

US3512248 (Prod: Jacksonville Center for Clinical Research Center)

Generated By: KC Joubran

Generated On: 10 Jun 2021 07:56:44

All time stamps listed in this document are displayed in GMT

US3512248

Form: Participant Creation

Data signed: (b) (4) 12 Feb 2021 22:11:58

Generated On: 10 Jun 2021 07:56:44

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Participant ID

US3512248

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

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US3512248

Folder: Screening

Form: Visit Date

Data signed: (b) (4) 12 Feb 2021 22:12:00

Generated On: 10 Jun 2021 07:56:44

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

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Folder: Screening

Form: Demographics

Data signed: (b) (4) 12 Feb 2021 22:11:59

Generated On: 10 Jun 2021 07:56:44

Date of Birth (MMM yyyy)	(b) (6) 1943
Age	76
Age Units	YEARS
Age (Derived)	77
Sex	Female <input type="radio"/> Male <input checked="" type="radio"/>
Ethnicity	Hispanic or Latino <input type="radio"/> Not Hispanic or Latino <input checked="" type="radio"/> Not Reported <input type="radio"/> Unknown <input type="radio"/>
Race (Check All That Apply)	
White	True
Black	False
Asian	False
American Indian or Alaska Native	False
Native Hawaiian or other Pacific Islander	False
Other	False
If race is Other, specify _____	
Unknown	False
Not reported	False



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Folder: Screening

Form: Enrollment

Data signed: (b) (4) 12 Feb 2021 22:11:59

Generated On: 10 Jun 2021 07:56:44

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

US3512248

Folder: Screening

Form: Inclusion/Exclusion Criteria Summary

Data signed: (b) (4) 12 Feb 2021 22:12:00

Generated On: 10 Jun 2021 07:56:44

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Did the participant meet all eligibility criteria?

Yes ☒

No ☐

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US3512248

Folder: Screening

Form: Medical History Summary

Data signed: (b) (4) 12 Feb 2021 22:12:00

Generated On: 10 Jun 2021 07:56:44

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Were any significant conditions reported?

Yes ☒  
No ☐

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Folder: Screening

Form: Medical History (1)

Data signed: (b) (4) 02 Apr 2021 19:30:26

Generated On: 10 Jun 2021 07:56:44

Condition	SEASONAL ALLERGIES
Start date (dd MMM yyyy)	UN UNK 1950
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 1950
Start Year (derived)	1950
Stop Month and Year (derived)	
Stop Year (derived)	

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Folder: Screening

Form: Medical History (2)

Data signed: (b) (4) 02 Apr 2021 19:30:26

Generated On: 10 Jun 2021 07:56:44

Condition	GASTROESOPHAGEAL REFLUX DISEASE
Start date (dd MMM yyyy)	UN UNK 2008
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 2008
Start Year (derived)	2008
Stop Month and Year (derived)	
Stop Year (derived)	

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Folder: Screening

Form: Medical History (3)

Data signed: (b) (4) 02 Apr 2021 19:30:26

Generated On: 10 Jun 2021 07:56:44

Condition	BENIGN COLON POLYPS
Start date (dd MMM yyyy)	UN UNK 2016
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 2016
Stop date completely unknown	False
Start Month and Year (derived)	JAN 2016
Start Year (derived)	2016
Stop Month and Year (derived)	JAN 2016
Stop Year (derived)	2016

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Folder: Screening

Form: Medical History (4)

Data signed: (b) (4) 02 Apr 2021 19:30:26

Generated On: 10 Jun 2021 07:56:44

Condition	ENLARGED PROSTATE
Start date (dd MMM yyyy)	UN UNK 2008
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 2008
Start Year (derived)	2008
Stop Month and Year (derived)	
Stop Year (derived)	

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Folder: Screening

Form: Medical History (5)

Data signed: (b) (4) 02 Apr 2021 19:30:26

Generated On: 10 Jun 2021 07:56:44

Condition	ERECTILE DYSFUNCTION
Start date (dd MMM yyyy)	UN UNK 2008
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 2008
Start Year (derived)	2008
Stop Month and Year (derived)	_____
Stop Year (derived)	_____



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Folder: Screening

Form: Medical History (6)

Data signed: (b) (4) 02 Apr 2021 19:30:26

Generated On: 10 Jun 2021 07:56:44

Condition	LOW LIBIDO
Start date (dd MMM yyyy)	UN UNK 2008
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 2008
Start Year (derived)	2008
Stop Month and Year (derived)	_____
Stop Year (derived)	_____

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Folder: Screening

Form: Medical History (7)

Data signed: (b) (4) 02 Apr 2021 19:30:26

Generated On: 10 Jun 2021 07:56:44

Condition	ANEMIA
Start date (dd MMM yyyy)	UN UNK 2016
Start date completely unknown	False
Condition ongoing at study entry	Yes <input checked="" type="radio"/> No <input type="radio"/>
If No, please specify the stop date (dd MMM yyyy) _____	
Stop date completely unknown	False
Start Month and Year (derived)	JAN 2016
Start Year (derived)	2016
Stop Month and Year (derived)	_____
Stop Year (derived)	_____

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Folder: Screening

Form: Medical History (8)

Data signed: (b) (4) 02 Apr 2021 19:30:26

Generated On: 10 Jun 2021 07:56:44

Condition	CATARACTS
Start date (dd MMM yyyy)	UN UNK 1993
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 1993
Start Year (derived)	1993
Stop Month and Year (derived)	_____
Stop Year (derived)	_____

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Folder: Screening

Form: Medical History (9)

Data signed: (b) (4) 02 Apr 2021 19:30:26

Generated On: 10 Jun 2021 07:56:44

Condition	PRESBYOPIA
Start date (dd MMM yyyy)	UN UNK 1993
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 1993
Start Year (derived)	1993
Stop Month and Year (derived)	_____
Stop Year (derived)	_____

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Folder: Screening

Form: Medical History (10)

Data signed: (b) (4) 02 Apr 2021 19:30:26

Generated On: 10 Jun 2021 07:56:44

Condition	AMBLYOPIA
Start date (dd MMM yyyy)	(b) (6) 1943
Start date completely unknown	False
Condition ongoing at study entry	Yes <input checked="" type="radio"/> No <input type="radio"/>
If No, please specify the stop date (dd MMM yyyy) _____	
Stop date completely unknown	False
Start Month and Year (derived)	(b) (6) 1943
Start Year (derived)	1943
Stop Month and Year (derived)	_____
Stop Year (derived)	_____

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Folder: Screening

Form: Medical History (11)

Data signed: (b) (4) 02 Apr 2021 19:30:26

Generated On: 10 Jun 2021 07:56:44

Condition	HEADACHES
Start date (dd MMM yyyy)	UN UNK 1945
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 1960
Stop date completely unknown	False
Start Month and Year (derived)	JAN 1945
Start Year (derived)	1945
Stop Month and Year (derived)	JAN 1960
Stop Year (derived)	1960

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Folder: Screening

Form: Medical History (12)

Data signed: (b) (4) 02 Apr 2021 19:30:26

Generated On: 10 Jun 2021 07:56:44

Condition	MIGRAINES
Start date (dd MMM yyyy)	UN UNK 1945
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 1960
Stop date completely unknown	False
Start Month and Year (derived)	JAN 1945
Start Year (derived)	1945
Stop Month and Year (derived)	JAN 1960
Stop Year (derived)	1960

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Folder: Screening

Form: Medical History (13)

Data signed: (b) (4) 02 Apr 2021 19:30:26

Generated On: 10 Jun 2021 07:56:44

Condition	DIABETIC NEUROPATHY BILATERAL HANDS
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) 02 Apr 2021 19:30:26

Generated On: 10 Jun 2021 07:56:44

Condition	CHRONIC OBSTRUCTIVE PULMONARY DISEASE
Start date (dd MMM yyyy)	UN UNK 2003
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 2003
Start Year (derived)	2003
Stop Month and Year (derived)	
Stop Year (derived)	

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Folder: Screening

Form: Medical History (15)

Data signed: (b) (4) 02 Apr 2021 19:30:26

Generated On: 10 Jun 2021 07:56:44

Condition	KERATOSIS ON BILATERAL ARMS, LEGS, HEAD AND SCALP
Start date (dd MMM yyyy)	UN UNK 1990
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 1990
Start Year (derived)	1990
Stop Month and Year (derived)	
Stop Year (derived)	

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Folder: Screening

Form: Medical History (16)

Data signed: (b) (4) 02 Apr 2021 19:30:26

Generated On: 10 Jun 2021 07:56:44

Condition	OSTEOARTHRITIS OF RIGHT FINGERS
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 (17)

Data signed: (b) (4) 02 Apr 2021 19:30:26

Generated On: 10 Jun 2021 07:56:44

Condition	OSTEOARTHRITIS OF ANKLE
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 (18)

Data signed: (b) (4) 02 Apr 2021 19:30:26

Generated On: 10 Jun 2021 07:56:44

Condition	BACK PAIN
Start date (dd MMM yyyy)	UN UNK 2000
Start date completely unknown	False
Condition ongoing at study entry	Yes <input checked="" type="radio"/> No <input type="radio"/>
If No, please specify the stop date (dd MMM yyyy) _____	
Stop date completely unknown	False
Start Month and Year (derived)	JAN 2000
Start Year (derived)	2000
Stop Month and Year (derived)	_____
Stop Year (derived)	_____

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Folder: Screening

Form: Medical History (19)

Data signed: (b) (4) 02 Apr 2021 19:30:26

Generated On: 10 Jun 2021 07:56:44

Condition	BROKEN RIGHT LEG
Start date (dd MMM yyyy)	UN UNK 1996
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 1996
Stop date completely unknown	False
Start Month and Year (derived)	JAN 1996
Start Year (derived)	1996
Stop Month and Year (derived)	JAN 1996
Stop Year (derived)	1996

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Folder: Screening

Form: Medical History (20)

Data signed: (b) (4) 02 Apr 2021 19:30:26

Generated On: 10 Jun 2021 07:56:44

Condition	REPAIR OF BROKEN RIGHT LEG
Start date (dd MMM yyyy)	UN UNK 1996
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 1996
Stop date completely unknown	False
Start Month and Year (derived)	JAN 1996
Start Year (derived)	1996
Stop Month and Year (derived)	JAN 1996
Stop Year (derived)	1996

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Folder: Screening

Form: Medical History (21)

Data signed: (b) (4) 02 Apr 2021 19:30:26

Generated On: 10 Jun 2021 07:56:44

Condition	BROKEN RIGHT ARM
Start date (dd MMM yyyy)	UN UNK 1996
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 1996
Stop date completely unknown	False
Start Month and Year (derived)	JAN 1996
Start Year (derived)	1996
Stop Month and Year (derived)	JAN 1996
Stop Year (derived)	1996



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Folder: Screening

Form: Medical History (22)

Data signed: (b) (4) 02 Apr 2021 19:30:26

Generated On: 10 Jun 2021 07:56:44

Condition	REPAIR OF BROKEN RIGHT ARM
Start date (dd MMM yyyy)	UN UNK 1996
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 1996
Stop date completely unknown	False
Start Month and Year (derived)	JAN 1996
Start Year (derived)	1996
Stop Month and Year (derived)	JAN 1996
Stop Year (derived)	1996

