27:58
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:41:17
User entered 'L'	(b) (4) Kelsey Kelley (b) (4)	25 Mar 2021 21:13:59

US3032249

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 09 Jun 2021 14:53:49

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:27:58
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:41:17
User entered 'other (OTHER)'	(b) (4) Kelsey Kelley (b) (4)	25 Mar 2021 21:13:59

US3032249

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 09 Jun 2021 14:53:49

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:27:58
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:41:17
User entered 'continuous'	Kelsey Kelley (b) (4)	25 Mar 2021 21:13:59

US3032249

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 09 Jun 2021 14:53:49

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:27:58
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:41:17
User entered 'Respiratory (Inhalation) (RESPIRATORY (INHALATION))'	Kelsey Kelley (b) (4)	25 Mar 2021 21:13:59

US3032249

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 09 Jun 2021 14:53:49

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:27:58
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:41:17
User entered empty.	Kelsey Kelley (b) (4)	25 Mar 2021 21:13:59

US3032249

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 09 Jun 2021 14:53:49

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:27:58
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:41:17
User entered '9 Feb 2021'	(b) (4) Kelsey Kelley (b) (4)	25 Mar 2021 21:13:59

US3032249

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 09 Jun 2021 14:53:49

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:27:58
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:41:17
User entered '0'	Kelsey Kelley (b) (4)	25 Mar 2021 21:13:59

US3032249

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 09 Jun 2021 14:53:49

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:27:58
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:41:17
User entered 'No (N)'	(b) (4) Kelsey Kelley (b) (4)	25 Mar 2021 21:13:59

US3032249

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 09 Jun 2021 14:53:49

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:27:58
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:41:17
User entered '12 Feb 2021'	(b) (4) Kelsey Kelley (b) (4)	25 Mar 2021 21:13:59
	(b) (4)	

US3032249

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 09 Jun 2021 14:53:49

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:27:58
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:41:17
User entered 'No (N)'	(b) (4) Kelsey Kelley (b) (4)	25 Mar 2021 21:13:59

US3032249

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 09 Jun 2021 14:53:49

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:27:58
User entered empty.	System	25 Mar 2021 21:13:59

US3032249

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 09 Jun 2021 14:53:49

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:27:58
User entered empty.	System	25 Mar 2021 21:13:59

US3032249

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 09 Jun 2021 14:53:49

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:27:58
User entered empty.	System	25 Mar 2021 21:13:59

US3032249

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 09 Jun 2021 14:53:49

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:55:10
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:41:17
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: OTHER ANALGESICS AND ANTIPYRETICS, ATC: ANILIDES, PRODUCT: PARACETAMOL, PRODUCTSYNONYM: ACETAMINOPHEN - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	25 Mar 2021 21:15:30
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	25 Mar 2021 21:15:30
Data point term sent to Coder	System	25 Mar 2021 21:14:40
User entered 'acetaminophen'	Kelsey Kelley (b) (4)	25 Mar 2021 21:14:26

US3032249

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 09 Jun 2021 14:53:49

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:55:10
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:41:17
User entered 'No (N)'	(b) (4) Kelsey Kelley (b) (4)	25 Mar 2021 21:14:26

US3032249

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 09 Jun 2021 14:53:49

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:55:10
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:41:17
User entered 'bilateral pneumonia'	Kelsey Kelley (b) (4)	25 Mar 2021 21:14:26

US3032249

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 09 Jun 2021 14:53:49

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:55:10
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:41:17
User entered '650'	(b) (4) Kelsey Kelley (b) (4)	25 Mar 2021 21:14:26

US3032249

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 09 Jun 2021 14:53:49

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:55:10
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:41:17
User entered 'mg (mg)'	(b) (4) Kelsey Kelley (b) (4)	25 Mar 2021 21:14:26

US3032249

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 09 Jun 2021 14:53:49

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:55:10
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:41:17
User entered empty.	(b) (4) Kelsey Kelley (b) (4)	25 Mar 2021 21:14:26
	(b) (4)	

US3032249

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 09 Jun 2021 14:53:49

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:55:10
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:41:17
User entered 'as needed (PRN)'	(b) (4) Kelsey Kelley (b) (4)	25 Mar 2021 21:14:26

US3032249

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 09 Jun 2021 14:53:49

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:55:10
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:41:17
User entered empty.	(b) (4) Kelsey Kelley (b) (4)	25 Mar 2021 21:14:26
	(b) (4)	

US3032249

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 09 Jun 2021 14:53:49

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:55:10
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:41:17
User entered 'Oral (ORAL)'	Kelsey Kelley (b) (4)	25 Mar 2021 21:14:26

US3032249

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 09 Jun 2021 14:53:49

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:55:10
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:41:17
User entered empty.	(b) (4) Kelsey Kelley (b) (4)	25 Mar 2021 21:14:26
	(b) (4)	

US3032249

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 09 Jun 2021 14:53:49

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:55:10
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:41:17
User entered '1 Mar 2021'	(b) (4) Kelsey Kelley (b) (4)	25 Mar 2021 21:14:26

US3032249

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 09 Jun 2021 14:53:49

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:55:10
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:41:17
User entered '0'	(b) (4) Kelsey Kelley (b) (4)	25 Mar 2021 21:14:26

US3032249

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 09 Jun 2021 14:53:49

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:55:10
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:41:17
User entered 'No (N)'	(b) (4) Kelsey Kelley (b) (4)	25 Mar 2021 21:14:26

US3032249

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 09 Jun 2021 14:53:49

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:55:10
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:41:17
User entered '5 Mar 2021'	(b) (4) Kelsey Kelley (b) (4)	25 Mar 2021 21:14:26
	(b) (4)	

US3032249

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 09 Jun 2021 14:53:49

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:55:10
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:41:17
User entered 'No (N)'	(b) (4) Kelsey Kelley (b) (4)	25 Mar 2021 21:14:26

US3032249

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 09 Jun 2021 14:53:49

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:55:10
User entered empty.	System	25 Mar 2021 21:14:26

US3032249

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 09 Jun 2021 14:53:49

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:55:10
User entered empty.	System	25 Mar 2021 21:14:26

US3032249

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 09 Jun 2021 14:53:49

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:55:10
User entered empty.	System	25 Mar 2021 21:14:26

US3032249

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 09 Jun 2021 14:53:49

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:55:16
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:41:17
User coded data point as ATC: RESPIRATORY SYSTEM, ATC: DRUGS FOR OBSTRUCTIVE AIRWAY DISEASES, ATC: ADRENERGICS, INHALANTS, ATC: SELECTIVE BETA-2-ADRENORECEPTOR AGONISTS, PRODUCT: SALBUTAMOL, PRODUCTSYNONYM: ALBUTEROL [SALBUTAMOL] - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4)	25 Mar 2021 21:16:31
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	25 Mar 2021 21:16:31
Data point term sent to Coder	System	25 Mar 2021 21:15:42
User entered 'Albuterol'	Kelsey Kelley (b) (4)	25 Mar 2021 21:15:07
	(b) (4)	

US3032249

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 09 Jun 2021 14:53:49

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:55:16
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:41:17
User entered 'No (N)'	(b) (4) Kelsey Kelley (b) (4)	25 Mar 2021 21:15:07

US3032249

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 09 Jun 2021 14:53:49

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:55:16
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:41:17
User entered 'bilateral pneumonia'	Kelsey Kelley (b) (4)	25 Mar 2021 21:15:07

US3032249

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 09 Jun 2021 14:53:49

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:55:16
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:41:17
User entered '2.5'	(b) (4) Kelsey Kelley (b) (4)	25 Mar 2021 21:15:07

US3032249

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 09 Jun 2021 14:53:49

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:55:16
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:41:17
User entered 'mg (mg)'	(b) (4) Kelsey Kelley (b) (4)	25 Mar 2021 21:15:07

US3032249

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 09 Jun 2021 14:53:49

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:55:16
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:41:17
User entered empty.	(b) (4) Kelsey Kelley (b) (4)	25 Mar 2021 21:15:07
	(b) (4)	

US3032249

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 09 Jun 2021 14:53:49

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:55:16
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:41:17
User entered 'as needed (PRN)'	Kelsey Kelley (b) (4)	25 Mar 2021 21:15:07

US3032249

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 09 Jun 2021 14:53:49

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:55:16
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:41:17
User entered empty.	(b) (4) Kelsey Kelley (b) (4)	25 Mar 2021 21:15:07
	(b) (4)	

US3032249

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 09 Jun 2021 14:53:49

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:55:16
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:41:17
User entered 'Respiratory (Inhalation) (RESPIRATORY (INHALATION))'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	25 Mar 2021 21:15:07

US3032249

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 09 Jun 2021 14:53:49

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:55:16
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:41:17
User entered empty.	(b) (4) Kelsey Kelley (b) (4)	25 Mar 2021 21:15:07
	(b) (4)	

US3032249

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 09 Jun 2021 14:53:49

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:55:16
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:41:17
User entered '1 Mar 2021'	(b) (4) Kelsey Kelley (b) (4)	25 Mar 2021 21:15:07

US3032249

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 09 Jun 2021 14:53:49

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:55:16
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:41:17
User entered '0'	Kelsey Kelley (b) (4)	25 Mar 2021 21:15:07

US3032249

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 09 Jun 2021 14:53:49

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:55:16
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:41:17
User entered 'No (N)'	(b) (4) Kelsey Kelley (b) (4)	25 Mar 2021 21:15:07

US3032249

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 09 Jun 2021 14:53:49

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:55:16
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:41:17
User entered '5 Mar 2021'	(b) (4) Kelsey Kelley (b) (4)	25 Mar 2021 21:15:07
	(b) (4)	

US3032249

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 09 Jun 2021 14:53:49

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:55:16
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:41:17
User entered 'No (N)'	Kelsey Kelley (b) (4)	25 Mar 2021 21:15:07

US3032249

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 09 Jun 2021 14:53:49

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:55:16
User entered empty.	System	25 Mar 2021 21:15:07

US3032249

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 09 Jun 2021 14:53:49

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:55:16
User entered empty.	System	25 Mar 2021 21:15:07

US3032249

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 09 Jun 2021 14:53:49

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:55:16
User entered empty.	System	25 Mar 2021 21:15:07

US3032249

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Generated On: 09 Jun 2021 14:53:49

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:55:22
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:41:17
User coded data point as ATC: RESPIRATORY SYSTEM, ATC: DRUGS FOR OBSTRUCTIVE AIRWAY DISEASES, ATC: ADRENERGICS, INHALANTS, ATC: ADRENERGICS IN COMBINATIONS WITH ANTICHOLINERGICS INCL. TRIPLE COMBINATIONS WITH CORTICOSTEROIDS, PRODUCT: IPRATROPIUM BROMIDE;SALBUTAMOL SULFATE, PRODUCTSYNONYM: DUONEB - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	30 Mar 2021 12:34:41
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	30 Mar 2021 12:34:41
Data point term sent to Coder	System	25 Mar 2021 21:15:46
User entered 'Duoneb'	Kelsey Kelley (b) (4)	25 Mar 2021 21:15:44

US3032249

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Generated On: 09 Jun 2021 14:53:49

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:55:22
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:41:17
User entered 'No (N)'	(b) (4) Kelsey Kelley (b) (4)	25 Mar 2021 21:15:44

US3032249

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Generated On: 09 Jun 2021 14:53:49

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:55:22
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:41:17
User entered 'bilateral pneumonia'	Kelsey Kelley (b) (4)	25 Mar 2021 21:15:44

US3032249

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Generated On: 09 Jun 2021 14:53:49

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:55:22
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:41:17
User entered '2.5/3'	Kelsey Kelley (b) (4)	25 Mar 2021 21:15:44

US3032249

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Generated On: 09 Jun 2021 14:53:49

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:55:22
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:41:17
User entered 'mg (mg)'	(b) (4) Kelsey Kelley (b) (4)	25 Mar 2021 21:15:44

US3032249

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Generated On: 09 Jun 2021 14:53:49

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:55:22
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:41:17
User entered empty.	(b) (4) Kelsey Kelley (b) (4)	25 Mar 2021 21:15:44
	(b) (4)	

US3032249

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Generated On: 09 Jun 2021 14:53:49

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:55:22
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:41:17
User entered 'twice daily (BID)'	(b) (4) Kelsey Kelley (b) (4)	25 Mar 2021 21:15:44

US3032249

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Generated On: 09 Jun 2021 14:53:49

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:55:22
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:41:17
User entered empty.	(b) (4) Kelsey Kelley (b) (4)	25 Mar 2021 21:15:44
	(b) (4)	

US3032249

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Generated On: 09 Jun 2021 14:53:49

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:55:22
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:41:17
User entered 'Subcutaneous (SUBCUTANEOUS)'	Kelsey Kelley (b) (4)	25 Mar 2021 21:15:44

US3032249

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Generated On: 09 Jun 2021 14:53:49