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Folder: Screening

Form: Medical History (23)

Data signed: (b) (4) 02 Apr 2021 19:30:26

Generated On: 10 Jun 2021 07:56:44

Condition	GENERAL ACHES AND PAINS
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)	_____

US3512248

Folder: Screening

Form: Medical History (24)

Data signed: (b) (4) 02 Apr 2021 19:30:26

Generated On: 10 Jun 2021 07:56:44

Condition	PRE-DIABETES
Start date (dd MMM yyyy)	UN UNK 2012
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 2012
Start Year (derived)	2012
Stop Month and Year (derived)	_____
Stop Year (derived)	_____

US3512248

Folder: Screening

Form: Medical History (25)

Data signed: (b) (4) 02 Apr 2021 19:30:26

Generated On: 10 Jun 2021 07:56:44

Condition	OVERWEIGHT
Start date (dd MMM yyyy)	UN UNK 1998
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 1998
Start Year (derived)	1998
Stop Month and Year (derived)	_____
Stop Year (derived)	_____

US3512248

Folder: Screening

Form: Medical History (26)

Data signed: (b) (4) 02 Apr 2021 19:30:26

Generated On: 10 Jun 2021 07:56:44

Condition	ATRIAL FIBRILLATION
Start date (dd MMM yyyy)	UN APR 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)	APR 2018
Start Year (derived)	2018
Stop Month and Year (derived)	_____
Stop Year (derived)	_____

US3512248

Folder: Screening

Form: Medical History (27)

Data signed: (b) (4) 02 Apr 2021 19:30:26

Generated On: 10 Jun 2021 07:56:44

Condition	CARDIAC ABLATION
Start date (dd MMM yyyy)	UN APR 2019
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 APR 2019
Stop date completely unknown	False
Start Month and Year (derived)	APR 2019
Start Year (derived)	2019
Stop Month and Year (derived)	APR 2019
Stop Year (derived)	2019

US3512248

Folder: Screening

Form: Medical History (28)

Data signed: (b) (4) 02 Apr 2021 19:30:26

Generated On: 10 Jun 2021 07:56:44

Condition	HEART CAUTERIZATION
Start date (dd MMM yyyy)	UN UNK 2006
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 2006
Stop date completely unknown	False
Start Month and Year (derived)	JAN 2006
Start Year (derived)	2006
Stop Month and Year (derived)	JAN 2006
Stop Year (derived)	2006

US3512248

Folder: Screening

Form: Medical History (29)

Data signed: (b) (4) 02 Apr 2021 19:30:26

Generated On: 10 Jun 2021 07:56:44

Condition	CORONARY ARTERY DISEASE
Start date (dd MMM yyyy)	UN UNK 2008
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 2008
Start Year (derived)	2008
Stop Month and Year (derived)	_____
Stop Year (derived)	_____



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Folder: Screening

Form: Medical History (30)

Data signed: (b) (4) 02 Apr 2021 19:30:26

Generated On: 10 Jun 2021 07:56:44

Condition	LEFT INGUINAL HERNIA
Start date (dd MMM yyyy)	UN AUG 2018
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 SEP 2018
Stop date completely unknown	False
Start Month and Year (derived)	AUG 2018
Start Year (derived)	2018
Stop Month and Year (derived)	SEP 2018
Stop Year (derived)	2018

US3512248

Folder: Screening

Form: Medical History (31)

Data signed: (b) (4) 02 Apr 2021 19:30:26

Generated On: 10 Jun 2021 07:56:44

Condition	LEFT INGUINAL HERNIA REPAIR
Start date (dd MMM yyyy)	UN UNK 2017
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 2017
Stop date completely unknown	False
Start Month and Year (derived)	JAN 2017
Start Year (derived)	2017
Stop Month and Year (derived)	JAN 2017
Stop Year (derived)	2017

US3512248

Folder: Screening

Form: Medical History (32)

Data signed: (b) (4) 02 Apr 2021 19:30:26

Generated On: 10 Jun 2021 07:56:44

Condition	LEFT INGUINAL HERNIA REPAIR
Start date (dd MMM yyyy)	UN SEP 2018
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 SEP 2018
Stop date completely unknown	False
Start Month and Year (derived)	SEP 2018
Start Year (derived)	2018
Stop Month and Year (derived)	SEP 2018
Stop Year (derived)	2018

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Folder: Screening

Form: Medical History (33)

Data signed: (b) (4) 02 Apr 2021 19:30:26

Generated On: 10 Jun 2021 07:56:44

Condition	RIGHT PATELLA FRACTURE
Start date (dd MMM yyyy)	08 AUG 2020
Start date completely unknown	False
Condition ongoing at study entry	Yes <input checked="" type="radio"/> No <input type="radio"/>
If No, please specify the stop date (dd MMM yyyy)	
Stop date completely unknown	False
Start Month and Year (derived)	AUG 2020
Start Year (derived)	2020
Stop Month and Year (derived)	
Stop Year (derived)	

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Folder: Screening

Form: Medical History (34)

Data signed: (b) (4) 02 Apr 2021 19:30:26

Generated On: 10 Jun 2021 07:56:44

Condition	VASECTOMY
Start date (dd MMM yyyy)	UN UNK 1972
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 1972
Stop date completely unknown	False
Start Month and Year (derived)	JAN 1972
Start Year (derived)	1972
Stop Month and Year (derived)	JAN 1972
Stop Year (derived)	1972

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Folder: Screening

Form: Medical History (35)

Data signed: (b) (4) 02 Apr 2021 19:30:26

Generated On: 10 Jun 2021 07:56:44

Condition	SMOKER
Start date (dd MMM yyyy)	UN UNK 1963
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 1993
Stop date completely unknown	False
Start Month and Year (derived)	JAN 1963
Start Year (derived)	1963
Stop Month and Year (derived)	JAN 1993
Stop Year (derived)	1993

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Folder: Screening

Form: Medical History (36)

Data signed: (b) (4) 02 Apr 2021 19:30:26

Generated On: 10 Jun 2021 07:56:44

Condition	HYPERCHOLESTEROLEMIA
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 (38)

Data signed: (b) (4) 02 Apr 2021 19:30:26

Generated On: 10 Jun 2021 07:56:44

Condition	LEFT MENISCUS TEAR
Start date (dd MMM yyyy)	UN UNK 2019
Start date completely unknown	False
Condition ongoing at study entry	Yes <input checked="" type="radio"/> No <input type="radio"/>
If No, please specify the stop date (dd MMM yyyy) _____	
Stop date completely unknown	False
Start Month and Year (derived)	JAN 2019
Start Year (derived)	2019
Stop Month and Year (derived)	_____
Stop Year (derived)	_____



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Folder: Screening

Form: Medical History (39)

Data signed: (b) (4) 02 Apr 2021 19:30:26

Generated On: 10 Jun 2021 07:56:44

Condition	RIGHT LATERAL MENISCUS EFFUSION
Start date (dd MMM yyyy)	08 AUG 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)	08 AUG 2020
Stop date completely unknown	False
Start Month and Year (derived)	AUG 2020
Start Year (derived)	2020
Stop Month and Year (derived)	AUG 2020
Stop Year (derived)	2020

US3512248

Folder: Screening

Form: Vital Signs

Data signed: (b) (4) 12 Feb 2021 22:12:00

Generated On: 10 Jun 2021 07:56:44

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment ( <i>dd MMM yyyy</i> )	10 SEP 2020
Time of assessment ( <i>00:00-23:59</i> )	11:31 (24 HR)
Vital Signs Date and Time (derived)	10 SEP 2020 11:31
Height ( <i>xxx.x</i> )	71 in
Weight ( <i>xxx.x</i> )	231.4 lb
BMI ( <i>xxx.x</i> )	32.34123 kg/m <sup>2</sup>
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)	

US3512248

Folder: Screening

Form: Physical Examination

Data signed: (b) (4) 12 Feb 2021 22:12:00

Generated On: 10 Jun 2021 07:56:44

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

10 SEP 2020

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

US3512248

Folder: Screening

Form: Risk of Exposure

Data signed: (b) (4) 12 Feb 2021 22:12:00

Generated On: 10 Jun 2021 07:56:44

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**Occupational Risk**

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

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

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

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

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

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

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

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

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

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

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

**Other** Yes ☐ No ☒

---

**Specify**

---

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

**No Risk Identified** False

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

US3512248

Folder: Screening

Form: Risk of Exposure

Data signed: (b) (4) 12 Feb 2021 22:12:00

Generated On: 10 Jun 2021 07:56:44

<b>Resides in Multi-family dwelling</b> (e.g., cohabitation in dwelling with > 5 people, includes grandparents living with children < 18yrs)	False
<b>Resides in high density housing</b> (e.g., high rise apartments with shared entrances or elevators)	False
<b>Resides in low density, multi-family setting without</b> (e.g., apartments complex without shared entrances or elevators, duplexes)	False
<b>Resides in a single family home</b> (i.e., detached housing)	True
<b>Other</b>	True
<b>Specify</b>	HAS ATTENDED LARGE GROUP EVENTS IN THE PAST FEW WEEKS (CHURCH); PLANS ON ROUTINELY GOING TO PLACES WHERE PEOPLE GATHER(GYM, RESTAURANT, GROCERY STORE); INTERACTS W/>5 PEOPLE OUTSIDE OF THE HOME

US3512248

Folder: Visit 1 Day 1

Form: Visit Date

Data signed: (b) (4) 12 Feb 2021 22:12:01

Generated On: 10 Jun 2021 07:56:44

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

US3512248

Folder: Visit 1 Day 1

Form: Randomization

Data signed: (b) (4) 12 Feb 2021 22:12:01

Generated On: 10 Jun 2021 07:56:44

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

What was the participant's randomization number? 190352

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 ☒

US3512248

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Data signed: (b) (4) 12 Feb 2021 22:12:01

Generated On: 10 Jun 2021 07:56:44

Height	ND - Not Done
Weight	ND - Not Done



US3512248

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 12 Feb 2021 22:12:01

Generated On: 10 Jun 2021 07:56:44

Height	ND - Not Done
Weight	ND - Not Done
Timepoint	Pre-Dose <input checked="" type="radio"/> Post-Dose <input type="radio"/>
Were vital signs assessed?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Date of assessment (dd MMM yyyy)	10 SEP 2020
Time of assessment (00:00-23:59)	11:31 (24 HR)
Vital Signs Date and Time (derived)	10 SEP 2020 11:31
Temperature (xxx.x)	98.7 F
Route of measurement	Oral <input checked="" type="radio"/> Axillary <input type="radio"/> Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	66 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	13 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	152 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	83 mmHg
Diastolic Blood Pressure units	MMHG

US3512248

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 12 Feb 2021 22:12:01

Generated On: 10 Jun 2021 07:56:44

Height	ND - Not Done
Weight	ND - Not Done
Timepoint	Pre-Dose <input type="radio"/> Post-Dose <input checked="" type="radio"/>
Were vital signs assessed?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Date of assessment (dd MMM yyyy)	10 SEP 2020
Time of assessment (00:00-23:59)	13:22 (24 HR)
Vital Signs Date and Time (derived)	10 SEP 2020 13:22
Temperature (xxx.x)	96.8 F
Route of measurement	Oral <input checked="" type="radio"/> Axillary <input type="radio"/> Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	78 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	14 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	173 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	76 mmHg
Diastolic Blood Pressure units	MMHG

US3512248

Folder: Visit 1 Day 1

Form: Physical Examination

Data signed: (b) (4) 12 Feb 2021 22:12:01

Generated On: 10 Jun 2021 07:56:44

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.*

US3512248

Folder: Visit 1 Day 1

Form: Exposure

Data signed: (b) (4) 12 Feb 2021 22:12:00

Generated On: 10 Jun 2021 07:56:44

Was study treatment given? Yes ☒ No ☐

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

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

What was the study treatment? MRNA-1273 OR PLACEBO

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

What was the treatment time? (00:00-23:59) 12:51 (24 HR)

Treatment Date and Time (derived) 10 SEP 2020 12:51

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

US3512248

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Data signed: (b) (4) 12 Feb 2021 22:12:00

Generated On: 10 Jun 2021 07:56:44

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (dd MMM yyyy)	10 SEP 2020
Collection time (00:00-23:59)	11:57 (24 HR)
Collection date and time (derived)	10 SEP 2020 11:57

US3512248

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab

Data signed: (b) (4) 12 Feb 2021 22:12:00

Generated On: 10 Jun 2021 07:56:44

Collection date (dd MMM yyyy)			10 SEP 2020
Lab Test	Was the sample collected?	Collection time (00:00 - 23:59)	Collection date and time (derived)
Nasopharyngeal Swab 1	Yes	11:47	10 SEP 2020 11:47
Nasopharyngeal Swab 2	No		

US3512248

Folder: Visit 1 Day 1

Form: Continuing

Data signed: (b) (4) 12 Feb 2021 22:12:00

Generated On: 10 Jun 2021 07:56:44

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3512248

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/1)

Generated On: 10 Jun 2021 07:56:44

**TIMEPOINT**

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

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒  
No ☐

Please record your **TEMPERATURE** in °F

96.8 °F

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

Yes ☐  
No ☒

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

PC Time Stamp 10 SEP 2020 13:29

PC Open Date & Time 10 SEP 2020 13:11

PC Close Date & Time 10 SEP 2020 15:41



US3512248

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/2)

Generated On: 10 Jun 2021 07:56:44

**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

97.0 °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

10 SEP 2020 18:44

PC Open Date & Time

10 SEP 2020 16:36

PC Close Date & Time

11 SEP 2020 11:59

US3512248

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(2)

Generated On: 10 Jun 2021 07:56:44

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**TIMEPOINT**

DAY 2

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

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

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

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

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

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

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

---

Was **TEMPERATURE** taken?

Yes ☒

No ☐

---

Please record your **TEMPERATURE** in °F

97.9 °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

11 SEP 2020 17:00

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PC Open Date & Time

11 SEP 2020 12:00

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PC Close Date & Time

12 SEP 2020 11:59

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US3512248

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(3)

Generated On: 10 Jun 2021 07:56:44

**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

97.9 °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

12 SEP 2020 21:01

PC Open Date & Time

12 SEP 2020 12:00

PC Close Date & Time

13 SEP 2020 11:59

US3512248

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(4)

Generated On: 10 Jun 2021 07:56:44

**TIMEPOINT**

DAY 4

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.6 °F

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

Yes ☐

No ☒

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

PC Time Stamp

13 SEP 2020 20:12

PC Open Date & Time

13 SEP 2020 12:00

PC Close Date & Time

14 SEP 2020 11:59

US3512248

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(5)

Generated On: 10 Jun 2021 07:56:44

**TIMEPOINT**

DAY 5

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

96.9 °F

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

Yes ☐

No ☒

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

PC Time Stamp

14 SEP 2020 22:13

PC Open Date & Time

14 SEP 2020 12:00

PC Close Date & Time

15 SEP 2020 11:59

US3512248

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(6)

Generated On: 10 Jun 2021 07:56:44

**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

97.9 °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

15 SEP 2020 21:27

PC Open Date & Time

15 SEP 2020 12:00

PC Close Date & Time

16 SEP 2020 11:59

US3512248

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(7)

Generated On: 10 Jun 2021 07:56:44

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**TIMEPOINT**

DAY 7

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

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

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

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

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

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

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

---

Was **TEMPERATURE** taken?

Yes ☒

No ☐

---

Please record your **TEMPERATURE** in °F

99.1 °F

---

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

Yes ☐

No ☒

---

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

---

PC Time Stamp

16 SEP 2020 20:32

---

PC Open Date & Time

16 SEP 2020 12:00

---

PC Close Date & Time

17 SEP 2020 11:59

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US3512248

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 10 Jun 2021 07:56:44

**TIMEPOINT**

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

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

Please select one response below

None ☒

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

Please select one response below

None ☒

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

PC Time Stamp

10 SEP 2020 13:30

PC Open Date & Time

10 SEP 2020 13:11

PC Close Date & Time

10 SEP 2020 15:41



US3512248

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 10 Jun 2021 07:56:44

**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

10 SEP 2020 18:45

PC Open Date & Time

10 SEP 2020 16:36

PC Close Date & Time

11 SEP 2020 11:59

US3512248

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 10 Jun 2021 07:56:44

**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

11 SEP 2020 17:01

PC Open Date & Time

11 SEP 2020 12:00

PC Close Date & Time

12 SEP 2020 11:59

US3512248

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 10 Jun 2021 07:56:44

**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

12 SEP 2020 21:02

PC Open Date & Time

12 SEP 2020 12:00

PC Close Date & Time

13 SEP 2020 11:59

US3512248

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 10 Jun 2021 07:56:44

**TIMEPOINT**

DAY 4

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

None ☐

Please select one response below

Does not interfere with activity ☒

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

Any use of prescription pain  
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

PC Time Stamp

13 SEP 2020 20:13

PC Open Date & Time

13 SEP 2020 12:00

PC Close Date & Time

14 SEP 2020 11:59

US3512248

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 10 Jun 2021 07:56:44

**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

14 SEP 2020 22:14

PC Open Date & Time

14 SEP 2020 12:00

PC Close Date & Time

15 SEP 2020 11:59

US3512248

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(6)

Generated On: 10 Jun 2021 07:56:44

**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

15 SEP 2020 21:27

PC Open Date & Time

15 SEP 2020 12:00

PC Close Date & Time

16 SEP 2020 11:59

US3512248

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 10 Jun 2021 07:56:44

**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

16 SEP 2020 20:33

PC Open Date & Time

16 SEP 2020 12:00

PC Close Date & Time

17 SEP 2020 11:59

US3512248

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 10 Jun 2021 07:56:44

**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 ☐



US3512248

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 10 Jun 2021 07:56:44

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

No ☒

Yes ☐

PC Time stamp	10 SEP 2020 13:31
PC Open Date & Time	10 SEP 2020 13:11
PC Close Date & Time	10 SEP 2020 15:41

US3512248

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 10 Jun 2021 07:56:44

**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 ☐

US3512248

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 10 Jun 2021 07:56:44

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

No ☒

Yes ☐

PC Time stamp	10 SEP 2020 18:46
PC Open Date & Time	10 SEP 2020 16:36
PC Close Date & Time	11 SEP 2020 11:59

US3512248

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 10 Jun 2021 07:56:44

**TIMEPOINT**

DAY 2

**HEADACHE**

None ☒

No interference with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

**FATIGUE**

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

**MUSCLE ACHES ALL OVER BODY**

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

**JOINT ACHES IN SEVERAL JOINTS**

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

**NAUSEA/VOMITING**

None ☒

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

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

Prevents daily activity, requires  
outpatient IV hydration ☐

**CHILLS**

None ☒

No interference with activity ☐

Some interference with activity  
not requiring medical attention ☐

Prevents daily activity and  
requires medical attention ☐

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

No ☒

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EAB) (1725)

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US3512248

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 10 Jun 2021 07:56:44

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

US3512248

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 10 Jun 2021 07:56:44

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 ☒

PRODUCTION RELEASE (v12.003  
EAB) (1725)

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US3512248

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 10 Jun 2021 07:56:44

Yes <input type="checkbox"/>	
PC Time stamp	12 SEP 2020 21:03
PC Open Date & Time	12 SEP 2020 12:00
PC Close Date & Time	13 SEP 2020 11:59

US3512248

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 10 Jun 2021 07:56:44

**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 ☒



US3512248

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 10 Jun 2021 07:56:44

Yes <input type="checkbox"/>	
PC Time stamp	13 SEP 2020 20:14
PC Open Date & Time	13 SEP 2020 12:00
PC Close Date & Time	14 SEP 2020 11:59

US3512248

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 10 Jun 2021 07:56:44

TIMEPOINT

DAY 5

HEADACHE

None ☐

No interference with activity ☒

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

Any use of prescription pain  
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☐

No interference with activity ☒

Some interference with activity ☐

Significant; prevents daily  
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires  
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity  
not requiring medical attention ☐

Prevents daily activity and  
requires medical attention ☐

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

No ☒

PRODUCTION RELEASE (v12.003

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EAB) (1725)

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Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 10 Jun 2021 07:56:44

Yes <input type="checkbox"/>	
PC Time stamp	14 SEP 2020 22:15
PC Open Date & Time	14 SEP 2020 12:00
PC Close Date & Time	15 SEP 2020 11:59

US3512248

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 10 Jun 2021 07:56:44

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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EAB) (1725)

US3512248

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 10 Jun 2021 07:56:44

Yes <input type="checkbox"/>	
PC Time stamp	15 SEP 2020 21:29
PC Open Date & Time	15 SEP 2020 12:00
PC Close Date & Time	16 SEP 2020 11:59

US3512248

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 10 Jun 2021 07:56:44

TIMEPOINT

DAY 7

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☐

No interference with activity ☒

Some interference with activity ☐

Significant; prevents daily  
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires  
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity  
not requiring medical attention ☐

Prevents daily activity and  
requires medical attention ☐

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

No ☒

PRODUCTION RELEASE (v12.003

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EAB) (1725)

US3512248

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 10 Jun 2021 07:56:44

Yes <input type="checkbox"/>	
PC Time stamp	16 SEP 2020 20:33
PC Open Date & Time	16 SEP 2020 12:00
PC Close Date & Time	17 SEP 2020 11:59

US3512248

Folder: Diary Dose 1 (1)

Form: JointsAche\_Day(8)

Generated On: 10 Jun 2021 07:56:44

**TIMEPOINT**

DAY 8

Select one response below to indicate the intensity of your **JOINT**  
**ACHES IN SEVERAL JOINTS**