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:55:22
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:41:17
User entered empty.	(b) (4) Kelsey Kelley (b) (4)	25 Mar 2021 21:15:44
	(b) (4)	

US3032249

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Generated On: 09 Jun 2021 14:53:49

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:55:22
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:41:17
User entered '1 Mar 2021'	(b) (4) Kelsey Kelley (b) (4)	25 Mar 2021 21:15:44
	(b) (4)	

US3032249

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Generated On: 09 Jun 2021 14:53:49

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:55:22
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:41:17
User entered '0'	(b) (4) Kelsey Kelley (b) (4)	25 Mar 2021 21:15:44

US3032249

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Generated On: 09 Jun 2021 14:53:49

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:55:22
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:41:17
User entered 'No (N)'	(b) (4) Kelsey Kelley (b) (4)	25 Mar 2021 21:15:44

US3032249

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Generated On: 09 Jun 2021 14:53:49

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:55:22
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:41:17
User closed query 'Ongoing is No, however End date is missing. Please provide.' (Site from System).	(b) (4)	25 Mar 2021 21:15:57
User entered '5 Mar 2021' reason for change: Data Entry Error	Kelsey Kelley (b) (4)	25 Mar 2021 21:15:57
User opened query 'Ongoing is No, however End date is missing. Please provide.' (Site from System).	(b) (4)	25 Mar 2021 21:15:44
User entered empty.	Kelsey Kelley (b) (4)	25 Mar 2021 21:15:44
	(b) (4)	

US3032249

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Generated On: 09 Jun 2021 14:53:49

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:55:22
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:41:17
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4)	
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	25 Mar 2021 21:15:57
User entered 'No (N)' reason for change: Data Entry Error	System	25 Mar 2021 21:15:57
User opened query 'Data is required. Please complete.' (Site from System).	Kelsey Kelley (b) (4)	25 Mar 2021 21:15:57
User entered empty.	(b) (4)	
	System	25 Mar 2021 21:15:44
	Kelsey Kelley (b) (4)	25 Mar 2021 21:15:44
	(b) (4)	

US3032249

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Generated On: 09 Jun 2021 14:53:49

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:55:22
User entered '2'	System	25 Mar 2021 21:15:44

US3032249

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Generated On: 09 Jun 2021 14:53:49

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:55:22
User entered '1'	System	25 Mar 2021 21:15:44

US3032249

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Generated On: 09 Jun 2021 14:53:49

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:55:22
User entered '804 (804)'	System	25 Mar 2021 21:15:44

US3032249

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (29)

Generated On: 09 Jun 2021 14:53:49

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:57:01
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:41:17
User coded data point as ATC: BLOOD AND BLOOD FORMING ORGANS, ATC: ANTITHROMBOTIC AGENTS, ATC: ANTITHROMBOTIC AGENTS, ATC: HEPARIN GROUP, PRODUCT: ENOXAPARIN - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4)	30 Mar 2021 00:56:23
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	30 Mar 2021 00:56:23
Data point term sent to Coder	System	25 Mar 2021 21:17:47
User entered 'enoxaparin'	Kelsey Kelley (b) (4)	25 Mar 2021 21:17:10
	(b) (4)	

US3032249

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (29)

Generated On: 09 Jun 2021 14:53:49

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:57:01
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:41:17
User entered 'No (N)'	(b) (4) Kelsey Kelley (b) (4)	25 Mar 2021 21:17:10

US3032249

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (29)

Generated On: 09 Jun 2021 14:53:49

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:57:01
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:41:17
User entered 'bilateral pneumonia'	(b) (4) Kelsey Kelley (b) (4)	25 Mar 2021 21:17:10

US3032249

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (29)

Generated On: 09 Jun 2021 14:53:49

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:57:01
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:41:17
User entered '100'	Kelsey Kelley (b) (4)	25 Mar 2021 21:17:10

US3032249

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (29)

Generated On: 09 Jun 2021 14:53:49

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:57:01
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:41:17
User entered 'mg (mg)'	(b) (4) Kelsey Kelley (b) (4)	25 Mar 2021 21:17:10

US3032249

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (29)

Generated On: 09 Jun 2021 14:53:49

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:57:01
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:41:17
User entered empty.	(b) (4) Kelsey Kelley (b) (4)	25 Mar 2021 21:17:10

US3032249

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (29)

Generated On: 09 Jun 2021 14:53:49

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:57:01
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:41:17
User entered 'twice daily (BID)'	(b) (4) Kelsey Kelley (b) (4)	25 Mar 2021 21:17:10

US3032249

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (29)

Generated On: 09 Jun 2021 14:53:49

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:57:01
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:41:17
User entered empty.	(b) (4) Kelsey Kelley (b) (4)	25 Mar 2021 21:17:10
	(b) (4)	

US3032249

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (29)

Generated On: 09 Jun 2021 14:53:49

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:57:01
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:41:17
User entered 'Subcutaneous (SUBCUTANEOUS)'	Kelsey Kelley (b) (4)	25 Mar 2021 21:17:10

US3032249

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (29)

Generated On: 09 Jun 2021 14:53:49

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:57:01
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:41:17
User entered empty.	(b) (4) Kelsey Kelley (b) (4)	25 Mar 2021 21:17:10
	(b) (4)	

US3032249

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (29)

Generated On: 09 Jun 2021 14:53:49

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:57:01
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:41:17
User entered '1 Mar 2021'	(b) (4) Kelsey Kelley (b) (4)	25 Mar 2021 21:17:10

US3032249

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (29)

Generated On: 09 Jun 2021 14:53:49

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:57:01
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:41:17
User entered '0'	(b) (4) Kelsey Kelley (b) (4)	25 Mar 2021 21:17:10

US3032249

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (29)

Generated On: 09 Jun 2021 14:53:49

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:57:01
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:41:17
User entered 'No (N)'	(b) (4) Kelsey Kelley (b) (4)	25 Mar 2021 21:17:10

US3032249

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (29)

Generated On: 09 Jun 2021 14:53:49

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:57:01
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:41:17
User entered '5 Mar 2021'	(b) (4) Kelsey Kelley (b) (4)	25 Mar 2021 21:17:10
	(b) (4)	

US3032249

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (29)

Generated On: 09 Jun 2021 14:53:49

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:57:01
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:41:17
User entered 'No (N)'	(b) (4) Kelsey Kelley (b) (4)	25 Mar 2021 21:17:10

US3032249

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (29)

Generated On: 09 Jun 2021 14:53:49

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:57:01
User entered '2'	System	25 Mar 2021 21:17:10

US3032249

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (29)

Generated On: 09 Jun 2021 14:53:49

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:57:01
User entered '1'	System	25 Mar 2021 21:17:10

US3032249

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (29)

Generated On: 09 Jun 2021 14:53:49

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:57:01
User entered '804 (804)'	System	25 Mar 2021 21:17:10

US3032249

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (30)

Generated On: 09 Jun 2021 14:53:49

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:56:51
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:41:17
User coded data point as ATC: ANTIINFECTIVES FOR SYSTEMIC USE, ATC: ANTIBACTERIALS FOR SYSTEMIC USE, ATC: QUINOLONE ANTIBACTERIALS, ATC: FLUOROQUINOLONES, PRODUCT: LEVOFLOXACIN - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4)	31 Mar 2021 14:01:28
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	31 Mar 2021 14:01:28
Data point term sent to Coder	System	25 Mar 2021 21:18:50
User entered 'levofloxacin'	Kelsey Kelley (b) (4)	25 Mar 2021 21:18:13

US3032249

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (30)

Generated On: 09 Jun 2021 14:53:49

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:56:51
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:41:17
User entered 'No (N)'	(b) (4) Kelsey Kelley (b) (4)	25 Mar 2021 21:18:13

US3032249

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (30)

Generated On: 09 Jun 2021 14:53:49

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:56:51
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:41:17
User entered 'bilateral pneumonia'	(b) (4) Kelsey Kelley (b) (4)	25 Mar 2021 21:18:13

US3032249

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (30)

Generated On: 09 Jun 2021 14:53:49

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:56:51
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:41:17
User entered '750'	(b) (4) Kelsey Kelley (b) (4)	25 Mar 2021 21:18:13

US3032249

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (30)

Generated On: 09 Jun 2021 14:53:49

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:56:51
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:41:17
User entered 'mg (mg)'	(b) (4) Kelsey Kelley (b) (4)	25 Mar 2021 21:18:13

US3032249

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (30)

Generated On: 09 Jun 2021 14:53:49

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:56:51
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:41:17
User entered empty.	(b) (4) Kelsey Kelley (b) (4)	25 Mar 2021 21:18:13
	(b) (4)	

US3032249

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (30)

Generated On: 09 Jun 2021 14:53:49

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:56:51
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:41:17
User entered 'other (OTHER)'	(b) (4) Kelsey Kelley (b) (4)	25 Mar 2021 21:18:13

US3032249

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (30)

Generated On: 09 Jun 2021 14:53:49

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:56:51
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:41:17
User entered 'Q48H'	(b) (4) Kelsey Kelley (b) (4)	25 Mar 2021 21:18:13

US3032249

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (30)

Generated On: 09 Jun 2021 14:53:49

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:56:51
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:41:17
User entered 'Intravenous (INTRAVENOUS)'	Kelsey Kelley (b) (4)	25 Mar 2021 21:18:13

US3032249

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (30)

Generated On: 09 Jun 2021 14:53:49

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:56:51
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:41:17
User entered empty.	(b) (4) Kelsey Kelley (b) (4)	25 Mar 2021 21:18:13

US3032249

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (30)

Generated On: 09 Jun 2021 14:53:49

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:56:51
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:41:17
User entered '1 Mar 2021'	(b) (4) Kelsey Kelley (b) (4)	25 Mar 2021 21:18:13
	(b) (4)	

US3032249

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (30)

Generated On: 09 Jun 2021 14:53:49

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:56:51
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:41:17
User entered '0'	(b) (4) Kelsey Kelley (b) (4)	25 Mar 2021 21:18:13

US3032249

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (30)

Generated On: 09 Jun 2021 14:53:49

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:56:51
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:41:17
User entered 'No (N)'	(b) (4) Kelsey Kelley (b) (4)	25 Mar 2021 21:18:13

US3032249

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (30)

Generated On: 09 Jun 2021 14:53:49

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:56:51
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:41:17
User entered '5 Mar 2021'	(b) (4) Kelsey Kelley (b) (4)	25 Mar 2021 21:18:13
	(b) (4)	

US3032249

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (30)

Generated On: 09 Jun 2021 14:53:49

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:56:51
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:41:17
User entered 'No (N)'	(b) (4) Kelsey Kelley (b) (4)	25 Mar 2021 21:18:13

US3032249

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (30)

Generated On: 09 Jun 2021 14:53:49

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:56:51
User entered empty.	System	25 Mar 2021 21:18:13

US3032249

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (30)

Generated On: 09 Jun 2021 14:53:49

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:56:51
User entered empty.	System	25 Mar 2021 21:18:13

US3032249

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (30)

Generated On: 09 Jun 2021 14:53:49

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:56:51
User entered empty.	System	25 Mar 2021 21:18:13

US3032249

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (31)

Generated On: 09 Jun 2021 14:53:49

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:56:39
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:41:17
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: DRUGS FOR ACID RELATED DISORDERS, ATC: DRUGS FOR PEPTIC ULCER AND GASTRO-OESOPHAGEAL REFLUX DISEASE (GORD), ATC: PROTON PUMP INHIBITORS, PRODUCT: PANTOPRAZOLE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	26 Mar 2021 10:45:49
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (6)	26 Mar 2021 10:45:49
Data point term sent to Coder	System	25 Mar 2021 21:18:50
User entered 'pantoprazole'	Kelsey Kelley (b) (4)	25 Mar 2021 21:18:42

US3032249

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (31)

Generated On: 09 Jun 2021 14:53:49

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:56:39
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:41:17
User entered 'No (N)'	(b) (4) Kelsey Kelley (b) (4)	25 Mar 2021 21:18:42

US3032249

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (31)

Generated On: 09 Jun 2021 14:53:49

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:56:39
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:41:17
User entered 'bilateral pneumonia'	(b) (4) Kelsey Kelley (b) (4)	25 Mar 2021 21:18:42

US3032249

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (31)

Generated On: 09 Jun 2021 14:53:49

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:56:39
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:41:17
User entered '40'	(b) (4) Kelsey Kelley (b) (4)	25 Mar 2021 21:18:42

US3032249

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (31)

Generated On: 09 Jun 2021 14:53:49

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:56:39
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:41:17
User entered 'mg (mg)'	(b) (4) Kelsey Kelley (b) (4)	25 Mar 2021 21:18:42

US3032249

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (31)

Generated On: 09 Jun 2021 14:53:49

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:56:39
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:41:17
User entered empty.	(b) (4) Kelsey Kelley (b) (4)	25 Mar 2021 21:18:42
	(b) (4)	

US3032249

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (31)