None ☐

No interference with activity ☒

Some interference with activity ☐

Significant; prevents daily  
activity ☐

PC Time stamp 17 SEP 2020 20:53

PC Open Date & Time 17 SEP 2020 12:00

PC Close Date & Time 18 SEP 2020 11:59



US3512248

Folder: Diary Dose 1 (1)

Form: JointsAche\_Day(9)

Generated On: 10 Jun 2021 07:56:44

**TIMEPOINT**

DAY 9

Select one response below to indicate the intensity of your **JOINT**  
**ACHES IN SEVERAL JOINTS**

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

PC Time stamp 18 SEP 2020 21:43

PC Open Date & Time 18 SEP 2020 12:00

PC Close Date & Time 19 SEP 2020 11:59

US3512248

Folder: Diary Dose 1 (1)

Form: Medical Attention\_Day(8)

Generated On: 10 Jun 2021 07:56:44

<b>TIMEPOINT</b>	DAY 8
Did you receive any <b>MEDICAL ATTENTION</b> (doctor visit, <b>other</b> ) for any illness or symptoms?	No <input checked="" type="radio"/> Yes <input type="radio"/>
PC Time stamp	17 SEP 2020 20:53
PC Open Date & Time	17 SEP 2020 12:00
PC Close Date & Time	18 SEP 2020 11:59

US3512248

Folder: Diary Dose 1 (1)

Form: Medical Attention\_Day(9)

Generated On: 10 Jun 2021 07:56:44

<b>TIMEPOINT</b>	DAY 9
Did you receive any <b>MEDICAL ATTENTION</b> (doctor visit, <b>other</b> ) for any illness or symptoms?	No <input checked="" type="radio"/> Yes <input type="radio"/>
PC Time stamp	18 SEP 2020 21:43
PC Open Date & Time	18 SEP 2020 12:00
PC Close Date & Time	19 SEP 2020 11:59

US3512248

Folder: Safety Call Day 8 (1)

Form: Safety Call

Data signed: (b) (4) 12 Feb 2021 22:11:59

Generated On: 10 Jun 2021 07:56:44

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

17 SEP 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

*If Contact Not Made, please provide Comments*

US3512248

Folder: Safety Call Day 8 (1)

Form: Continuing

Data signed: (b) (4) 12 Feb 2021 22:11:59

Generated On: 10 Jun 2021 07:56:44

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3512248

Folder: Safety Call Day 15 (1)

Form: Safety Call

Data signed: (b) (4) 12 Feb 2021 22:11:59

Generated On: 10 Jun 2021 07:56:44

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

24 SEP 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

*If Contact Not Made, please provide Comments*

US3512248

Folder: Safety Call Day 15 (1)

Form: Continuing

Data signed: (b) (4) 12 Feb 2021 22:11:59

Generated On: 10 Jun 2021 07:56:44

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3512248

Folder: Safety Call Day 22 (1)

Form: Safety Call

Data signed: (b) (4) 12 Feb 2021 22:11:59

Generated On: 10 Jun 2021 07:56:44

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

01 OCT 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

*If Contact Not Made, please provide Comments*



US3512248

Folder: Safety Call Day 22 (1)

Form: Continuing

Data signed: (b) (4) 12 Feb 2021 22:11:59

Generated On: 10 Jun 2021 07:56:44

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3512248

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Data signed: (b) (4) 12 Feb 2021 22:12:01

Generated On: 10 Jun 2021 07:56:44

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

US3512248

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 12 Feb 2021 22:12:01

Generated On: 10 Jun 2021 07:56:44

Timepoint	Pre-Dose <input checked="" type="radio"/>
	Post-Dose <input type="radio"/>
Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (dd MMM yyyy)	8 OCT 2020
Time of assessment (00:00-23:59)	11:09 (24 HR)
Vital Signs Date and Time (derived)	8 OCT 2020 11:09
Temperature (xxx.x)	97.3 F
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	64 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	20 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	148 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	77 mmHg
Diastolic Blood Pressure units	MMHG

US3512248

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 12 Feb 2021 22:12:01

Generated On: 10 Jun 2021 07:56:44

Timepoint	Pre-Dose <input type="checkbox"/>
	Post-Dose <input checked="" type="checkbox"/>
Were vital signs assessed?	Yes <input checked="" type="checkbox"/>
	No <input type="checkbox"/>
Date of assessment (dd MMM yyyy)	8 OCT 2020
Time of assessment (00:00-23:59)	12:20 (24 HR)
Vital Signs Date and Time (derived)	8 OCT 2020 12:20
Temperature (xxx.x)	97.8 F
Route of measurement	Oral <input checked="" type="checkbox"/>
	Axillary <input type="checkbox"/>
	Other <input type="checkbox"/>
If Other, specify	
Pulse (xxx)	65 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	127 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	70 mmHg
Diastolic Blood Pressure units	MMHG

US3512248

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Data signed: (b) (4) 12 Feb 2021 22:12:01

Generated On: 10 Jun 2021 07:56:44

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

08 OCT 2020

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

US3512248

Folder: Visit 2 Day 29 (1)

Form: Exposure

Data signed: (b) (4) 12 Feb 2021 22:12:01

Generated On: 10 Jun 2021 07:56:44

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) 8 OCT 2020

What was the treatment time? (00:00-23:59) 11:49 (24 HR)

Treatment Date and Time (derived) 8 OCT 2020 11:49

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

US3512248

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 12 Feb 2021 22:12:01

Generated On: 10 Jun 2021 07:56:44

Was the sample collected?

Yes ☒

No ☐

Collection date (dd MMM yyyy)

8 OCT 2020

Collection time (00:00-23:59)

11:25 (24 HR)

Collection date and time (derived)

8 OCT 2020 11:25

US3512248

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab

Data signed: (b) (4) 12 Feb 2021 22:12:01

Generated On: 10 Jun 2021 07:56:44

Collection date (dd MMM yyyy)			8 OCT 2020
Lab Test	Was the sample collected?	Collection time (00:00 - 23:59)	Collection date and time (derived)
Nasopharyngeal Swab 1	Yes	11:20	8 OCT 2020 11:20
Nasopharyngeal Swab 2	No		



US3512248

Folder: Visit 2 Day 29 (1)

Form: Continuing

Data signed: (b) (4) 12 Feb 2021 22:12:01

Generated On: 10 Jun 2021 07:56:44

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3512248

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/1)

Generated On: 10 Jun 2021 07:56:44

**TIMEPOINT**

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

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.8 °F

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

Yes ☐

No ☒

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

PC Time Stamp

08 OCT 2020 12:25

PC Open Date & Time

08 OCT 2020 12:09

PC Close Date & Time

08 OCT 2020 14:39

US3512248

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/2)

Generated On: 10 Jun 2021 07:56:44

**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	08 OCT 2020 15:38
PC Open Date & Time	08 OCT 2020 15:34
PC Close Date & Time	09 OCT 2020 11:59

US3512248

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(2)

Generated On: 10 Jun 2021 07:56:44

**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

97.0 °F

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

Yes ☐

No ☒

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

PC Time Stamp

09 OCT 2020 22:00

PC Open Date & Time

09 OCT 2020 12:00

PC Close Date & Time

10 OCT 2020 11:59

US3512248

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(3)

Generated On: 10 Jun 2021 07:56:44

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**TIMEPOINT**

DAY 3

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

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

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

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

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

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

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

---

Was **TEMPERATURE** taken?

Yes ☒

No ☐

---

Please record your **TEMPERATURE** in °F

97.9 °F

---

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

Yes ☐

No ☒

---

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

---

PC Time Stamp

10 OCT 2020 20:48

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PC Open Date & Time

10 OCT 2020 12:00

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PC Close Date & Time

11 OCT 2020 11:59

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US3512248

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(4)

Generated On: 10 Jun 2021 07:56:44

**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

97.9 °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

11 OCT 2020 15:36

PC Open Date & Time

11 OCT 2020 12:00

PC Close Date & Time

12 OCT 2020 11:59

US3512248

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(5)

Generated On: 10 Jun 2021 07:56:44

**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

12 OCT 2020 13:53

PC Open Date & Time

12 OCT 2020 12:00

PC Close Date & Time

13 OCT 2020 11:59

US3512248

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(6)

Generated On: 10 Jun 2021 07:56:44

**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

97.6 °F

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

Yes ☐

No ☒

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

PC Time Stamp

13 OCT 2020 14:52

PC Open Date & Time

13 OCT 2020 12:00

PC Close Date & Time

14 OCT 2020 11:59



US3512248

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(7)

Generated On: 10 Jun 2021 07:56:44

**TIMEPOINT**

DAY 7

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.1 °F

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

Yes ☐

No ☒

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

PC Time Stamp

14 OCT 2020 15:53

PC Open Date & Time

14 OCT 2020 12:00

PC Close Date & Time

15 OCT 2020 11:59

US3512248

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/1)

Generated On: 10 Jun 2021 07:56:44

**TIMEPOINT**

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

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

Please select one response below

None ☒

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

Please select one response below

None ☒

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

PC Time Stamp

08 OCT 2020 12:25

PC Open Date & Time

08 OCT 2020 12:09

PC Close Date & Time

08 OCT 2020 14:39

US3512248

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/2)

Generated On: 10 Jun 2021 07:56:44

**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

08 OCT 2020 15:37

PC Open Date & Time

08 OCT 2020 15:34

PC Close Date & Time

09 OCT 2020 11:59

US3512248

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(2)

Generated On: 10 Jun 2021 07:56:44

**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

09 OCT 2020 22:01

PC Open Date & Time

09 OCT 2020 12:00

PC Close Date & Time

10 OCT 2020 11:59

US3512248

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(3)

Generated On: 10 Jun 2021 07:56:44

**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

10 OCT 2020 20:48

PC Open Date & Time

10 OCT 2020 12:00

PC Close Date & Time

11 OCT 2020 11:59

US3512248

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(4)

Generated On: 10 Jun 2021 07:56:44

**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

11 OCT 2020 15:36

PC Open Date & Time

11 OCT 2020 12:00

PC Close Date & Time

12 OCT 2020 11:59

US3512248

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(5)

Generated On: 10 Jun 2021 07:56:44

**TIMEPOINT**

DAY 5

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

PC Time Stamp

12 OCT 2020 13:53

PC Open Date & Time

12 OCT 2020 12:00

PC Close Date & Time

13 OCT 2020 11:59

US3512248

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(6)

Generated On: 10 Jun 2021 07:56:44

**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

13 OCT 2020 14:53

PC Open Date & Time

13 OCT 2020 12:00

PC Close Date & Time

14 OCT 2020 11:59



US3512248

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(7)

Generated On: 10 Jun 2021 07:56:44

**TIMEPOINT**

DAY 7

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

PC Time Stamp

14 OCT 2020 15:54

PC Open Date & Time

14 OCT 2020 12:00

PC Close Date & Time

15 OCT 2020 11:59

US3512248

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 10 Jun 2021 07:56:44

**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 ☐

US3512248

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 10 Jun 2021 07:56:44

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

No ☒

Yes ☐

PC Time stamp	08 OCT 2020 12:26
PC Open Date & Time	08 OCT 2020 12:09
PC Close Date & Time	08 OCT 2020 14:39

US3512248

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 10 Jun 2021 07:56:44

**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 ☐

US3512248

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 10 Jun 2021 07:56:44

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

No ☒

Yes ☐

PC Time stamp	08 OCT 2020 15:39
PC Open Date & Time	08 OCT 2020 15:34
PC Close Date & Time	09 OCT 2020 11:59

US3512248

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 10 Jun 2021 07:56:44

TIMEPOINT

DAY 2

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires  
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity  
not requiring medical attention ☐

Prevents daily activity and  
requires medical attention ☐

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

No ☒

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EAB) (1725)

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US3512248

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 10 Jun 2021 07:56:44

Yes <input type="checkbox"/>	
PC Time stamp	09 OCT 2020 22:01
PC Open Date & Time	09 OCT 2020 12:00
PC Close Date & Time	10 OCT 2020 11:59

US3512248

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 10 Jun 2021 07:56:44

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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Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 10 Jun 2021 07:56:44

Yes <input type="checkbox"/>	
PC Time stamp	10 OCT 2020 20:49
PC Open Date & Time	10 OCT 2020 12:00
PC Close Date & Time	11 OCT 2020 11:59

US3512248

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 10 Jun 2021 07:56:44

**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 ☒

US3512248

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 10 Jun 2021 07:56:44

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

US3512248

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 10 Jun 2021 07:56:44

TIMEPOINT

DAY 5

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires  
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity  
not requiring medical attention ☐

Prevents daily activity and  
requires medical attention ☐

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

No ☒

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EAB) (1725)

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Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 10 Jun 2021 07:56:44

Yes <input type="checkbox"/>	
PC Time stamp	12 OCT 2020 13:54
PC Open Date & Time	12 OCT 2020 12:00
PC Close Date & Time	13 OCT 2020 11:59

US3512248

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 10 Jun 2021 07:56:44

TIMEPOINT

DAY 6

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires  
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity  
not requiring medical attention ☐

Prevents daily activity and  
requires medical attention ☐

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

No ☒

PRODUCTION RELEASE (v12.003

EAB) (1725)

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US3512248

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 10 Jun 2021 07:56:44

Yes <input type="checkbox"/>	
PC Time stamp	13 OCT 2020 14:53
PC Open Date & Time	13 OCT 2020 12:00
PC Close Date & Time	14 OCT 2020 11:59

US3512248

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 10 Jun 2021 07:56:44

**TIMEPOINT**

DAY 7

**HEADACHE**

None ☒

No interference with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

**FATIGUE**

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

**MUSCLE ACHES ALL OVER BODY**

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

**JOINT ACHES IN SEVERAL JOINTS**

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

**NAUSEA/VOMITING**

None ☒

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

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

Prevents daily activity, requires  
outpatient IV hydration ☐

**CHILLS**

None ☒

No interference with activity ☐

Some interference with activity  
not requiring medical attention ☐

Prevents daily activity and  
requires medical attention ☐

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

No ☒

PRODUCTION RELEASE (v12.003

EAB) (1725)

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Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 10 Jun 2021 07:56:44

Yes <input type="checkbox"/>	
PC Time stamp	14 OCT 2020 15:55
PC Open Date & Time	14 OCT 2020 12:00
PC Close Date & Time	15 OCT 2020 11:59

US3512248

Folder: Safety Call Day 36 (1)

Form: Safety Call

Data signed: (b) (4) 12 Feb 2021 22:11:59

Generated On: 10 Jun 2021 07:56:44

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

15 OCT 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

*If Contact Not Made, please provide Comments*

US3512248

Folder: Safety Call Day 36 (1)

Form: Continuing

Data signed: (b) (4) 12 Feb 2021 22:11:59

Generated On: 10 Jun 2021 07:56:44

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3512248

Folder: Safety Call Day 43 (1)

Form: Safety Call

Data signed: (b) (4) 12 Feb 2021 22:11:59

Generated On: 10 Jun 2021 07:56:44

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

22 OCT 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

*If Contact Not Made, please provide Comments*

US3512248

Folder: Safety Call Day 43 (1)

Form: Continuing

Data signed: (b) (4) 12 Feb 2021 22:11:59

Generated On: 10 Jun 2021 07:56:44

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3512248

Folder: Safety Call Day 50 (1)

Form: Safety Call

Data signed: (b) (4) 12 Feb 2021 22:11:59

Generated On: 10 Jun 2021 07:56:44

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

29 OCT 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

*If Contact Not Made, please provide Comments*

US3512248

Folder: Safety Call Day 50 (1)

Form: Continuing

Data signed: (b) (4) 12 Feb 2021 22:11:59

Generated On: 10 Jun 2021 07:56:44

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3512248

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Data signed: (b) (4) 12 Feb 2021 22:12:01

Generated On: 10 Jun 2021 07:56:44

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	5 NOV 2020
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	VISIT3



US3512248

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Data signed: (b) (4) 12 Feb 2021 22:12:01

Generated On: 10 Jun 2021 07:56:44

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (dd MMM yyyy)	5 NOV 2020
Time of assessment (00:00-23:59)	11:10 (24 HR)
Vital Signs Date and Time (derived)	5 NOV 2020 11:10
Temperature (xxx.x)	97.3 F
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	66 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	18 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	145 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	88 mmHg
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

US3512248

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Data signed: (b) (4) 12 Feb 2021 22:12:01

Generated On: 10 Jun 2021 07:56:44

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.*

US3512248

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 12 Feb 2021 22:12:01

Generated On: 10 Jun 2021 07:56:44

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (dd MMM yyyy)	5 NOV 2020
Collection time (00:00-23:59)	11:16 (24 HR)
Collection date and time (derived)	5 NOV 2020 11:16

US3512248

Folder: Visit 3 Day 57 (1)

Form: Continuing

Data signed: (b) (4) 12 Feb 2021 22:12:01

Generated On: 10 Jun 2021 07:56:44

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3512248

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:56:44

**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

13 NOV 2020 16:01:32

Patient Cloud Open Date & Time

10 NOV 2020 00:01

Patient Cloud Close Date & Time

14 NOV 2020 23:59

US3512248

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:56:44

TIMEPOINT	DAY 71
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$ )	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you 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"/>

**US3512248**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:56:44**

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

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

Date and time of submission

Patient Cloud Open Date & Time

17 NOV 2020 00:01

Patient Cloud Close Date & Time

21 NOV 2020 23:59

US3512248

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:56:44

TIMEPOINT	DAY 75
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input 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	24 NOV 2020 07:11:37
Patient Cloud Open Date & Time	21 NOV 2020 00:01
Patient Cloud Close Date & Time	25 NOV 2020 23:59



US3512248

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:56:44

TIMEPOINT	DAY 82
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input 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	30 NOV 2020 23:08:40
Patient Cloud Open Date & Time	28 NOV 2020 00:01
Patient Cloud Close Date & Time	02 DEC 2020 23:59

US3512248

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:56:44

**TIMEPOINT**

DAY 89

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

05 DEC 2020 07:08:22

Patient Cloud Open Date & Time

05 DEC 2020 00:01

Patient Cloud Close Date & Time

09 DEC 2020 23:59

US3512248

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:56:44

**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 ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

12 DEC 2020 08:48:18

Patient Cloud Open Date & Time

12 DEC 2020 00:01

Patient Cloud Close Date & Time

16 DEC 2020 23:59

US3512248

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:56:44

**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

19 DEC 2020 07:40:30

Patient Cloud Open Date & Time

19 DEC 2020 00:01

Patient Cloud Close Date & Time

23 DEC 2020 23:59

US3512248

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:56:44

**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

28 DEC 2020 19:16:39

Patient Cloud Open Date & Time

26 DEC 2020 00:01

Patient Cloud Close Date & Time

30 DEC 2020 23:59

US3512248

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:56:44

**TIMEPOINT**

DAY 117

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

02 JAN 2021 19:21:04

Patient Cloud Open Date & Time

02 JAN 2021 00:01

Patient Cloud Close Date & Time

06 JAN 2021 23:59

US3512248

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:56:44

**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

09 JAN 2021 09:49:33

Patient Cloud Open Date & Time

09 JAN 2021 00:01

Patient Cloud Close Date & Time

13 JAN 2021 23:59

US3512248

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:56:44

**TIMEPOINT**

DAY 131

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

16 JAN 2021 20:16:44

Patient Cloud Open Date & Time

16 JAN 2021 00:01

Patient Cloud Close Date & Time

20 JAN 2021 23:59



US3512248

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:56:44

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

Date and time of submission

23 JAN 2021 00:01:54

Patient Cloud Open Date & Time

23 JAN 2021 00:01

Patient Cloud Close Date & Time

27 JAN 2021 23:59

US3512248

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:56:44

**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

30 JAN 2021 08:18:48

Patient Cloud Open Date & Time

30 JAN 2021 00:01

Patient Cloud Close Date & Time

03 FEB 2021 23:59

US3512248

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:56:44

**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

06 FEB 2021 12:54:41

Patient Cloud Open Date & Time

06 FEB 2021 00:01

Patient Cloud Close Date & Time

10 FEB 2021 23:59

US3512248

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:56:44

**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

15 FEB 2021 12:18:59

Patient Cloud Open Date & Time

13 FEB 2021 00:01

Patient Cloud Close Date & Time

17 FEB 2021 23:59

US3512248

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:56:44

TIMEPOINT	DAY 166
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="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 checked="" type="radio"/> Yes <input type="radio"/>
Date and time of submission	20 FEB 2021 00:26:08
Patient Cloud Open Date & Time	20 FEB 2021 00:01
Patient Cloud Close Date & Time	24 FEB 2021 23:59

US3512248

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:56:44

**TIMEPOINT**

DAY 173

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

02 MAR 2021 18:00:15

Patient Cloud Open Date & Time

27 FEB 2021 00:01

Patient Cloud Close Date & Time

03 MAR 2021 23:59

US3512248

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:56:44

**TIMEPOINT**

DAY 180

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

08 MAR 2021 12:20:31

Patient Cloud Open Date & Time

06 MAR 2021 00:01

Patient Cloud Close Date & Time

10 MAR 2021 23:59

US3512248

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:56:44

**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

15 MAR 2021 16:38:44

Patient Cloud Open Date & Time

13 MAR 2021 00:01

Patient Cloud Close Date & Time

17 MAR 2021 23:59



US3512248

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:56:44

**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

22 MAR 2021 12:14:00

Patient Cloud Open Date & Time

20 MAR 2021 00:01

Patient Cloud Close Date & Time

24 MAR 2021 23:59

US3512248

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:56:44

**TIMEPOINT**

DAY 201

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

29 MAR 2021 15:49:29

Patient Cloud Open Date & Time

27 MAR 2021 00:01

Patient Cloud Close Date & Time

31 MAR 2021 23:59

US3512248

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:56:44

**TIMEPOINT**

DAY 208

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

07 APR 2021 15:21:03

Patient Cloud Open Date & Time

03 APR 2021 00:01

Patient Cloud Close Date & Time

07 APR 2021 23:59

US3512248

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:56:44

**TIMEPOINT**

DAY 215

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

10 APR 2021 11:16:13

Patient Cloud Open Date & Time

10 APR 2021 00:01

Patient Cloud Close Date & Time

14 APR 2021 23:59

US3512248

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:56:44

TIMEPOINT	DAY 222
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="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 type="radio"/> Yes <input checked="" type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$ )	False
Chills	False
Cough	True
Shortness of breath	False
Difficulty breathing	False
Fatigue	False
Muscle aches	False
Body aches	False
Headache	False
New loss of taste	False
New loss of smell	False
Sore throat	False
Congestion	False
Runny nose	True
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 checked="" type="radio"/> Yes <input type="radio"/>
Date and time of submission	17 APR 2021 10:39:12
Patient Cloud Open Date & Time	17 APR 2021 00:01
Patient Cloud Close Date & Time	21 APR 2021 23:59