Generated On: 09 Jun 2021 14:53:49

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:56:39
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:41:17
User entered 'once daily (QD)'	Kelsey Kelley (b) (4)	25 Mar 2021 21:18:42

US3032249

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (31)

Generated On: 09 Jun 2021 14:53:49

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:56:39
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:41:17
User entered empty.	(b) (4) Kelsey Kelley (b) (4)	25 Mar 2021 21:18:42
	(b) (4)	

US3032249

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (31)

Generated On: 09 Jun 2021 14:53:49

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:56:39
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:41:17
User entered 'Oral (ORAL)'	(b) (4) Kelsey Kelley (b) (4)	25 Mar 2021 21:18:42
	(b) (4)	

US3032249

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (31)

Generated On: 09 Jun 2021 14:53:49

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:56:39
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:41:17
User entered empty.	(b) (4) Kelsey Kelley (b) (4)	25 Mar 2021 21:18:42
	(b) (4)	

US3032249

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (31)

Generated On: 09 Jun 2021 14:53:49

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:56:39
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:41:17
User entered '1 Mar 2021'	(b) (4) Kelsey Kelley (b) (4)	25 Mar 2021 21:18:42
	(b) (4)	

US3032249

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (31)

Generated On: 09 Jun 2021 14:53:49

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:56:39
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:41:17
User entered '0'	(b) (4) Kelsey Kelley (b) (4)	25 Mar 2021 21:18:42

US3032249

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (31)

Generated On: 09 Jun 2021 14:53:49

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:56:39
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:41:17
User entered 'No (N)'	(b) (4) Kelsey Kelley (b) (4)	25 Mar 2021 21:18:42

US3032249

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (31)

Generated On: 09 Jun 2021 14:53:49

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:56:39
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:41:17
User entered '5 Mar 2021'	(b) (4) Kelsey Kelley (b) (4)	25 Mar 2021 21:18:42
	(b) (4)	

US3032249

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (31)

Generated On: 09 Jun 2021 14:53:49

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:56:39
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:41:17
User entered 'No (N)'	(b) (4) Kelsey Kelley (b) (4)	25 Mar 2021 21:18:42

US3032249

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (31)

Generated On: 09 Jun 2021 14:53:49

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:56:39
User entered '1'	System	25 Mar 2021 21:18:42

US3032249

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (31)

Generated On: 09 Jun 2021 14:53:49

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:56:39
User entered '1'	System	25 Mar 2021 21:18:42

US3032249

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (31)

Generated On: 09 Jun 2021 14:53:49

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:56:39
User entered '804 (804)'	System	25 Mar 2021 21:18:42

US3032249

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (32)

Generated On: 09 Jun 2021 14:53:49

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:56:28
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:41:17
User coded data point as ATC: RESPIRATORY SYSTEM, ATC: COUGH AND COLD PREPARATIONS, ATC: COUGH SUPPRESSANTS, EXCL. COMBINATIONS WITH EXPECTORANTS, ATC: OTHER COUGH SUPPRESSANTS, PRODUCT: BENZONATATE, PRODUCTSYNONYM: TESSALON PERLE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	30 Mar 2021 08:37:31
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	30 Mar 2021 08:37:31
Data point term sent to Coder	System	25 Mar 2021 21:19:54
User entered 'tessalon perles'	Kelsey Kelley (b) (4)	25 Mar 2021 21:19:53

US3032249

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (32)

Generated On: 09 Jun 2021 14:53:49

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:56:28
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:41:17
User entered 'No (N)'	(b) (4) Kelsey Kelley (b) (4)	25 Mar 2021 21:19:53

US3032249

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (32)

Generated On: 09 Jun 2021 14:53:49

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:56:28
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:41:17
User entered 'bilateral pneumonia'	Kelsey Kelley (b) (4)	25 Mar 2021 21:19:53

US3032249

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (32)

Generated On: 09 Jun 2021 14:53:49

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:56:28
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:41:17
User entered '200'	(b) (4) Kelsey Kelley (b) (4)	25 Mar 2021 21:19:53

US3032249

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (32)

Generated On: 09 Jun 2021 14:53:49

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:56:28
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:41:17
User entered 'mg (mg)'	(b) (4) Kelsey Kelley (b) (4)	25 Mar 2021 21:19:53

US3032249

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (32)

Generated On: 09 Jun 2021 14:53:49

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:56:28
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:41:17
User entered empty.	(b) (4) Kelsey Kelley (b) (4)	25 Mar 2021 21:19:53
	(b) (4)	

US3032249

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (32)

Generated On: 09 Jun 2021 14:53:49

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:56:28
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:41:17
User entered 'as needed (PRN)'	Kelsey Kelley (b) (4)	25 Mar 2021 21:19:53

US3032249

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (32)

Generated On: 09 Jun 2021 14:53:49

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:56:28
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:41:17
User entered empty.	(b) (4) Kelsey Kelley (b) (4)	25 Mar 2021 21:19:53
	(b) (4)	

US3032249

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (32)

Generated On: 09 Jun 2021 14:53:49

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:56:28
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:41:17
User entered 'Oral (ORAL)'	Kelsey Kelley (b) (4)	25 Mar 2021 21:19:53

US3032249

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (32)

Generated On: 09 Jun 2021 14:53:49

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:56:28
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:41:17
User entered empty.	(b) (4) Kelsey Kelley (b) (4)	25 Mar 2021 21:19:53

US3032249

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (32)

Generated On: 09 Jun 2021 14:53:49

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:56:28
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:41:17
User entered '1 Mar 2021'	(b) (4) Kelsey Kelley (b) (4)	25 Mar 2021 21:19:53

US3032249

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (32)

Generated On: 09 Jun 2021 14:53:49

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:56:28
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:41:17
User entered '0'	Kelsey Kelley (b) (4)	25 Mar 2021 21:19:53

US3032249

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (32)

Generated On: 09 Jun 2021 14:53:49

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:56:28
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:41:17
User entered 'No (N)'	(b) (4) Kelsey Kelley (b) (4)	25 Mar 2021 21:19:53

US3032249

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (32)

Generated On: 09 Jun 2021 14:53:49

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:56:28
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:41:17
User entered '5 Mar 2021'	Kelsey Kelley (b) (4)	25 Mar 2021 21:19:53

US3032249

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (32)

Generated On: 09 Jun 2021 14:53:49

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:56:28
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:41:17
User entered 'No (N)'	Kelsey Kelley (b) (4)	25 Mar 2021 21:19:53

US3032249

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (32)

Generated On: 09 Jun 2021 14:53:49

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:56:28
User entered empty.	System	25 Mar 2021 21:19:53

US3032249

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (32)

Generated On: 09 Jun 2021 14:53:49

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:56:28
User entered empty.	System	25 Mar 2021 21:19:53

US3032249

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (32)

Generated On: 09 Jun 2021 14:53:49

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:56:28
User entered empty.	System	25 Mar 2021 21:19:53

US3032249

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (33)

Generated On: 09 Jun 2021 14:53:49

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:56:18
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:41:17
User coded data point as ATC: ANTIINFECTIVES FOR SYSTEMIC USE, ATC: ANTIBACTERIALS FOR SYSTEMIC USE, ATC: BETA-LACTAM ANTIBACTERIALS, PENICILLINS, ATC: COMBINATIONS OF PENICILLINS, INCL. BETA-LACTAMASE INHIBITORS, PRODUCT: PIPERACILLIN SODIUM;TAZOBACTAM SODIUM, PRODUCTSYNONYM: ZOSYN - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	25 Mar 2021 21:23:30
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	25 Mar 2021 21:23:30
Data point term sent to Coder	System	25 Mar 2021 21:23:01
User entered 'zosyn'	Kelsey Kelley (b) (4)	25 Mar 2021 21:22:27

US3032249

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (33)

Generated On: 09 Jun 2021 14:53:49

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:56:18
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:41:17
User entered 'No (N)'	(b) (4) Kelsey Kelley (b) (4)	25 Mar 2021 21:22:27

US3032249

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (33)

Generated On: 09 Jun 2021 14:53:49

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:56:18
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:41:17
User entered 'bilateral pneumonia'	Kelsey Kelley (b) (4)	25 Mar 2021 21:22:27

US3032249

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (33)

Generated On: 09 Jun 2021 14:53:49

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:56:18
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:41:17
User entered '3.375'	(b) (4) Kelsey Kelley (b) (4)	25 Mar 2021 21:22:27

US3032249

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (33)

Generated On: 09 Jun 2021 14:53:49

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:56:18
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:41:17
User entered 'mg (mg)'	(b) (4) Kelsey Kelley (b) (4)	25 Mar 2021 21:22:27

US3032249

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (33)

Generated On: 09 Jun 2021 14:53:49

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:56:18
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:41:17
User entered empty.	(b) (4) Kelsey Kelley (b) (4)	25 Mar 2021 21:22:27
	(b) (4)	

US3032249

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (33)

Generated On: 09 Jun 2021 14:53:49

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:56:18
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:41:17
User entered 'other (OTHER)'	(b) (4) Kelsey Kelley (b) (4)	25 Mar 2021 21:22:27

US3032249

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (33)

Generated On: 09 Jun 2021 14:53:49

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:56:18
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:41:17
User entered 'Q6H'	Kelsey Kelley (b) (4)	25 Mar 2021 21:22:27

US3032249

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (33)

Generated On: 09 Jun 2021 14:53:49

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:56:18
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:41:17
User entered 'Intravenous (INTRAVENOUS)'	Kelsey Kelley (b) (4)	25 Mar 2021 21:22:27

US3032249

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (33)

Generated On: 09 Jun 2021 14:53:49

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:56:18
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:41:17
User entered empty.	(b) (4) Kelsey Kelley (b) (4)	25 Mar 2021 21:22:27

US3032249

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (33)

Generated On: 09 Jun 2021 14:53:49

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:56:18
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:41:17
User entered '1 Mar 2021'	(b) (4) Kelsey Kelley (b) (4)	25 Mar 2021 21:22:27

US3032249

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (33)

Generated On: 09 Jun 2021 14:53:49

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:56:18
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:41:17
User entered '0'	(b) (4) Kelsey Kelley (b) (4)	25 Mar 2021 21:22:27

US3032249

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (33)

Generated On: 09 Jun 2021 14:53:49

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:56:18
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:41:17
User entered 'No (N)'	(b) (4) Kelsey Kelley (b) (4)	25 Mar 2021 21:22:27

US3032249

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (33)

Generated On: 09 Jun 2021 14:53:49

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:56:18
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:41:17
User entered '5 Mar 2021'	(b) (4) Kelsey Kelley (b) (4)	25 Mar 2021 21:22:27
	(b) (4)	

US3032249

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (33)

Generated On: 09 Jun 2021 14:53:49

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:56:18
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:41:17
User entered 'No (N)'	Kelsey Kelley (b) (4)	25 Mar 2021 21:22:27

US3032249

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (33)

Generated On: 09 Jun 2021 14:53:49

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:56:18
User entered empty.	System	25 Mar 2021 21:22:27

US3032249

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (33)

Generated On: 09 Jun 2021 14:53:49

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:56:18
User entered empty.	System	25 Mar 2021 21:22:27

US3032249

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (33)

Generated On: 09 Jun 2021 14:53:49

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:56:18
User entered empty.	System	25 Mar 2021 21:22:27

US3032249

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (34)

Generated On: 09 Jun 2021 14:53:49

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:41:17
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 - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4)	30 Mar 2021 14:03:00
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	30 Mar 2021 14:03:00
Data point term sent to Coder	System	25 Mar 2021 21:26:02
User entered 'estradiol'	Kelsey Kelley (b) (4)	25 Mar 2021 21:25:20

US3032249

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (34)

Generated On: 09 Jun 2021 14:53:49

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:41:17
User entered 'No (N)'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	25 Mar 2021 21:25:20

US3032249

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (34)

Generated On: 09 Jun 2021 14:53:49

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:41:17
User entered 'estrogen deficiency'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	25 Mar 2021 21:25:20

US3032249

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (34)

Generated On: 09 Jun 2021 14:53:49

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:41:17
User entered '0.5'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	25 Mar 2021 21:25:20

US3032249

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (34)

Generated On: 09 Jun 2021 14:53:49

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:41:17
	(b) (4)	
User entered 'mg (mg)'	Kelsey Kelley (b) (4)	25 Mar 2021 21:25:20
	(b) (4)	

US3032249

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (34)

Generated On: 09 Jun 2021 14:53:49

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:41:17
	(b) (4)	
User entered empty.	Kelsey Kelley (b) (4)	25 Mar 2021 21:25:20
	(b) (4)	

US3032249

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (34)

Generated On: 09 Jun 2021 14:53:49

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:41:17
User entered 'other (OTHER)'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	25 Mar 2021 21:25:20

US3032249

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (34)

Generated On: 09 Jun 2021 14:53:49

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:41:17
	(b) (4)	
User entered 'every two weeks'	Kelsey Kelley (b) (4)	25 Mar 2021 21:25:20
	(b) (4)	

US3032249

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (34)

Generated On: 09 Jun 2021 14:53:49

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:41:17
	(b) (4)	
User entered 'Other (OTHER)'	Kelsey Kelley (b) (4)	25 Mar 2021 21:25:20
	(b) (4)	

US3032249

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (34)

Generated On: 09 Jun 2021 14:53:49

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:41:17
	(b) (4)	
User entered 'intravaginal'	Kelsey Kelley (b) (4)	25 Mar 2021 21:25:20
	(b) (4)	

US3032249

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (34)

Generated On: 09 Jun 2021 14:53:49

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:41:17
	(b) (4)	
User entered 'un UNK 2018'	Kelsey Kelley (b) (4)	25 Mar 2021 21:25:20
	(b) (4)	

US3032249

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (34)

Generated On: 09 Jun 2021 14:53:49

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:41:17
	(b) (4)	
User entered '0'	Kelsey Kelley (b) (4)	25 Mar 2021 21:25:20
	(b) (4)	

US3032249

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (34)

Generated On: 09 Jun 2021 14:53:49

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:41:17
	(b) (4)	
User entered 'Yes (Y)'	Kelsey Kelley (b) (4)	25 Mar 2021 21:25:20
	(b) (4)	

US3032249

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (34)

Generated On: 09 Jun 2021 14:53:49

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:41:17
	(b) (4)	
User entered empty.	Kelsey Kelley (b) (4)	25 Mar 2021 21:25:20
	(b) (4)	

US3032249

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (34)

Generated On: 09 Jun 2021 14:53:49

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:41:17
	(b) (4)	
User entered 'No (N)'	Kelsey Kelley (b) (4)	25 Mar 2021 21:25:20
	(b) (4)	

US3032249

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (34)

Generated On: 09 Jun 2021 14:53:49

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	25 Mar 2021 21:25:20

US3032249

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (34)

Generated On: 09 Jun 2021 14:53:49

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	25 Mar 2021 21:25:20

US3032249

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (34)

Generated On: 09 Jun 2021 14:53:49

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	25 Mar 2021 21:25:20

US3032249

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (35)

Generated On: 09 Jun 2021 14:53:49

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:55:59
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:41:17
User coded data point as ATC: ANTIINFECTIVES FOR SYSTEMIC USE, ATC: ANTIMYCOTICS FOR SYSTEMIC USE, ATC: ANTIMYCOTICS FOR SYSTEMIC USE, ATC: TRIAZOLE DERIVATIVES, PRODUCT: FLUCONAZOLE - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4)	30 Mar 2021 14:03:38
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	30 Mar 2021 14:03:38
Data point term sent to Coder	System	25 Mar 2021 21:27:02
User entered 'fluconazole'	Kelsey Kelley (b) (4)	25 Mar 2021 21:26:12

US3032249

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (35)

Generated On: 09 Jun 2021 14:53:49

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:55:59
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:41:17
User entered 'No (N)'	(b) (4) Kelsey Kelley (b) (4)	25 Mar 2021 21:26:12
	(b) (4)	

US3032249

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (35)

Generated On: 09 Jun 2021 14:53:49

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:55:59
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:41:17
User entered 'perineal irritation in female'	(b) (4) Kelsey Kelley (b) (4)	25 Mar 2021 21:26:12

US3032249

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (35)

Generated On: 09 Jun 2021 14:53:49

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:55:59
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:41:17
User entered '150'	(b) (4) Kelsey Kelley (b) (4)	25 Mar 2021 21:26:12

US3032249

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (35)

Generated On: 09 Jun 2021 14:53:49

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:55:59
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:41:17
User entered 'mg (mg)'	(b) (4) Kelsey Kelley (b) (4)	25 Mar 2021 21:26:12

US3032249

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (35)

Generated On: 09 Jun 2021 14:53:49

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:55:59
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:41:17
User entered empty.	(b) (4) Kelsey Kelley (b) (4)	25 Mar 2021 21:26:12
	(b) (4)	

US3032249

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (35)

Generated On: 09 Jun 2021 14:53:49

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:55:59
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:41:17
User entered 'once (ONCE)'	(b) (4) Kelsey Kelley (b) (4)	25 Mar 2021 21:26:12

US3032249

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (35)

Generated On: 09 Jun 2021 14:53:49

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:55:59
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:41:17
User entered empty.	(b) (4) Kelsey Kelley (b) (4)	25 Mar 2021 21:26:12
	(b) (4)	

US3032249

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (35)

Generated On: 09 Jun 2021 14:53:49

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:55:59
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:41:17
User entered 'Oral (ORAL)'	(b) (4) Kelsey Kelley (b) (4)	25 Mar 2021 21:26:12

US3032249

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (35)

Generated On: 09 Jun 2021 14:53:49

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:55:59
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:41:17
User entered empty.	(b) (4) Kelsey Kelley (b) (4)	25 Mar 2021 21:26:12
	(b) (4)	

US3032249

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (35)

Generated On: 09 Jun 2021 14:53:49

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:55:59
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:41:17
User entered '19 Mar 2021'	(b) (4) Kelsey Kelley (b) (4)	25 Mar 2021 21:26:12
	(b) (4)	

US3032249

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (35)

Generated On: 09 Jun 2021 14:53:49

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:55:59
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:41:17
User entered '0'	(b) (4) Kelsey Kelley (b) (4)	25 Mar 2021 21:26:12

US3032249

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (35)

Generated On: 09 Jun 2021 14:53:49

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:55:59
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:41:17
User entered 'No (N)'	(b) (4) Kelsey Kelley (b) (4)	25 Mar 2021 21:26:12

US3032249

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (35)

Generated On: 09 Jun 2021 14:53:49

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:55:59
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:41:17
User entered '19 Mar 2021'	(b) (4) Kelsey Kelley (b) (4)	25 Mar 2021 21:26:12
	(b) (4)	

US3032249

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (35)

Generated On: 09 Jun 2021 14:53:49

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:55:59
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:41:17
User entered 'No (N)'	(b) (4) Kelsey Kelley (b) (4)	25 Mar 2021 21:26:12

US3032249

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (35)

Generated On: 09 Jun 2021 14:53:49

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:55:59
User entered empty.	System	25 Mar 2021 21:26:12

US3032249

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (35)

Generated On: 09 Jun 2021 14:53:49

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:55:59
User entered empty.	System	25 Mar 2021 21:26:12

US3032249

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (35)

Generated On: 09 Jun 2021 14:53:49

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:55:59
User entered empty.	System	25 Mar 2021 21:26:12

US3032249

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (36)

Generated On: 09 Jun 2021 14:53:49

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:55:48
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:41:17
User coded data point as ATC: DERMATOLOGICALS, ATC: ANTIFUNGALS FOR DERMATOLOGICAL USE, ATC: ANTIFUNGALS FOR TOPICAL USE, ATC: ANTIBIOTICS, PRODUCT: NYSTATIN - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4) (b) (4)	26 Mar 2021 10:36:42
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	26 Mar 2021 10:36:42
Data point term sent to Coder	System	25 Mar 2021 21:28:04
User entered 'nystatin cream'	Kelsey Kelley (b) (4) (b) (4)	25 Mar 2021 21:27:03

US3032249

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (36)

Generated On: 09 Jun 2021 14:53:49

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:55:48
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:41:17
User entered 'No (N)'	(b) (4) Kelsey Kelley (b) (4)	25 Mar 2021 21:27:03

US3032249

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (36)

Generated On: 09 Jun 2021 14:53:49

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:55:48
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:41:17
User entered 'perineal irritation in female'	(b) (4) Kelsey Kelley (b) (4)	25 Mar 2021 21:27:03

US3032249

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (36)

Generated On: 09 Jun 2021 14:53:49

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:55:48
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:41:17
User entered '100000'	Kelsey Kelley (b) (4)	25 Mar 2021 21:27:03

US3032249

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (36)

Generated On: 09 Jun 2021 14:53:49

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:55:48
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:41:17
User entered 'Other (OTHER)'	Kelsey Kelley (b) (4)	25 Mar 2021 21:27:03

US3032249

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (36)

Generated On: 09 Jun 2021 14:53:49

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:55:48
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:41:17
User entered 'units'	(b) (4) Kelsey Kelley (b) (4)	25 Mar 2021 21:27:03
	(b) (4)	

US3032249

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (36)

Generated On: 09 Jun 2021 14:53:49

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:55:48
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:41:17
User entered 'twice daily (BID)'	Kelsey Kelley (b) (4)	25 Mar 2021 21:27:03

US3032249

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (36)

Generated On: 09 Jun 2021 14:53:49

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:55:48
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:41:17
User entered empty.	(b) (4) Kelsey Kelley (b) (4)	25 Mar 2021 21:27:03
	(b) (4)	

US3032249

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (36)

Generated On: 09 Jun 2021 14:53:49

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:55:48
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:41:17
User entered 'Topical (TOPICAL)'	Kelsey Kelley (b) (4)	25 Mar 2021 21:27:03

US3032249

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (36)

Generated On: 09 Jun 2021 14:53:49

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:55:48
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:41:17
User entered empty.	(b) (4) Kelsey Kelley (b) (4)	25 Mar 2021 21:27:03

US3032249

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (36)

Generated On: 09 Jun 2021 14:53:49

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:55:48
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:41:17
User entered '19 Mar 2021'	(b) (4) Kelsey Kelley (b) (4)	25 Mar 2021 21:27:03
	(b) (4)	

US3032249

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (36)

Generated On: 09 Jun 2021 14:53:49

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:55:48
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:41:17
User entered '0'	Kelsey Kelley (b) (4)	25 Mar 2021 21:27:03

US3032249

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (36)

Generated On: 09 Jun 2021 14:53:49

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:55:48
User closed query 'Per DM CLR: Please review if a stop date should be recorded as the corresponding AE has resolved. If yes, please update CM stop date as applicable. Otherwise, provide clarification for continued use of medication.' (Site from DM). User signature succeeded.	(b) (4), (b) (6) Keith Vrbicky (b) (4)	07 Apr 2021 11:22:41 06 Apr 2021 15:41:17
Query 'Per DM CLR: Please review if a stop date should be recorded as the corresponding AE has resolved. If yes, please update CM stop date as applicable. Otherwise, provide clarification for continued use of medication.' answered with 'updated. thank you' (Site from DM). User entered 'No (N)' reason for change: Data Entry Error	Chelsie Nutsch (b) (4) (b) (4) Chelsie Nutsch (b) (4)	06 Apr 2021 13:44:32 06 Apr 2021 13:44:20
User opened query 'Per DM CLR: Please review if a stop date should be recorded as the corresponding AE has resolved. If yes, please update CM stop date as applicable. Otherwise, provide clarification for continued use of medication.' (Site from DM). User entered 'Yes (Y)'	(b) (4), (b) (6) Kelsey Kelley (b) (4)	05 Apr 2021 02:40:17 25 Mar 2021 21:27:03

US3032249

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (36)

Generated On: 09 Jun 2021 14:53:49

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:55:48
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:41:17
User entered '22 Mar 2021' reason for change: Data Entry Error	(b) (4)	06 Apr 2021 13:44:20
User entered empty.	Chelsie Nutsch (b) (4)	06 Apr 2021 13:44:20
	(b) (4)	
	Kelsey Kelley (b) (4)	25 Mar 2021 21:27:03
	(b) (4)	

US3032249

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (36)

Generated On: 09 Jun 2021 14:53:49

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:55:48
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:41:17
User entered 'No (N)'	(b) (4) Kelsey Kelley (b) (4)	25 Mar 2021 21:27:03

US3032249

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (36)

Generated On: 09 Jun 2021 14:53:49

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:55:48
User entered '2'	System	25 Mar 2021 21:27:03

US3032249

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (36)

Generated On: 09 Jun 2021 14:53:49

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:55:48
User entered '1'	System	25 Mar 2021 21:27:03

US3032249

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (36)

Generated On: 09 Jun 2021 14:53:49

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:55:48
User entered '804 (804)'	System	25 Mar 2021 21:27:03

US3032249

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (37)

Generated On: 09 Jun 2021 14:53:49

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:41:17
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: LIPID MODIFYING AGENTS, ATC: LIPID MODIFYING AGENTS, PLAIN, ATC: BILE ACID SEQUESTRANTS, PRODUCT: COLESEVELAM - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4) (b) (4)	30 Mar 2021 12:14:04
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	30 Mar 2021 12:14:04
Data point term sent to Coder	System	25 Mar 2021 22:00:30
User entered 'colesevelam'	Kelsey Kelley (b) (4) (b) (4)	25 Mar 2021 21:59:56

US3032249

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (37)

Generated On: 09 Jun 2021 14:53:49

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:41:17
User entered 'No (N)'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	25 Mar 2021 21:59:56

US3032249

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (37)

Generated On: 09 Jun 2021 14:53:49

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:41:17
User entered 'dyslipidemia'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	25 Mar 2021 21:59:56