US3512248

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:56:44

**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

27 APR 2021 21:50:32

Patient Cloud Open Date & Time

24 APR 2021 00:01

Patient Cloud Close Date & Time

28 APR 2021 23:59

US3512248

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:56:44

**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

01 MAY 2021 08:25:41

Patient Cloud Open Date & Time

01 MAY 2021 00:01

Patient Cloud Close Date & Time

05 MAY 2021 23:59

US3512248

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:56:44

TIMEPOINT	DAY 243
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$ )	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>



**US3512248**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:56:44**

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

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[Patient Cloud Open Date & Time](#)

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08 MAY 2021 00:01

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[Patient Cloud Close Date & Time](#)

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12 MAY 2021 23:59

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US3512248

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:56:44

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

**US3512248**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:56:44**

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

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[Patient Cloud Open Date & Time](#)

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15 MAY 2021 00:01

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[Patient Cloud Close Date & Time](#)

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19 MAY 2021 23:59

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US3512248

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:56:44

**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 ☐

**US3512248**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:56:44**

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

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[Patient Cloud Open Date & Time](#)

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22 MAY 2021 00:01

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[Patient Cloud Close Date & Time](#)

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26 MAY 2021 23:59

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US3512248

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:56:44

TIMEPOINT	DAY 264
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$ )	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>

**US3512248**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:56:44**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

29 MAY 2021 00:01

[Patient Cloud Close Date & Time](#)

02 JUN 2021 23:59

US3512248

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:56:44

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



**US3512248**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:56:44**

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

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[Patient Cloud Open Date & Time](#)

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05 JUN 2021 00:01

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[Patient Cloud Close Date & Time](#)

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09 JUN 2021 23:59

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US3512248

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:56:44

**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 ☐

**US3512248**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:56:44**

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

12 JUN 2021 00:01

[Patient Cloud Close Date & Time](#)

16 JUN 2021 23:59

US3512248

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:56:44

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"/>

**US3512248**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:56:44**

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

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[Patient Cloud Open Date & Time](#)

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19 JUN 2021 00:01

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[Patient Cloud Close Date & Time](#)

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23 JUN 2021 23:59

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US3512248

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:56:44

**TIMEPOINT**

DAY 292

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

**US3512248**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:56:44**

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

26 JUN 2021 00:01

[Patient Cloud Close Date & Time](#)

30 JUN 2021 23:59

US3512248

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:56:44

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"/>



**US3512248**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:56:44**

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

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[Patient Cloud Open Date & Time](#)

03 JUL 2021 00:01

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[Patient Cloud Close Date & Time](#)

07 JUL 2021 23:59

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US3512248

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:56:44

**TIMEPOINT**

DAY 306

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

**US3512248**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:56:44**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

10 JUL 2021 00:01

[Patient Cloud Close Date & Time](#)

14 JUL 2021 23:59

US3512248

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:56:44

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

**US3512248**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:56:44**

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

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[Patient Cloud Open Date & Time](#)

17 JUL 2021 00:01

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[Patient Cloud Close Date & Time](#)

21 JUL 2021 23:59

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US3512248

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:56:44

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"/>

**US3512248**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:56:44**

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

24 JUL 2021 00:01

[Patient Cloud Close Date & Time](#)

28 JUL 2021 23:59

US3512248

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:56:44

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



**US3512248**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:56:44**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

31 JUL 2021 00:01

[Patient Cloud Close Date & Time](#)

04 AUG 2021 23:59

US3512248

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:56:44

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

**US3512248**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:56:44**

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

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[Patient Cloud Open Date & Time](#)

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07 AUG 2021 00:01

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[Patient Cloud Close Date & Time](#)

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11 AUG 2021 23:59

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US3512248

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:56:44

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"/>

**US3512248**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:56:44**

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

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<a href="#">Patient Cloud Open Date &amp; Time</a>	14 AUG 2021 00:01
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<a href="#">Patient Cloud Close Date &amp; Time</a>	18 AUG 2021 23:59
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US3512248

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:56:44

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"/>

**US3512248**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:56:44**

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

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[Patient Cloud Open Date & Time](#)

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21 AUG 2021 00:01

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[Patient Cloud Close Date & Time](#)

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25 AUG 2021 23:59

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US3512248

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:56:44

TIMEPOINT	DAY 355
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$ )	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>



**US3512248**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:56:44**

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

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[Patient Cloud Open Date & Time](#)

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28 AUG 2021 00:01

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[Patient Cloud Close Date & Time](#)

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01 SEP 2021 23:59

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US3512248

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:56:44

TIMEPOINT	DAY 362
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$ )	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

**US3512248**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:56:44**

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

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[Patient Cloud Open Date & Time](#)

04 SEP 2021 00:01

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[Patient Cloud Close Date & Time](#)

08 SEP 2021 23:59

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US3512248

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:56:44

**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°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 ☐

**US3512248**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:56:44**

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

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[Patient Cloud Open Date & Time](#)

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11 SEP 2021 00:01

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[Patient Cloud Close Date & Time](#)

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15 SEP 2021 23:59

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US3512248

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:56:44

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

**US3512248**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:56:44**

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

US3512248

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:56:44

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



**US3512248**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:56:44**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

25 SEP 2021 00:01

[Patient Cloud Close Date & Time](#)

29 SEP 2021 23:59

US3512248

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:56:44

**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 ☐

**US3512248**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:56:44**

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

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<a href="#">Patient Cloud Open Date &amp; Time</a>	02 OCT 2021 00:01
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<a href="#">Patient Cloud Close Date &amp; Time</a>	06 OCT 2021 23:59
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US3512248

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:56:44

**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 ☐

**US3512248**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:56:44**

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

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[Patient Cloud Open Date & Time](#)

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09 OCT 2021 00:01

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[Patient Cloud Close Date & Time](#)

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13 OCT 2021 23:59

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US3512248

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:56:44

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"/>

**US3512248**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:56:44**

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

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[Patient Cloud Open Date & Time](#)

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16 OCT 2021 00:01

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[Patient Cloud Close Date & Time](#)

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20 OCT 2021 23:59

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US3512248

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:56:44

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"/>



**US3512248**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:56:44**

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

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<a href="#">Patient Cloud Open Date &amp; Time</a>	23 OCT 2021 00:01
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<a href="#">Patient Cloud Close Date &amp; Time</a>	27 OCT 2021 23:59
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US3512248

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:56:44

**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 ☐

**US3512248**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:56:44**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

30 OCT 2021 00:01

[Patient Cloud Close Date & Time](#)

03 NOV 2021 23:59

US3512248

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:56:44

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"/>

**US3512248**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:56:44**

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

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[Patient Cloud Open Date & Time](#)

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06 NOV 2021 00:01

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[Patient Cloud Close Date & Time](#)

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10 NOV 2021 23:59

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US3512248

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:56:44

TIMEPOINT	DAY 432
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$ )	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

**US3512248**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:56:44**

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

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[Patient Cloud Open Date & Time](#)

13 NOV 2021 00:01

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[Patient Cloud Close Date & Time](#)

17 NOV 2021 23:59

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US3512248

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:56:44

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



**US3512248**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:56:44**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

20 NOV 2021 00:01

[Patient Cloud Close Date & Time](#)

24 NOV 2021 23:59

US3512248

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:56:44

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"/>

**US3512248**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:56:44**

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

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[Patient Cloud Open Date & Time](#)

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27 NOV 2021 00:01

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[Patient Cloud Close Date & Time](#)

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01 DEC 2021 23:59

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US3512248

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:56:44

**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 ☐

**US3512248**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:56:44**

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

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[Patient Cloud Open Date & Time](#)

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04 DEC 2021 00:01

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[Patient Cloud Close Date & Time](#)

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08 DEC 2021 23:59

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US3512248

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:56:44

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"/>

**US3512248**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:56:44**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
<a href="#">Patient Cloud Open Date &amp; Time</a>	11 DEC 2021 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	15 DEC 2021 23:59

US3512248

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:56:44

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



**US3512248**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:56:44**

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

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[Patient Cloud Open Date & Time](#)

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18 DEC 2021 00:01

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[Patient Cloud Close Date & Time](#)

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22 DEC 2021 23:59

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US3512248

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:56:44

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

**US3512248**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:56:44**

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

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<a href="#">Patient Cloud Open Date &amp; Time</a>	25 DEC 2021 00:01
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<a href="#">Patient Cloud Close Date &amp; Time</a>	29 DEC 2021 23:59
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US3512248

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:56:44

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

**US3512248**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:56:44**

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

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[Patient Cloud Open Date & Time](#)

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01 JAN 2022 00:01

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[Patient Cloud Close Date & Time](#)

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05 JAN 2022 23:59

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US3512248

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:56:44

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"/>

**US3512248**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:56:44**

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

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[Patient Cloud Open Date & Time](#)

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08 JAN 2022 00:01

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[Patient Cloud Close Date & Time](#)

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12 JAN 2022 23:59

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US3512248

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:56:44

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"/>



**US3512248**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:56:44**

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

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[Patient Cloud Open Date & Time](#)

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15 JAN 2022 00:01

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[Patient Cloud Close Date & Time](#)

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19 JAN 2022 23:59

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US3512248

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:56:44

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

**US3512248**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:56:44**

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

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[Patient Cloud Open Date & Time](#)

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22 JAN 2022 00:01

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[Patient Cloud Close Date & Time](#)

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26 JAN 2022 23:59

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US3512248

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:56:44

**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 ☐

**US3512248**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:56:44**

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

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[Patient Cloud Open Date & Time](#)

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29 JAN 2022 00:01

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[Patient Cloud Close Date & Time](#)

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02 FEB 2022 23:59

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US3512248

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:56:44

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

**US3512248**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:56:44**

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

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[Patient Cloud Open Date & Time](#)

05 FEB 2022 00:01

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[Patient Cloud Close Date & Time](#)

09 FEB 2022 23:59

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US3512248

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:56:44

**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 ☐



**US3512248**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:56:44**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
<a href="#">Patient Cloud Open Date &amp; Time</a>	12 FEB 2022 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	16 FEB 2022 23:59

US3512248

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:56:44

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

**US3512248**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:56:44**

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

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[Patient Cloud Open Date & Time](#)

19 FEB 2022 00:01

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[Patient Cloud Close Date & Time](#)