US3032249

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (37)

Generated On: 09 Jun 2021 14:53:49

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:41:17
	(b) (4)	
User entered '2500'	Kelsey Kelley (b) (4)	25 Mar 2021 21:59:56
	(b) (4)	

US3032249

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (37)

Generated On: 09 Jun 2021 14:53:49

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:41:17
	(b) (4)	
User entered 'mg (mg)'	Kelsey Kelley (b) (4)	25 Mar 2021 21:59:56
	(b) (4)	

US3032249

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (37)

Generated On: 09 Jun 2021 14:53:49

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:41:17
	(b) (4)	
User entered empty.	Kelsey Kelley (b) (4)	25 Mar 2021 21:59:56
	(b) (4)	

US3032249

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (37)

Generated On: 09 Jun 2021 14:53:49

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:41:17
User entered 'twice daily (BID)'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	25 Mar 2021 21:59:56

US3032249

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (37)

Generated On: 09 Jun 2021 14:53:49

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:41:17
	(b) (4)	
User entered empty.	Kelsey Kelley (b) (4)	25 Mar 2021 21:59:56
	(b) (4)	

US3032249

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (37)

Generated On: 09 Jun 2021 14:53:49

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:41:17
User entered 'Respiratory (Inhalation) (RESPIRATORY (INHALATION))'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	25 Mar 2021 21:59:56

US3032249

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (37)

Generated On: 09 Jun 2021 14:53:49

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:41:17
	(b) (4)	
User entered empty.	Kelsey Kelley (b) (4)	25 Mar 2021 21:59:56
	(b) (4)	

US3032249

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (37)

Generated On: 09 Jun 2021 14:53:49

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:41:17
User entered 'un UNK 2018'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	25 Mar 2021 21:59:56

US3032249

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (37)

Generated On: 09 Jun 2021 14:53:49

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:41:17
	(b) (4)	
User entered '0'	Kelsey Kelley (b) (4)	25 Mar 2021 21:59:56
	(b) (4)	

US3032249

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (37)

Generated On: 09 Jun 2021 14:53:49

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:41:17
User entered 'Yes (Y)'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	25 Mar 2021 21:59:56

US3032249

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (37)

Generated On: 09 Jun 2021 14:53:49

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:41:17
	(b) (4)	
User entered empty.	Kelsey Kelley (b) (4)	25 Mar 2021 21:59:56
	(b) (4)	

US3032249

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (37)

Generated On: 09 Jun 2021 14:53:49

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:41:17
User entered 'No (N)'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	25 Mar 2021 21:59:56

US3032249

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (37)

Generated On: 09 Jun 2021 14:53:49

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '2'	System	25 Mar 2021 21:59:56

US3032249

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (37)

Generated On: 09 Jun 2021 14:53:49

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	25 Mar 2021 21:59:56

US3032249

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (37)

Generated On: 09 Jun 2021 14:53:49

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	25 Mar 2021 21:59:56

US3032249

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures Summary

Generated On: 09 Jun 2021 14:53:49

[Were any concomitant procedures performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 06:09:06
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:41:17
Signature has been broken.	Kelsey Kelley (b) (4)	25 Mar 2021 21:27:44
User entered 'Yes (Y)' reason for change: New Information	Kelsey Kelley (b) (4)	25 Mar 2021 21:27:44
User signature succeeded.	Keith Vrbicky (b) (4)	18 Mar 2021 21:21:02
User entered 'No (N)'	Linden DeBoer (b) (4)	18 Mar 2021 13:33:17

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Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 09 Jun 2021 14:53:49

Procedure/Surgery date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:41:17
	(b) (4)	
User entered '9 Feb 2021'	Kelsey Kelley (b) (4)	25 Mar 2021 21:28:01
	(b) (4)	

US3032249

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 09 Jun 2021 14:53:49

[Procedure/Surgery](#)

Audit	User	Time (GMT)
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:41:17
	(b) (4)	
User entered 'rapid covid-19 test'	Kelsey Kelley (b) (4)	25 Mar 2021 21:28:01
	(b) (4)	

US3032249

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 09 Jun 2021 14:53:49

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:41:17
	(b) (4)	
User entered 'Adverse Event (AE)'	Kelsey Kelley (b) (4)	25 Mar 2021 21:28:01
	(b) (4)	

US3032249

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 09 Jun 2021 14:53:49

[If indication is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:41:17
	(b) (4)	
User entered empty.	Kelsey Kelley (b) (4)	25 Mar 2021 21:28:01
	(b) (4)	

US3032249

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (2)

Generated On: 09 Jun 2021 14:53:49

Procedure/Surgery date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:57:41
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:41:17
User entered '1 Mar 2021'	(b) (4) Kelsey Kelley (b) (4)	25 Mar 2021 21:28:12

US3032249

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (2)

Generated On: 09 Jun 2021 14:53:49

[Procedure/Surgery](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:57:41
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:41:17
User entered 'chest x-ray'	(b) (4) Kelsey Kelley (b) (4)	25 Mar 2021 21:28:12

US3032249

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (2)

Generated On: 09 Jun 2021 14:53:49

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:57:41
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:41:17
User entered 'Adverse Event (AE)'	(b) (4) Kelsey Kelley (b) (4)	25 Mar 2021 21:28:12

US3032249

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (2)

Generated On: 09 Jun 2021 14:53:49

[If indication is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:57:41
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:41:17
User entered empty.	(b) (4) Kelsey Kelley (b) (4)	25 Mar 2021 21:28:12

US3032249

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (3)

Generated On: 09 Jun 2021 14:53:49

Procedure/Surgery date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:57:46
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:41:17
User entered '1 Mar 2021'	(b) (4) Kelsey Kelley (b) (4)	25 Mar 2021 21:28:25

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Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (3)

Generated On: 09 Jun 2021 14:53:49

[Procedure/Surgery](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:57:46
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:41:17
User entered 'elevated d-dimer'	Kelsey Kelley (b) (4)	25 Mar 2021 21:28:25

US3032249

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (3)

Generated On: 09 Jun 2021 14:53:49

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:57:46
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:41:17
User entered 'Adverse Event (AE)'	Kelsey Kelley (b) (4)	25 Mar 2021 21:28:25

US3032249

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (3)

Generated On: 09 Jun 2021 14:53:49

[If indication is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:57:46
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:41:17
User entered empty.	(b) (4) Kelsey Kelley (b) (4)	25 Mar 2021 21:28:25

US3032249

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (4)

Generated On: 09 Jun 2021 14:53:49

Procedure/Surgery date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:57:48
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:41:17
User entered '1 Mar 2021'	Kelsey Kelley (b) (4)	25 Mar 2021 21:28:44

US3032249

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (4)

Generated On: 09 Jun 2021 14:53:49

[Procedure/Surgery](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:57:48
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:41:17
User entered 'CT angiogram chest with contrast'	Kelsey Kelley (b) (4)	25 Mar 2021 21:28:44

US3032249

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (4)

Generated On: 09 Jun 2021 14:53:49

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:57:48
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:41:17
User entered 'Adverse Event (AE)'	Kelsey Kelley (b) (4)	25 Mar 2021 21:28:44

US3032249

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (4)

Generated On: 09 Jun 2021 14:53:49

[If indication is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:57:48
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:41:17
User entered empty.	(b) (4) Kelsey Kelley (b) (4)	25 Mar 2021 21:28:44

US3032249

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (5)

Generated On: 09 Jun 2021 14:53:49

Procedure/Surgery date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:57:50
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:41:17
User entered '1 Mar 2021'	(b) (4) Kelsey Kelley (b) (4)	25 Mar 2021 21:29:19

US3032249

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (5)

Generated On: 09 Jun 2021 14:53:49

[Procedure/Surgery](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:57:50
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:41:17
User entered 'pro-calcitonin'	(b) (4) Kelsey Kelley (b) (4)	25 Mar 2021 21:29:19

US3032249

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (5)

Generated On: 09 Jun 2021 14:53:49

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:57:50
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:41:17
User entered 'Adverse Event (AE)'	Kelsey Kelley (b) (4)	25 Mar 2021 21:29:19

US3032249

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (5)

Generated On: 09 Jun 2021 14:53:49

[If indication is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:57:50
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:41:17
User entered empty.	(b) (4) Kelsey Kelley (b) (4)	25 Mar 2021 21:29:19

US3032249

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (6)

Generated On: 09 Jun 2021 14:53:49

Procedure/Surgery date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:57:54
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:41:17
User entered '1 Mar 2021'	Kelsey Kelley (b) (4)	25 Mar 2021 21:29:37

US3032249

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (6)

Generated On: 09 Jun 2021 14:53:49

[Procedure/Surgery](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:57:54
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:41:17
User entered 'complete blood count'	Kelsey Kelley (b) (4)	25 Mar 2021 21:29:37

US3032249

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (6)

Generated On: 09 Jun 2021 14:53:49

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:57:54
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:41:17
User entered 'Adverse Event (AE)'	(b) (4) Kelsey Kelley (b) (4)	25 Mar 2021 21:29:37

US3032249

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (6)

Generated On: 09 Jun 2021 14:53:49

[If indication is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:57:54
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:41:17
User entered empty.	(b) (4) Kelsey Kelley (b) (4)	25 Mar 2021 21:29:37

US3032249

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (7)

Generated On: 09 Jun 2021 14:53:49

Procedure/Surgery date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:57:55
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:41:17
User entered '1 Mar 2021'	(b) (4) Kelsey Kelley (b) (4)	25 Mar 2021 21:30:08

US3032249

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (7)

Generated On: 09 Jun 2021 14:53:49

[Procedure/Surgery](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:57:55
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:41:17
User entered 'blood cultures'	(b) (4) Kelsey Kelley (b) (4)	25 Mar 2021 21:30:08

US3032249

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (7)

Generated On: 09 Jun 2021 14:53:49

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:57:55
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:41:17
User entered 'Adverse Event (AE)'	(b) (4) Kelsey Kelley (b) (4)	25 Mar 2021 21:30:08

US3032249

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (7)

Generated On: 09 Jun 2021 14:53:49

[If indication is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:57:55
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:41:17
User entered empty.	(b) (4) Kelsey Kelley (b) (4)	25 Mar 2021 21:30:08

US3032249

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (8)

Generated On: 09 Jun 2021 14:53:49

Procedure/Surgery date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:57:57
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:41:17
User entered '1 Mar 2021'	(b) (4) Kelsey Kelley (b) (4)	25 Mar 2021 21:30:40

US3032249

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (8)

Generated On: 09 Jun 2021 14:53:49

[Procedure/Surgery](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:57:57
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:41:17
User entered 'flutter/pcp therapy'	Kelsey Kelley (b) (4)	25 Mar 2021 21:30:40

US3032249

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (8)

Generated On: 09 Jun 2021 14:53:49

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:57:57
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:41:17
User entered 'Adverse Event (AE)'	(b) (4) Kelsey Kelley (b) (4)	25 Mar 2021 21:30:40

US3032249

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (8)

Generated On: 09 Jun 2021 14:53:49

[If indication is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:57:57
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:41:17
User entered empty.	(b) (4) Kelsey Kelley (b) (4)	25 Mar 2021 21:30:40

US3032249

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (9)

Generated On: 09 Jun 2021 14:53:49

Procedure/Surgery date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:58:00
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:41:17
User entered '3 Mar 2021'	(b) (4) Kelsey Kelley (b) (4)	25 Mar 2021 21:30:53

US3032249

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (9)

Generated On: 09 Jun 2021 14:53:49

[Procedure/Surgery](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:58:00
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:41:17
User entered 'chest x-ray'	(b) (4) Kelsey Kelley (b) (4)	25 Mar 2021 21:30:53

US3032249

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (9)

Generated On: 09 Jun 2021 14:53:49

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:58:00
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:41:17
User entered 'Adverse Event (AE)'	Kelsey Kelley (b) (4)	25 Mar 2021 21:30:53

US3032249

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (9)

Generated On: 09 Jun 2021 14:53:49

[If indication is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:58:00
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:41:17
User entered empty.	(b) (4) Kelsey Kelley (b) (4)	25 Mar 2021 21:30:53

US3032249

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (10)

Generated On: 09 Jun 2021 14:53:49

Procedure/Surgery date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:58:01
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:41:17
User entered '1 Mar 2021'	(b) (4) Kelsey Kelley (b) (4)	25 Mar 2021 21:31:33

US3032249

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (10)

Generated On: 09 Jun 2021 14:53:49

[Procedure/Surgery](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:58:01
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:41:17
User entered 'basal metabolic panel'	Kelsey Kelley (b) (4)	25 Mar 2021 21:31:33

US3032249

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (10)

Generated On: 09 Jun 2021 14:53:49

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:58:01
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:41:17
User entered 'Adverse Event (AE)'	(b) (4) Kelsey Kelley (b) (4)	25 Mar 2021 21:31:33

US3032249

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (10)

Generated On: 09 Jun 2021 14:53:49

[If indication is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:58:01
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:41:17
User entered empty.	(b) (4) Kelsey Kelley (b) (4)	25 Mar 2021 21:31:33

US3032249

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (11)

Generated On: 09 Jun 2021 14:53:49

Procedure/Surgery date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:58:05
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:41:17
User entered '9 Feb 2021'	(b) (4) Kelsey Kelley (b) (4)	25 Mar 2021 21:32:15

US3032249

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (11)

Generated On: 09 Jun 2021 14:53:49

[Procedure/Surgery](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:58:05
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:41:17
User entered 'chest X-ray'	(b) (4) Kelsey Kelley (b) (4)	25 Mar 2021 21:32:15

US3032249

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (11)

Generated On: 09 Jun 2021 14:53:49

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:58:05
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:41:17
User entered 'Adverse Event (AE)'	Kelsey Kelley (b) (4)	25 Mar 2021 21:32:15

US3032249

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (11)

Generated On: 09 Jun 2021 14:53:49

[If indication is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:58:05
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:41:17
User entered empty.	(b) (4) Kelsey Kelley (b) (4)	25 Mar 2021 21:32:15

US3032249

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (12)

Generated On: 09 Jun 2021 14:53:49

Procedure/Surgery date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:58:08
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:41:17
User entered '9 Feb 2021'	(b) (4) Kelsey Kelley (b) (4)	25 Mar 2021 21:32:27

US3032249

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (12)

Generated On: 09 Jun 2021 14:53:49

[Procedure/Surgery](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:58:08
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:41:17
User entered 'complete blood count'	Kelsey Kelley (b) (4)	25 Mar 2021 21:32:27

US3032249

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (12)

Generated On: 09 Jun 2021 14:53:49

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:58:08
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:41:17
User entered 'Adverse Event (AE)'	(b) (4) Kelsey Kelley (b) (4)	25 Mar 2021 21:32:27

US3032249

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (12)

Generated On: 09 Jun 2021 14:53:49

[If indication is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:58:08
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:41:17
User entered empty.	(b) (4) Kelsey Kelley (b) (4)	25 Mar 2021 21:32:27

US3032249

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (13)

Generated On: 09 Jun 2021 14:53:49

Procedure/Surgery date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:58:11
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:41:17
User entered '9 Feb 2021'	(b) (4) Kelsey Kelley (b) (4)	25 Mar 2021 21:32:40

US3032249

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (13)

Generated On: 09 Jun 2021 14:53:49

[Procedure/Surgery](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:58:11
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:41:17
User entered 'basal metabolic panel'	Kelsey Kelley (b) (4)	25 Mar 2021 21:32:40

US3032249

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (13)

Generated On: 09 Jun 2021 14:53:49

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:58:11
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:41:17
User entered 'Adverse Event (AE)'	(b) (4) Kelsey Kelley (b) (4)	25 Mar 2021 21:32:40

US3032249

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (13)

Generated On: 09 Jun 2021 14:53:49

[If indication is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:58:11
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:41:17
User entered empty.	(b) (4) Kelsey Kelley (b) (4)	25 Mar 2021 21:32:40

US3032249

Folder: SAE USA-US032-2021-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 09 Jun 2021 14:53:49

[SAEID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Feb 2021 20:38:07
User signature succeeded.	Keith Vrbicky (b) (4)	12 Feb 2021 19:56:47
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	12 Feb 2021 13:29:59
User entered 'USA-US032-2021-MRNA-1273-P301000008'	System	12 Feb 2021 13:29:02

US3032249

Folder: SAE USA-US032-2021-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 09 Jun 2021 14:53:49

Serious

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Feb 2021 20:38:07
User signature succeeded.	Keith Vrbicky (b) (4)	12 Feb 2021 19:56:47
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	12 Feb 2021 13:29:59
User entered 'Yes (Y)'	System	12 Feb 2021 13:29:02

US3032249

Folder: SAE USA-US032-2021-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 09 Jun 2021 14:53:49

[Death](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Feb 2021 20:38:07
User signature succeeded.	Keith Vrbicky (b) (4)	12 Feb 2021 19:56:47
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	12 Feb 2021 13:29:59
User entered 'No (N)'	System	12 Feb 2021 13:29:02

US3032249

Folder: SAE USA-US032-2021-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 09 Jun 2021 14:53:49

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Feb 2021 20:38:07
User signature succeeded.	Keith Vrbicky (b) (4)	12 Feb 2021 19:56:47
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	12 Feb 2021 13:29:59
User entered 'No (N)'	System	12 Feb 2021 13:29:02

US3032249

Folder: SAE USA-US032-2021-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 09 Jun 2021 14:53:49

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Feb 2021 20:38:07
User signature succeeded.	Keith Vrbicky (b) (4)	12 Feb 2021 19:56:47
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	12 Feb 2021 13:29:59
User entered 'Yes (Y)'	System	12 Feb 2021 13:29:02

US3032249

Folder: SAE USA-US032-2021-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 09 Jun 2021 14:53:49

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Feb 2021 20:38:07
User signature succeeded.	Keith Vrbicky (b) (4)	12 Feb 2021 19:56:47
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	12 Feb 2021 13:29:59
User entered 'No (N)'	System	12 Feb 2021 13:29:02

US3032249

Folder: SAE USA-US032-2021-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 09 Jun 2021 14:53:49

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Feb 2021 20:38:07
User signature succeeded.	Keith Vrbicky (b) (4)	12 Feb 2021 19:56:47
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	12 Feb 2021 13:29:59
User entered 'No (N)'	System	12 Feb 2021 13:29:02

US3032249

Folder: SAE USA-US032-2021-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 09 Jun 2021 14:53:49

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Feb 2021 20:38:07
User signature succeeded.	Keith Vrbicky (b) (4)	12 Feb 2021 19:56:47
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	12 Feb 2021 13:29:59
User entered 'No (N)'	System	12 Feb 2021 13:29:02

US3032249

Folder: SAE USA-US032-2021-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 09 Jun 2021 14:53:49

[Investigator's First Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Feb 2021 20:38:07
User signature succeeded.	Keith Vrbicky (b) (4)	12 Feb 2021 19:56:47
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	12 Feb 2021 13:29:59
User entered 'Keith'	System	12 Feb 2021 13:29:02

US3032249

Folder: SAE USA-US032-2021-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 09 Jun 2021 14:53:49

[Investigator's Last Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Feb 2021 20:38:07
User signature succeeded.	Keith Vrbicky (b) (4)	12 Feb 2021 19:56:47
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	12 Feb 2021 13:29:59
User entered 'Vrbicky'	System	12 Feb 2021 13:29:02

US3032249

Folder: SAE USA-US032-2021-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 09 Jun 2021 14:53:49

[Investigator Country](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	04 Mar 2021 14:40:04
DataPoint Verified.		23 Feb 2021 20:38:07
User signature succeeded.	Keith Vrbicky (b) (4)	12 Feb 2021 19:56:47
User entered 'US'	(b) (4) System	12 Feb 2021 13:30:22

US3032249

Folder: SAE USA-US032-2021-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 09 Jun 2021 14:53:49

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '6'	System	26 Mar 2021 17:26:16
User entered '5'	System	24 Mar 2021 16:06:08
User entered '4'	System	10 Mar 2021 16:02:16
User entered '3'	System	04 Mar 2021 14:45:15
User entered '2'	System	04 Mar 2021 14:40:19
User signature succeeded.	Keith Vrbicky (b) (4)	12 Feb 2021 19:56:47
	(b) (4)	
User entered '1'	System	12 Feb 2021 13:30:22

US3032249

Folder: SAE USA-US032-2021-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 09 Jun 2021 14:53:49

[SAEID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Feb 2021 20:38:07
User signature succeeded.	Keith Vrbicky (b) (4)	12 Feb 2021 19:56:47
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	12 Feb 2021 13:29:59
User entered 'USA-US032-2021-MRNA-1273-P301000008'	System	12 Feb 2021 13:29:02

US3032249

Folder: SAE USA-US032-2021-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 09 Jun 2021 14:53:49

Serious

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Feb 2021 20:38:07
User signature succeeded.	Keith Vrbicky (b) (4)	12 Feb 2021 19:56:47
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	12 Feb 2021 13:29:59
User entered 'Yes (Y)'	System	12 Feb 2021 13:29:02

US3032249

Folder: SAE USA-US032-2021-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 09 Jun 2021 14:53:49

[Death](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Feb 2021 20:38:07
User signature succeeded.	Keith Vrbicky (b) (4)	12 Feb 2021 19:56:47
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	12 Feb 2021 13:29:59
User entered 'No (N)'	System	12 Feb 2021 13:29:02

US3032249

Folder: SAE USA-US032-2021-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 09 Jun 2021 14:53:49

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Feb 2021 20:38:07
User signature succeeded.	Keith Vrbicky (b) (4)	12 Feb 2021 19:56:47
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	12 Feb 2021 13:29:59
User entered 'No (N)'	System	12 Feb 2021 13:29:02

US3032249

Folder: SAE USA-US032-2021-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 09 Jun 2021 14:53:49

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Feb 2021 20:38:07
User signature succeeded.	Keith Vrbicky (b) (4)	12 Feb 2021 19:56:47
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	12 Feb 2021 13:29:59
User entered 'Yes (Y)'	System	12 Feb 2021 13:29:02

US3032249

Folder: SAE USA-US032-2021-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 09 Jun 2021 14:53:49

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Feb 2021 20:38:07
User signature succeeded.	Keith Vrbicky (b) (4)	12 Feb 2021 19:56:47
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	12 Feb 2021 13:29:59
User entered 'No (N)'	System	12 Feb 2021 13:29:02

US3032249

Folder: SAE USA-US032-2021-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 09 Jun 2021 14:53:49

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Feb 2021 20:38:07
User signature succeeded.	Keith Vrbicky (b) (4)	12 Feb 2021 19:56:47
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	12 Feb 2021 13:29:59
User entered 'No (N)'	System	12 Feb 2021 13:29:02

US3032249

Folder: SAE USA-US032-2021-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 09 Jun 2021 14:53:49

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Feb 2021 20:38:07
User signature succeeded.	Keith Vrbicky (b) (4)	12 Feb 2021 19:56:47
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	12 Feb 2021 13:29:59
User entered 'No (N)'	System	12 Feb 2021 13:29:02

US3032249

Folder: SAE USA-US032-2021-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 09 Jun 2021 14:53:49

[Investigator's First Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Feb 2021 20:38:07
User signature succeeded.	Keith Vrbicky (b) (4)	12 Feb 2021 19:56:47
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	12 Feb 2021 13:29:59
User entered 'Keith'	System	12 Feb 2021 13:29:02

US3032249

Folder: SAE USA-US032-2021-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 09 Jun 2021 14:53:49

[Investigator's Last Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Feb 2021 20:38:07
User signature succeeded.	Keith Vrbicky (b) (4)	12 Feb 2021 19:56:47
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	12 Feb 2021 13:29:59
User entered 'Vrbicky'	System	12 Feb 2021 13:29:02

US3032249

Folder: SAE USA-US032-2021-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 09 Jun 2021 14:53:49

[Investigator Country](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	04 Mar 2021 14:40:04
DataPoint Verified.		23 Feb 2021 20:38:07
User signature succeeded.	Keith Vrbicky (b) (4)	12 Feb 2021 19:56:47
User entered 'US'	(b) (4) System	12 Feb 2021 13:30:22

US3032249

Folder: SAE USA-US032-2021-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 09 Jun 2021 14:53:49

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '6'	System	26 Mar 2021 17:26:16
User entered '5'	System	24 Mar 2021 16:06:08
User entered '4'	System	10 Mar 2021 16:02:16
User entered '3'	System	04 Mar 2021 14:45:15
User entered '2'	System	04 Mar 2021 14:40:19
User signature succeeded.	Keith Vrbicky (b) (4)	12 Feb 2021 19:56:47
	(b) (4)	
User entered '1'	System	12 Feb 2021 13:30:22

US3032249

Folder: SAE USA-US032-2021-MRNA-1273-P301000008

Form: Safety Report Form (1)

Generated On: 09 Jun 2021 14:53:49

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Feb 2021 20:38:07
User signature succeeded.	Keith Vrbicky (b) (4)	12 Feb 2021 19:56:47
User entered '12/Feb/2021 08:30'	(b) (4) System	12 Feb 2021 13:30:22

US3032249

Folder: SAE USA-US032-2021-MRNA-1273-P301000008

Form: Safety Report Form (1)

Generated On: 09 Jun 2021 14:53:49

Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	04 Mar 2021 14:40:04
DataPoint Verified.		23 Feb 2021 20:38:07
User signature succeeded.	Keith Vrbicky (b) (4)	12 Feb 2021 19:56:47
User entered 'I'	(b) (4) (b) (4), (b) (6)	12 Feb 2021 13:30:22