23 FEB 2022 23:59

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US3512248

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:56:44

**TIMEPOINT**

DAY 537

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

**US3512248**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:56:44**

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

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[Patient Cloud Open Date & Time](#)

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26 FEB 2022 00:01

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[Patient Cloud Close Date & Time](#)

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02 MAR 2022 23:59

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US3512248

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:56:44

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

**US3512248**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:56:44**

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

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[Patient Cloud Open Date & Time](#)

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05 MAR 2022 00:01

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[Patient Cloud Close Date & Time](#)

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09 MAR 2022 23:59

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US3512248

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:56:44

**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 ☐



**US3512248**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:56:44**

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

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[Patient Cloud Open Date & Time](#)

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12 MAR 2022 00:01

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[Patient Cloud Close Date & Time](#)

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16 MAR 2022 23:59

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US3512248

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:56:44

**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 ☐

**US3512248**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:56:44**

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

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[Patient Cloud Open Date & Time](#)

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19 MAR 2022 00:01

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[Patient Cloud Close Date & Time](#)

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23 MAR 2022 23:59

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US3512248

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:56:44

**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 ☐

**US3512248**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:56:44**

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

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[Patient Cloud Open Date & Time](#)

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26 MAR 2022 00:01

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[Patient Cloud Close Date & Time](#)

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30 MAR 2022 23:59

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US3512248

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:56:44

**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 ☐

**US3512248**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:56:44**

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

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[Patient Cloud Open Date & Time](#)

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02 APR 2022 00:01

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[Patient Cloud Close Date & Time](#)

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06 APR 2022 23:59

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US3512248

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:56:44

**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 ☐



**US3512248**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:56:44**

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

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[Patient Cloud Open Date & Time](#)

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09 APR 2022 00:01

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[Patient Cloud Close Date & Time](#)

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13 APR 2022 23:59

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US3512248

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:56:44

**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 ☐

**US3512248**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:56:44**

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

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[Patient Cloud Open Date & Time](#)

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16 APR 2022 00:01

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[Patient Cloud Close Date & Time](#)

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20 APR 2022 23:59

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US3512248

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:56:44

**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 ☐

**US3512248**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:56:44**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

23 APR 2022 00:01

[Patient Cloud Close Date & Time](#)

27 APR 2022 23:59

US3512248

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:56:44

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

**US3512248**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:56:44**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

30 APR 2022 00:01

[Patient Cloud Close Date & Time](#)

04 MAY 2022 23:59

US3512248

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:56:44

**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 ☐



**US3512248**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:56:44**

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

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[Patient Cloud Open Date & Time](#)

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07 MAY 2022 00:01

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[Patient Cloud Close Date & Time](#)

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11 MAY 2022 23:59

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US3512248

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:56:44

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"/>

**US3512248**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:56:44**

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

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[Patient Cloud Open Date & Time](#)

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14 MAY 2022 00:01

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[Patient Cloud Close Date & Time](#)

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18 MAY 2022 23:59

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US3512248

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:56:44

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

**US3512248**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:56:44**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

21 MAY 2022 00:01

[Patient Cloud Close Date & Time](#)

25 MAY 2022 23:59

US3512248

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:56:44

**TIMEPOINT**

DAY 628

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

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

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

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

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

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

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 ☐

**US3512248**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:56:44**

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

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[Patient Cloud Open Date & Time](#)

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28 MAY 2022 00:01

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[Patient Cloud Close Date & Time](#)

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01 JUN 2022 23:59

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US3512248

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:56:44

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



**US3512248**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:56:44**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

04 JUN 2022 00:01

[Patient Cloud Close Date & Time](#)

08 JUN 2022 23:59

US3512248

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:56:44

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"/>

**US3512248**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:56:44**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
<a href="#">Patient Cloud Open Date &amp; Time</a>	11 JUN 2022 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	15 JUN 2022 23:59

US3512248

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:56:44

**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°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 ☐

**US3512248**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:56:44**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
<a href="#">Patient Cloud Open Date &amp; Time</a>	18 JUN 2022 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	22 JUN 2022 23:59

US3512248

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:56:44

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

**US3512248**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:56:44**

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

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[Patient Cloud Open Date & Time](#)

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25 JUN 2022 00:01

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[Patient Cloud Close Date & Time](#)

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29 JUN 2022 23:59

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US3512248

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:56:44

**TIMEPOINT**

DAY 663

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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



**US3512248**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:56:44**

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

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[Patient Cloud Open Date & Time](#)

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02 JUL 2022 00:01

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[Patient Cloud Close Date & Time](#)

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06 JUL 2022 23:59

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US3512248

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:56:44

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"/>

**US3512248**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:56:44**

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

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[Patient Cloud Open Date & Time](#)

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09 JUL 2022 00:01

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[Patient Cloud Close Date & Time](#)

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13 JUL 2022 23:59

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US3512248

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:56:44

**TIMEPOINT**

DAY 677

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

**US3512248**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:56:44**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

16 JUL 2022 00:01

[Patient Cloud Close Date & Time](#)

20 JUL 2022 23:59

US3512248

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:56:44

**TIMEPOINT**

DAY 684

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

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

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

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

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

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

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 ☐

**US3512248**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:56:44**

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

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[Patient Cloud Open Date & Time](#)

23 JUL 2022 00:01

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[Patient Cloud Close Date & Time](#)

27 JUL 2022 23:59

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US3512248

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:56:44

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"/>



**US3512248**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:56:44**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
<a href="#">Patient Cloud Open Date &amp; Time</a>	30 JUL 2022 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	03 AUG 2022 23:59

US3512248

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:56:44

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"/>

**US3512248**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:56:44**

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

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[Patient Cloud Open Date & Time](#)

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06 AUG 2022 00:01

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[Patient Cloud Close Date & Time](#)

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10 AUG 2022 23:59

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US3512248

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:56:44

TIMEPOINT	DAY 705
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$ )	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

**US3512248**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:56:44**

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

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<a href="#">Patient Cloud Open Date &amp; Time</a>	13 AUG 2022 00:01
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<a href="#">Patient Cloud Close Date &amp; Time</a>	17 AUG 2022 23:59
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US3512248

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:56:44

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

**US3512248**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:56:44**

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

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<a href="#">Patient Cloud Open Date &amp; Time</a>	20 AUG 2022 00:01
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<a href="#">Patient Cloud Close Date &amp; Time</a>	24 AUG 2022 23:59
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US3512248

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:56:44

**TIMEPOINT**

DAY 719

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

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

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

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

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

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

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 ☐



**US3512248**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:56:44**

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

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[Patient Cloud Open Date & Time](#)

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27 AUG 2022 00:01

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[Patient Cloud Close Date & Time](#)

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31 AUG 2022 23:59

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US3512248

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:56:44

**TIMEPOINT**

DAY 726

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

**US3512248**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:56:44**

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

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[Patient Cloud Open Date & Time](#)

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03 SEP 2022 00:01

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[Patient Cloud Close Date & Time](#)

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07 SEP 2022 23:59

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US3512248

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:56:44

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

**US3512248**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:56:44**

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

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[Patient Cloud Open Date & Time](#)

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10 SEP 2022 00:01

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[Patient Cloud Close Date & Time](#)

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14 SEP 2022 23:59

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US3512248

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:56:44

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"/>

**US3512248**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:56:44**

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

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[Patient Cloud Open Date & Time](#)

17 SEP 2022 00:01

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[Patient Cloud Close Date & Time](#)

21 SEP 2022 23:59

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US3512248

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:56:44

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



**US3512248**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:56:44**

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

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[Patient Cloud Open Date & Time](#)

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24 SEP 2022 00:01

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[Patient Cloud Close Date & Time](#)

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28 SEP 2022 23:59

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US3512248

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:56:44

**TIMEPOINT**

DAY 754

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

**US3512248**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:56:44**

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

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<a href="#">Patient Cloud Open Date &amp; Time</a>	01 OCT 2022 00:01
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<a href="#">Patient Cloud Close Date &amp; Time</a>	05 OCT 2022 23:59
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US3512248

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:56:44

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"/>

**US3512248**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:56:44**

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

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[Patient Cloud Open Date & Time](#)

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08 OCT 2022 00:01

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[Patient Cloud Close Date & Time](#)

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12 OCT 2022 23:59

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US3512248

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:56:44

**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 ☐

**US3512248**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:56:44**

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

US3512248

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:56:44

**TIMEPOINT**

DAY 775

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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



**US3512248**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:56:44**

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

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[Patient Cloud Open Date & Time](#)

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22 OCT 2022 00:01

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[Patient Cloud Close Date & Time](#)

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26 OCT 2022 23:59

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US3512248

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:56:44

**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 ☐

**US3512248**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:56:44**

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

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[Patient Cloud Open Date & Time](#)

29 OCT 2022 00:01

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[Patient Cloud Close Date & Time](#)

02 NOV 2022 23:59

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US3512248

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:56:44

**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 ☐

**US3512248**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:56:44**

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

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[Patient Cloud Open Date & Time](#)

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05 NOV 2022 00:01

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[Patient Cloud Close Date & Time](#)

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09 NOV 2022 23:59

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US3512248

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:56:44

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"/>

**US3512248**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:56:44**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

12 NOV 2022 00:01

[Patient Cloud Close Date & Time](#)

16 NOV 2022 23:59

**US3512248**

**Folder: Cosmetic Injections and Dermal Fillers**

**Form: Cosmetic Injection\_ Dermal Filler eDiary**

**Generated On: 10 Jun 2021 07:56:44**

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		02 MAR 2021 18:29:59



US3512248

Folder: Safety Call Day 85 (1)

Form: Safety Call

Data signed: (b) (4) 12 Feb 2021 22:11:59

Generated On: 10 Jun 2021 07:56:44

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

6 DEC 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

*If Contact Not Made, please provide Comments*

US3512248

Folder: Safety Call Day 85 (1)

Form: Continuing

Data signed: (b) (4) 12 Feb 2021 22:11:59

Generated On: 10 Jun 2021 07:56:44

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3512248

Folder: Safety Call Day 119 (1)

Form: Safety Call

Data signed: (b) (4) 12 Feb 2021 22:11:59

Generated On: 10 Jun 2021 07:56:44

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

7 JAN 2021

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

*If Contact Not Made, please provide Comments*

US3512248

Folder: Safety Call Day 119 (1)

Form: Continuing

Data signed: (b) (4) 12 Feb 2021 22:11:59

Generated On: 10 Jun 2021 07:56:44

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3512248

Folder: Safety Call Day 149 (1)

Form: Safety Call

Data signed: (b) (4) 12 Feb 2021 22:11:59

Generated On: 10 Jun 2021 07:56:44

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

4 FEB 2021

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

*If Contact Not Made, please provide Comments*

US3512248

Folder: Safety Call Day 149 (1)

Form: Continuing

Data signed: (b) (4) 12 Feb 2021 22:11:59

Generated On: 10 Jun 2021 07:56:44

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3512248

Folder: Safety Call Day 179 (1)

Form: Safety Call

Data signed: (b) (4) 05 Mar 2021 22:44:46

Generated On: 10 Jun 2021 07:56:44

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

4 MAR 2021

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

*If Contact Not Made, please provide Comments*

US3512248

Folder: Safety Call Day 179 (1)

Form: Continuing

Data signed: (b) (4) 05 Mar 2021 22:44:46

Generated On: 10 Jun 2021 07:56:44

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1



US3512248

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Data signed: (b) (4) 31 Mar 2021 17:34:59

Generated On: 10 Jun 2021 07:56:44

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

Visit date (dd MMM yyyy)	25 MAR 2021
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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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US3512248

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Data signed: (b) (4) 31 Mar 2021 17:34:59

Generated On: 10 Jun 2021 07:56:44

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) \_\_\_\_\_

US3512248

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Data signed: (b) (4) 31 Mar 2021 17:34:59

Generated On: 10 Jun 2021 07:56:44

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.*

US3512248

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 31 Mar 2021 17:34:59

Generated On: 10 Jun 2021 07:56:44

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (dd MMM yyyy)	25 MAR 2021
Collection time (00:00-23:59)	14:10 (24 HR)
Collection date and time (derived)	25 MAR 2021 14:10

US3512248

Folder: Visit 4 Day 209 (1)

Form: Continuing

Data signed: (b) (4) 31 Mar 2021 17:34:59

Generated On: 10 Jun 2021 07:56:44

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3512248

Folder: Safety Call Day 239 (1)

Form: Safety Call

Generated On: 10 Jun 2021 07:56:44

Was Contact Attempted?