US3032249

Folder: SAE USA-US032-2021-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 09 Jun 2021 14:53:49

[SAEID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Feb 2021 20:38:07
User signature succeeded.	Keith Vrbicky (b) (4)	12 Feb 2021 19:56:47
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	12 Feb 2021 13:29:59
User entered 'USA-US032-2021-MRNA-1273-P301000008'	System	12 Feb 2021 13:29:02

US3032249

Folder: SAE USA-US032-2021-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 09 Jun 2021 14:53:49

Serious

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Feb 2021 20:38:07
User signature succeeded.	Keith Vrbicky (b) (4)	12 Feb 2021 19:56:47
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	12 Feb 2021 13:29:59
User entered 'Yes (Y)'	System	12 Feb 2021 13:29:02

US3032249

Folder: SAE USA-US032-2021-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 09 Jun 2021 14:53:49

[Death](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Feb 2021 20:38:07
User signature succeeded.	Keith Vrbicky (b) (4)	12 Feb 2021 19:56:47
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	12 Feb 2021 13:29:59
User entered 'No (N)'	System	12 Feb 2021 13:29:02

US3032249

Folder: SAE USA-US032-2021-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 09 Jun 2021 14:53:49

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Feb 2021 20:38:07
User signature succeeded.	Keith Vrbicky (b) (4)	12 Feb 2021 19:56:47
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	12 Feb 2021 13:29:59
User entered 'No (N)'	System	12 Feb 2021 13:29:02

US3032249

Folder: SAE USA-US032-2021-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 09 Jun 2021 14:53:49

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Feb 2021 20:38:07
User signature succeeded.	Keith Vrbicky (b) (4)	12 Feb 2021 19:56:47
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	12 Feb 2021 13:29:59
User entered 'Yes (Y)'	System	12 Feb 2021 13:29:02

US3032249

Folder: SAE USA-US032-2021-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 09 Jun 2021 14:53:49

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Feb 2021 20:38:07
User signature succeeded.	Keith Vrbicky (b) (4)	12 Feb 2021 19:56:47
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	12 Feb 2021 13:29:59
User entered 'No (N)'	System	12 Feb 2021 13:29:02

US3032249

Folder: SAE USA-US032-2021-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 09 Jun 2021 14:53:49

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Feb 2021 20:38:07
User signature succeeded.	Keith Vrbicky (b) (4)	12 Feb 2021 19:56:47
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	12 Feb 2021 13:29:59
User entered 'No (N)'	System	12 Feb 2021 13:29:02

US3032249

Folder: SAE USA-US032-2021-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 09 Jun 2021 14:53:49

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Feb 2021 20:38:07
User signature succeeded.	Keith Vrbicky (b) (4)	12 Feb 2021 19:56:47
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	12 Feb 2021 13:29:59
User entered 'No (N)'	System	12 Feb 2021 13:29:02

US3032249

Folder: SAE USA-US032-2021-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 09 Jun 2021 14:53:49

[Investigator's First Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Feb 2021 20:38:07
User signature succeeded.	Keith Vrbicky (b) (4)	12 Feb 2021 19:56:47
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	12 Feb 2021 13:29:59
User entered 'Keith'	System	12 Feb 2021 13:29:02

US3032249

Folder: SAE USA-US032-2021-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 09 Jun 2021 14:53:49

[Investigator's Last Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Feb 2021 20:38:07
User signature succeeded.	Keith Vrbicky (b) (4)	12 Feb 2021 19:56:47
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	12 Feb 2021 13:29:59
User entered 'Vrbicky'	System	12 Feb 2021 13:29:02

US3032249

Folder: SAE USA-US032-2021-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 09 Jun 2021 14:53:49

[Investigator Country](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	04 Mar 2021 14:40:04
DataPoint Verified.		23 Feb 2021 20:38:07
User signature succeeded.	Keith Vrbicky (b) (4)	12 Feb 2021 19:56:47
User entered 'US'	(b) (4) System	12 Feb 2021 13:30:22

US3032249

Folder: SAE USA-US032-2021-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 09 Jun 2021 14:53:49

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '6'	System	26 Mar 2021 17:26:16
User entered '5'	System	24 Mar 2021 16:06:08
User entered '4'	System	10 Mar 2021 16:02:16
User entered '3'	System	04 Mar 2021 14:45:15
User entered '2'	System	04 Mar 2021 14:40:19
User signature succeeded.	Keith Vrbicky (b) (4)	12 Feb 2021 19:56:47
	(b) (4)	
User entered '1'	System	12 Feb 2021 13:30:22

US3032249

Folder: SAE USA-US032-2021-MRNA-1273-P301000008

Form: Safety Report Form (2)

Generated On: 09 Jun 2021 14:53:49

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Keith Vrbicky (b) (4)	04 Mar 2021 16:04:32
User entered '04/Mar/2021 09:40'	(b) (4) System	04 Mar 2021 14:40:19

US3032249

Folder: SAE USA-US032-2021-MRNA-1273-P301000008

Form: Safety Report Form (2)

Generated On: 09 Jun 2021 14:53:49

Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.

Audit	User	Time (GMT)
User signature succeeded.	Keith Vrbicky (b) (4)	04 Mar 2021 16:04:32
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	04 Mar 2021 14:44:58
User entered 'I'		04 Mar 2021 14:40:19

US3032249

Folder: SAE USA-US032-2021-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 09 Jun 2021 14:53:49

[SAEID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Feb 2021 20:38:07
User signature succeeded.	Keith Vrbicky (b) (4)	12 Feb 2021 19:56:47
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	12 Feb 2021 13:29:59
User entered 'USA-US032-2021-MRNA-1273-P301000008'	System	12 Feb 2021 13:29:02

US3032249

Folder: SAE USA-US032-2021-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 09 Jun 2021 14:53:49

Serious

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Feb 2021 20:38:07
User signature succeeded.	Keith Vrbicky (b) (4)	12 Feb 2021 19:56:47
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	12 Feb 2021 13:29:59
User entered 'Yes (Y)'	System	12 Feb 2021 13:29:02

US3032249

Folder: SAE USA-US032-2021-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 09 Jun 2021 14:53:49

[Death](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Feb 2021 20:38:07
User signature succeeded.	Keith Vrbicky (b) (4)	12 Feb 2021 19:56:47
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	12 Feb 2021 13:29:59
User entered 'No (N)'	System	12 Feb 2021 13:29:02

US3032249

Folder: SAE USA-US032-2021-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 09 Jun 2021 14:53:49

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Feb 2021 20:38:07
User signature succeeded.	Keith Vrbicky (b) (4)	12 Feb 2021 19:56:47
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	12 Feb 2021 13:29:59
User entered 'No (N)'	System	12 Feb 2021 13:29:02

US3032249

Folder: SAE USA-US032-2021-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 09 Jun 2021 14:53:49

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Feb 2021 20:38:07
User signature succeeded.	Keith Vrbicky (b) (4)	12 Feb 2021 19:56:47
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	12 Feb 2021 13:29:59
User entered 'Yes (Y)'	System	12 Feb 2021 13:29:02

US3032249

Folder: SAE USA-US032-2021-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 09 Jun 2021 14:53:49

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Feb 2021 20:38:07
User signature succeeded.	Keith Vrbicky (b) (4)	12 Feb 2021 19:56:47
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	12 Feb 2021 13:29:59
User entered 'No (N)'	System	12 Feb 2021 13:29:02

US3032249

Folder: SAE USA-US032-2021-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 09 Jun 2021 14:53:49

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Feb 2021 20:38:07
User signature succeeded.	Keith Vrbicky (b) (4)	12 Feb 2021 19:56:47
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	12 Feb 2021 13:29:59
User entered 'No (N)'	System	12 Feb 2021 13:29:02

US3032249

Folder: SAE USA-US032-2021-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 09 Jun 2021 14:53:49

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Feb 2021 20:38:07
User signature succeeded.	Keith Vrbicky (b) (4)	12 Feb 2021 19:56:47
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	12 Feb 2021 13:29:59
User entered 'No (N)'	System	12 Feb 2021 13:29:02

US3032249

Folder: SAE USA-US032-2021-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 09 Jun 2021 14:53:49

[Investigator's First Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Feb 2021 20:38:07
User signature succeeded.	Keith Vrbicky (b) (4)	12 Feb 2021 19:56:47
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	12 Feb 2021 13:29:59
User entered 'Keith'	System	12 Feb 2021 13:29:02

US3032249

Folder: SAE USA-US032-2021-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 09 Jun 2021 14:53:49

[Investigator's Last Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Feb 2021 20:38:07
User signature succeeded.	Keith Vrbicky (b) (4)	12 Feb 2021 19:56:47
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	12 Feb 2021 13:29:59
User entered 'Vrbicky'	System	12 Feb 2021 13:29:02

US3032249

Folder: SAE USA-US032-2021-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 09 Jun 2021 14:53:49

[Investigator Country](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	04 Mar 2021 14:40:04
DataPoint Verified.		23 Feb 2021 20:38:07
User signature succeeded.	Keith Vrbicky (b) (4)	12 Feb 2021 19:56:47
User entered 'US'	(b) (4) System	12 Feb 2021 13:30:22

US3032249

Folder: SAE USA-US032-2021-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 09 Jun 2021 14:53:49

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '6'	System	26 Mar 2021 17:26:16
User entered '5'	System	24 Mar 2021 16:06:08
User entered '4'	System	10 Mar 2021 16:02:16
User entered '3'	System	04 Mar 2021 14:45:15
User entered '2'	System	04 Mar 2021 14:40:19
User signature succeeded.	Keith Vrbicky (b) (4)	12 Feb 2021 19:56:47
	(b) (4)	
User entered '1'	System	12 Feb 2021 13:30:22

US3032249

Folder: SAE USA-US032-2021-MRNA-1273-P301000008

Form: Safety Report Form (3)

Generated On: 09 Jun 2021 14:53:49

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Keith Vrbicky (b) (4)	04 Mar 2021 16:04:32
User entered '04/Mar/2021 09:45'	(b) (4) System	04 Mar 2021 14:45:15

US3032249

Folder: SAE USA-US032-2021-MRNA-1273-P301000008

Form: Safety Report Form (3)

Generated On: 09 Jun 2021 14:53:49

Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	10 Mar 2021 16:05:37
User signature succeeded.	Keith Vrbicky (b) (4)	04 Mar 2021 16:04:32
User entered 'I'	(b) (4) (b) (4), (b) (6)	04 Mar 2021 14:45:15

US3032249

Folder: SAE USA-US032-2021-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 09 Jun 2021 14:53:49

[SAEID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Feb 2021 20:38:07
User signature succeeded.	Keith Vrbicky (b) (4)	12 Feb 2021 19:56:47
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	12 Feb 2021 13:29:59
User entered 'USA-US032-2021-MRNA-1273-P301000008'	System	12 Feb 2021 13:29:02

US3032249

Folder: SAE USA-US032-2021-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 09 Jun 2021 14:53:49

Serious

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Feb 2021 20:38:07
User signature succeeded.	Keith Vrbicky (b) (4)	12 Feb 2021 19:56:47
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	12 Feb 2021 13:29:59
User entered 'Yes (Y)'	System	12 Feb 2021 13:29:02

US3032249

Folder: SAE USA-US032-2021-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 09 Jun 2021 14:53:49

[Death](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Feb 2021 20:38:07
User signature succeeded.	Keith Vrbicky (b) (4)	12 Feb 2021 19:56:47
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	12 Feb 2021 13:29:59
User entered 'No (N)'	System	12 Feb 2021 13:29:02

US3032249

Folder: SAE USA-US032-2021-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 09 Jun 2021 14:53:49

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Feb 2021 20:38:07
User signature succeeded.	Keith Vrbicky (b) (4)	12 Feb 2021 19:56:47
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	12 Feb 2021 13:29:59
User entered 'No (N)'	System	12 Feb 2021 13:29:02

US3032249

Folder: SAE USA-US032-2021-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 09 Jun 2021 14:53:49

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Feb 2021 20:38:07
User signature succeeded.	Keith Vrbicky (b) (4)	12 Feb 2021 19:56:47
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	12 Feb 2021 13:29:59
User entered 'Yes (Y)'	System	12 Feb 2021 13:29:02

US3032249

Folder: SAE USA-US032-2021-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 09 Jun 2021 14:53:49

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Feb 2021 20:38:07
User signature succeeded.	Keith Vrbicky (b) (4)	12 Feb 2021 19:56:47
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	12 Feb 2021 13:29:59
User entered 'No (N)'	System	12 Feb 2021 13:29:02

US3032249

Folder: SAE USA-US032-2021-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 09 Jun 2021 14:53:49

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Feb 2021 20:38:07
User signature succeeded.	Keith Vrbicky (b) (4)	12 Feb 2021 19:56:47
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	12 Feb 2021 13:29:59
User entered 'No (N)'	System	12 Feb 2021 13:29:02

US3032249

Folder: SAE USA-US032-2021-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 09 Jun 2021 14:53:49

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Feb 2021 20:38:07
User signature succeeded.	Keith Vrbicky (b) (4)	12 Feb 2021 19:56:47
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	12 Feb 2021 13:29:59
User entered 'No (N)'	System	12 Feb 2021 13:29:02

US3032249

Folder: SAE USA-US032-2021-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 09 Jun 2021 14:53:49

[Investigator's First Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Feb 2021 20:38:07
User signature succeeded.	Keith Vrbicky (b) (4)	12 Feb 2021 19:56:47
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	12 Feb 2021 13:29:59
User entered 'Keith'	System	12 Feb 2021 13:29:02

US3032249

Folder: SAE USA-US032-2021-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 09 Jun 2021 14:53:49

[Investigator's Last Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Feb 2021 20:38:07
User signature succeeded.	Keith Vrbicky (b) (4)	12 Feb 2021 19:56:47
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	12 Feb 2021 13:29:59
User entered 'Vrbicky'	System	12 Feb 2021 13:29:02

US3032249

Folder: SAE USA-US032-2021-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 09 Jun 2021 14:53:49

[Investigator Country](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	04 Mar 2021 14:40:04
DataPoint Verified.	(b) (4), (b) (6)	23 Feb 2021 20:38:07
User signature succeeded.	Keith Vrbicky (b) (4)	12 Feb 2021 19:56:47
User entered 'US'	(b) (4) System	12 Feb 2021 13:30:22

US3032249

Folder: SAE USA-US032-2021-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 09 Jun 2021 14:53:49

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '6'	System	26 Mar 2021 17:26:16
User entered '5'	System	24 Mar 2021 16:06:08
User entered '4'	System	10 Mar 2021 16:02:16
User entered '3'	System	04 Mar 2021 14:45:15
User entered '2'	System	04 Mar 2021 14:40:19
User signature succeeded.	Keith Vrbicky (b) (4)	12 Feb 2021 19:56:47
	(b) (4)	
User entered '1'	System	12 Feb 2021 13:30:22

US3032249

Folder: SAE USA-US032-2021-MRNA-1273-P301000008

Form: Safety Report Form (4)

Generated On: 09 Jun 2021 14:53:49

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Keith Vrbicky (b) (4)	18 Mar 2021 21:21:02
User entered '10/Mar/2021 11:02'	(b) (4) System	10 Mar 2021 16:02:16

US3032249

Folder: SAE USA-US032-2021-MRNA-1273-P301000008

Form: Safety Report Form (4)

Generated On: 09 Jun 2021 14:53:49

Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.

Audit	User	Time (GMT)
User signature succeeded.	Keith Vrbicky (b) (4)	18 Mar 2021 21:21:02
Reviewed for Safety.	(b) (4) (v) (4), (b) (6)	10 Mar 2021 16:05:37
User entered 'I'		10 Mar 2021 16:02:16

US3032249

Folder: SAE USA-US032-2021-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 09 Jun 2021 14:53:49

[SAEID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Feb 2021 20:38:07
User signature succeeded.	Keith Vrbicky (b) (4)	12 Feb 2021 19:56:47
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	12 Feb 2021 13:29:59
User entered 'USA-US032-2021-MRNA-1273-P301000008'	System	12 Feb 2021 13:29:02

US3032249

Folder: SAE USA-US032-2021-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 09 Jun 2021 14:53:49

Serious

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Feb 2021 20:38:07
User signature succeeded.	Keith Vrbicky (b) (4)	12 Feb 2021 19:56:47
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	12 Feb 2021 13:29:59
User entered 'Yes (Y)'	System	12 Feb 2021 13:29:02

US3032249

Folder: SAE USA-US032-2021-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 09 Jun 2021 14:53:49

[Death](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Feb 2021 20:38:07
User signature succeeded.	Keith Vrbicky (b) (4)	12 Feb 2021 19:56:47
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	12 Feb 2021 13:29:59
User entered 'No (N)'	System	12 Feb 2021 13:29:02

US3032249

Folder: SAE USA-US032-2021-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 09 Jun 2021 14:53:49

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Feb 2021 20:38:07
User signature succeeded.	Keith Vrbicky (b) (4)	12 Feb 2021 19:56:47
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	12 Feb 2021 13:29:59
User entered 'No (N)'	System	12 Feb 2021 13:29:02

US3032249

Folder: SAE USA-US032-2021-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 09 Jun 2021 14:53:49

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Feb 2021 20:38:07
User signature succeeded.	Keith Vrbicky (b) (4)	12 Feb 2021 19:56:47
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	12 Feb 2021 13:29:59
User entered 'Yes (Y)'	System	12 Feb 2021 13:29:02

US3032249

Folder: SAE USA-US032-2021-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 09 Jun 2021 14:53:49

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Feb 2021 20:38:07
User signature succeeded.	Keith Vrbicky (b) (4)	12 Feb 2021 19:56:47
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	12 Feb 2021 13:29:59
User entered 'No (N)'	System	12 Feb 2021 13:29:02

US3032249

Folder: SAE USA-US032-2021-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 09 Jun 2021 14:53:49

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Feb 2021 20:38:07
User signature succeeded.	Keith Vrbicky (b) (4)	12 Feb 2021 19:56:47
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	12 Feb 2021 13:29:59
User entered 'No (N)'	System	12 Feb 2021 13:29:02

US3032249

Folder: SAE USA-US032-2021-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 09 Jun 2021 14:53:49

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Feb 2021 20:38:07
User signature succeeded.	Keith Vrbicky (b) (4)	12 Feb 2021 19:56:47
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	12 Feb 2021 13:29:59
User entered 'No (N)'	System	12 Feb 2021 13:29:02

US3032249

Folder: SAE USA-US032-2021-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 09 Jun 2021 14:53:49

[Investigator's First Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Feb 2021 20:38:07
User signature succeeded.	Keith Vrbicky (b) (4)	12 Feb 2021 19:56:47
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	12 Feb 2021 13:29:59
User entered 'Keith'	System	12 Feb 2021 13:29:02

US3032249

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[Investigator's Last Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Feb 2021 20:38:07
User signature succeeded.	Keith Vrbicky (b) (4)	12 Feb 2021 19:56:47
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	12 Feb 2021 13:29:59
User entered 'Vrbicky'	System	12 Feb 2021 13:29:02

US3032249

Folder: SAE USA-US032-2021-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 09 Jun 2021 14:53:49

[Investigator Country](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	04 Mar 2021 14:40:04
DataPoint Verified.	(b) (4), (b) (6)	23 Feb 2021 20:38:07
User signature succeeded.	Keith Vrbicky (b) (4)	12 Feb 2021 19:56:47
User entered 'US'	(b) (4) System	12 Feb 2021 13:30:22

US3032249

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Form: Safety Report Form

Generated On: 09 Jun 2021 14:53:49

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Audit	User	Time (GMT)
User entered '6'	System	26 Mar 2021 17:26:16
User entered '5'	System	24 Mar 2021 16:06:08
User entered '4'	System	10 Mar 2021 16:02:16
User entered '3'	System	04 Mar 2021 14:45:15
User entered '2'	System	04 Mar 2021 14:40:19
User signature succeeded.	Keith Vrbicky (b) (4)	12 Feb 2021 19:56:47
	(b) (4)	
User entered '1'	System	12 Feb 2021 13:30:22

US3032249

Folder: SAE USA-US032-2021-MRNA-1273-P301000008

Form: Safety Report Form (5)

Generated On: 09 Jun 2021 14:53:49

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:41:55
User entered '24/Mar/2021 12:05'	(b) (4) System	24 Mar 2021 16:06:08

US3032249

Folder: SAE USA-US032-2021-MRNA-1273-P301000008

Form: Safety Report Form (5)

Generated On: 09 Jun 2021 14:53:49

Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.

Audit	User	Time (GMT)
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:41:55
User entered 'I'	(b) (4) (b) (4), (b) (6)	24 Mar 2021 16:06:08

US3032249

Folder: SAE USA-US032-2021-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 09 Jun 2021 14:53:49

[SAEID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Feb 2021 20:38:07
User signature succeeded.	Keith Vrbicky (b) (4)	12 Feb 2021 19:56:47
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	12 Feb 2021 13:29:59
User entered 'USA-US032-2021-MRNA-1273-P301000008'	System	12 Feb 2021 13:29:02

US3032249

Folder: SAE USA-US032-2021-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 09 Jun 2021 14:53:49

Serious

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Feb 2021 20:38:07
User signature succeeded.	Keith Vrbicky (b) (4)	12 Feb 2021 19:56:47
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	12 Feb 2021 13:29:59
User entered 'Yes (Y)'	System	12 Feb 2021 13:29:02

US3032249

Folder: SAE USA-US032-2021-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 09 Jun 2021 14:53:49

[Death](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Feb 2021 20:38:07
User signature succeeded.	Keith Vrbicky (b) (4)	12 Feb 2021 19:56:47
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	12 Feb 2021 13:29:59
User entered 'No (N)'	System	12 Feb 2021 13:29:02

US3032249

Folder: SAE USA-US032-2021-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 09 Jun 2021 14:53:49

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Feb 2021 20:38:07
User signature succeeded.	Keith Vrbicky (b) (4)	12 Feb 2021 19:56:47
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	12 Feb 2021 13:29:59
User entered 'No (N)'	System	12 Feb 2021 13:29:02

US3032249

Folder: SAE USA-US032-2021-MRNA-1273-P301000008

Form: Safety Report Form

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[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Feb 2021 20:38:07
User signature succeeded.	Keith Vrbicky (b) (4)	12 Feb 2021 19:56:47
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	12 Feb 2021 13:29:59
User entered 'Yes (Y)'	System	12 Feb 2021 13:29:02

US3032249

Folder: SAE USA-US032-2021-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 09 Jun 2021 14:53:49

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Feb 2021 20:38:07
User signature succeeded.	Keith Vrbicky (b) (4)	12 Feb 2021 19:56:47
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	12 Feb 2021 13:29:59
User entered 'No (N)'	System	12 Feb 2021 13:29:02

US3032249

Folder: SAE USA-US032-2021-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 09 Jun 2021 14:53:49

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Feb 2021 20:38:07
User signature succeeded.	Keith Vrbicky (b) (4)	12 Feb 2021 19:56:47
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	12 Feb 2021 13:29:59
User entered 'No (N)'	System	12 Feb 2021 13:29:02

US3032249

Folder: SAE USA-US032-2021-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 09 Jun 2021 14:53:49

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Feb 2021 20:38:07
User signature succeeded.	Keith Vrbicky (b) (4)	12 Feb 2021 19:56:47
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	12 Feb 2021 13:29:59
User entered 'No (N)'	System	12 Feb 2021 13:29:02

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Form: Safety Report Form

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[Investigator's First Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Feb 2021 20:38:07
User signature succeeded.	Keith Vrbicky (b) (4)	12 Feb 2021 19:56:47
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	12 Feb 2021 13:29:59
User entered 'Keith'	System	12 Feb 2021 13:29:02

US3032249

Folder: SAE USA-US032-2021-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 09 Jun 2021 14:53:49

[Investigator's Last Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Feb 2021 20:38:07
User signature succeeded.	Keith Vrbicky (b) (4)	12 Feb 2021 19:56:47
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	12 Feb 2021 13:29:59
User entered 'Vrbicky'	System	12 Feb 2021 13:29:02

US3032249

Folder: SAE USA-US032-2021-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 09 Jun 2021 14:53:49

[Investigator Country](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	04 Mar 2021 14:40:04
DataPoint Verified.	(b) (4), (b) (6)	23 Feb 2021 20:38:07
User signature succeeded.	Keith Vrbicky (b) (4)	12 Feb 2021 19:56:47
User entered 'US'	(b) (4) System	12 Feb 2021 13:30:22

US3032249

Folder: SAE USA-US032-2021-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 09 Jun 2021 14:53:49

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '6'	System	26 Mar 2021 17:26:16
User entered '5'	System	24 Mar 2021 16:06:08
User entered '4'	System	10 Mar 2021 16:02:16
User entered '3'	System	04 Mar 2021 14:45:15
User entered '2'	System	04 Mar 2021 14:40:19
User signature succeeded.	Keith Vrbicky (b) (4)	12 Feb 2021 19:56:47
	(b) (4)	
User entered '1'	System	12 Feb 2021 13:30:22

US3032249

Folder: SAE USA-US032-2021-MRNA-1273-P301000008

Form: Safety Report Form (6)

Generated On: 09 Jun 2021 14:53:49

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:41:55
User entered '26/Mar/2021 10:26'	(b) (4) System	26 Mar 2021 17:26:16

US3032249

Folder: SAE USA-US032-2021-MRNA-1273-P301000008

Form: Safety Report Form (6)

Generated On: 09 Jun 2021 14:53:49

Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.

Audit	User	Time (GMT)
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:41:55
User entered 'I'	(b) (4) (b) (4), (b) (6)	26 Mar 2021 17:26:16