Yes ☒

No ☐

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

3 MAY 2021

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

*If Contact Not Made, please provide Comments*

US3512248

Folder: Safety Call Day 239 (1)

Form: Continuing

Generated On: 10 Jun 2021 07:56:44

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

**US3512248**

**Folder: Safety Call Day 269 (1)**

**Form: Safety Call**

**Generated On: 10 Jun 2021 07:56:44**

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*



**US3512248**

**Folder: Safety Call Day 269 (1)**

**Form: Continuing**

**Generated On: 10 Jun 2021 07:56:44**

Is the participant continuing to the next visit?

Yes ☐

No ☐

Continuing Flag

US3512248

Folder: Covid-19 Assessment 19 Apr 2021

Form: COVID-19 Contact

Data signed: (b) (4) 26 Apr 2021 15:25:39

Generated On: 10 Jun 2021 07:56:44

Date of Contact	19 APR 2021
Time of Contact	19:00
Date and Time of Contact (derived)	19 APR 2021 19:00
Type of Contact	<div>Clinic Visit - Scheduled<input type="checkbox"/></div> <div>Clinical Visit - Unscheduled<input type="checkbox"/></div> <div>Safety Call<input checked="" type="checkbox"/></div> <div>Convalescent Tele-visit<input type="checkbox"/></div>
Has the subject reported symptoms of SARS-COV-2?	<div>Yes<input checked="" type="checkbox"/></div> <div>No<input type="checkbox"/></div>

US3512248

Folder: Covid-19 Assessment 19 Apr 2021

Form: Symptom Log (1)

Data signed: (b) (4) 28 Apr 2021 21:04:49

Generated On: 10 Jun 2021 07:56:44

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"/>

US3512248

Folder: Covid-19 Assessment 19 Apr 2021

Form: Symptom Log (1)

Data signed: (b) (4) 28 Apr 2021 21:04:49

Generated On: 10 Jun 2021 07:56:44

	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 APR 2021
------	-------------

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

O2 Saturation	
---------------	--

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

Temperature	
-------------	--

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

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

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

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

PRODUCTION RELEASE (v12.003

EAB) (1725)

359 of 3746

US3512248

Folder: Covid-19 Assessment 19 Apr 2021

Form: Symptom Log (1)

Data signed: (b) (4) 28 Apr 2021 21:04:49

Generated On: 10 Jun 2021 07:56:44

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

PRODUCTION RELEASE (v12.003

EAB) (1725)

360 of 3746

US3512248

Folder: Covid-19 Assessment 19 Apr 2021

Form: Symptom Log (1)

Data signed: (b) (4) 28 Apr 2021 21:04:49

Generated On: 10 Jun 2021 07:56:44

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

US3512248

Folder: Covid-19 Assessment 19 Apr 2021

Form: Symptom Log (2)

Data signed: (b) (4) 28 Apr 2021 21:04:49

Generated On: 10 Jun 2021 07:56:44

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"/>

US3512248

Folder: Covid-19 Assessment 19 Apr 2021

Form: Symptom Log (2)

Data signed: (b) (4) 28 Apr 2021 21:04:49

Generated On: 10 Jun 2021 07:56:44

	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 APR 2021
------	-------------

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

O2 Saturation	
---------------	--

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

Temperature	
-------------	--

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

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

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

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

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Folder: Covid-19 Assessment 19 Apr 2021

Form: Symptom Log (2)

Data signed: (b) (4) 28 Apr 2021 21:04:49

Generated On: 10 Jun 2021 07:56:44

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

PRODUCTION RELEASE (v12.003

EAB) (1725)

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Folder: Covid-19 Assessment 19 Apr 2021

Form: Symptom Log (2)

Data signed: (b) (4) 28 Apr 2021 21:04:49

Generated On: 10 Jun 2021 07:56:44

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

US3512248

Folder: Covid-19 Assessment 19 Apr 2021

Form: Symptom Log (3)

Data signed: (b) (4) 28 Apr 2021 21:04:49

Generated On: 10 Jun 2021 07:56:44

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 19 Apr 2021

Form: Symptom Log (3)

Data signed: (b) (4) 28 Apr 2021 21:04:49

Generated On: 10 Jun 2021 07:56:44

	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 APR 2021
------	-------------

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

O2 Saturation	
---------------	--

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

Temperature	
-------------	--

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

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

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

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

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EAB) (1725)

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Folder: Covid-19 Assessment 19 Apr 2021

Form: Symptom Log (3)

Data signed: (b) (4) 28 Apr 2021 21:04:49

Generated On: 10 Jun 2021 07:56:44

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

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Folder: Covid-19 Assessment 19 Apr 2021

Form: Symptom Log (3)

Data signed: (b) (4) 28 Apr 2021 21:04:49

Generated On: 10 Jun 2021 07:56:44

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

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Folder: Covid-19 Assessment 19 Apr 2021

Form: Symptom Log (4)

Data signed: (b) (4) 28 Apr 2021 21:04:49

Generated On: 10 Jun 2021 07:56:44

Symptom Day

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

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Folder: Covid-19 Assessment 19 Apr 2021

Form: Symptom Log (4)

Data signed: (b) (4) 28 Apr 2021 21:04:49

Generated On: 10 Jun 2021 07:56:44

	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 APR 2021
------	-------------

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

O2 Saturation	
---------------	--

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

Temperature	
-------------	--

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

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

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

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

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Folder: Covid-19 Assessment 19 Apr 2021

Form: Symptom Log (4)

Data signed: (b) (4) 28 Apr 2021 21:04:49

Generated On: 10 Jun 2021 07:56:44

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

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Folder: Covid-19 Assessment 19 Apr 2021

Form: Symptom Log (4)

Data signed: (b) (4) 28 Apr 2021 21:04:49

Generated On: 10 Jun 2021 07:56:44

Nasal Congestion

None ☐  
Mild ☒  
Moderate ☐  
Severe ☐  
Not Done ☐

Runny Nose (Rhinorrhea)

None ☐  
Mild ☐  
Moderate ☒  
Severe ☐  
Not Done ☐

Nausea

None ☒  
Mild ☐  
Moderate ☐  
Severe ☐  
Not Done ☐

Vomiting

None ☒  
Mild ☐  
Moderate ☐  
Severe ☐  
Not Done ☐

Diarrhea

None ☒  
Mild ☐  
Moderate ☐  
Severe ☐  
Not Done ☐

Sore Throat

None ☒  
Mild ☐  
Moderate ☐  
Severe ☐  
Not Done ☐

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Folder: Covid-19 Assessment 19 Apr 2021

Form: Symptom Log (5)

Data signed: (b) (4) 28 Apr 2021 21:04:49

Generated On: 10 Jun 2021 07:56:44

Symptom Day

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

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Folder: Covid-19 Assessment 19 Apr 2021

Form: Symptom Log (5)

Data signed: (b) (4) 28 Apr 2021 21:04:49

Generated On: 10 Jun 2021 07:56:44

	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 APR 2021	
Assessment Not Done	False	
O2 Saturation	<input type="text"/>	
O2 Saturation Units	<input type="text"/>	
Temperature	<input type="text"/>	
Chills	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Cough	None	<input type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input checked="" type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Shortness of Breath	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Difficulty Breathing	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>

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Folder: Covid-19 Assessment 19 Apr 2021

Form: Symptom Log (5)

Data signed: (b) (4) 28 Apr 2021 21:04:49

Generated On: 10 Jun 2021 07:56:44

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

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Folder: Covid-19 Assessment 19 Apr 2021

Form: Symptom Log (5)

Data signed: (b) (4) 28 Apr 2021 21:04:49

Generated On: 10 Jun 2021 07:56:44

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

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Folder: Covid-19 Assessment 19 Apr 2021

Form: Symptom Log (6)

Data signed: (b) (4) 28 Apr 2021 21:04:49

Generated On: 10 Jun 2021 07:56:44

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"/>

US3512248

Folder: Covid-19 Assessment 19 Apr 2021

Form: Symptom Log (6)

Data signed: (b) (4) 28 Apr 2021 21:04:49

Generated On: 10 Jun 2021 07:56:44

	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 APR 2021
------	-------------

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

O2 Saturation	
---------------	--

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

Temperature	
-------------	--

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

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

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

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

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Folder: Covid-19 Assessment 19 Apr 2021

Form: Symptom Log (6)

Data signed: (b) (4) 28 Apr 2021 21:04:49

Generated On: 10 Jun 2021 07:56:44

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

PRODUCTION RELEASE (v12.003

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Folder: Covid-19 Assessment 19 Apr 2021

Form: Symptom Log (6)

Data signed: (b) (4) 28 Apr 2021 21:04:49

Generated On: 10 Jun 2021 07:56:44

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

US3512248

Folder: Covid-19 Assessment 19 Apr 2021

Form: Symptom Log (7)

Data signed: (b) (4) 28 Apr 2021 21:04:49

Generated On: 10 Jun 2021 07:56:44

Symptom Day

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

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Folder: Covid-19 Assessment 19 Apr 2021

Form: Symptom Log (7)

Data signed: (b) (4) 28 Apr 2021 21:04:49

Generated On: 10 Jun 2021 07:56:44

	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 APR 2021
------	-------------

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

O2 Saturation	96 %
---------------	------

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

Temperature	
-------------	--

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

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

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

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

PRODUCTION RELEASE (v12.003

EAB) (1725)

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Folder: Covid-19 Assessment 19 Apr 2021

Form: Symptom Log (7)

Data signed: (b) (4) 28 Apr 2021 21:04:49

Generated On: 10 Jun 2021 07:56:44

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

PRODUCTION RELEASE (v12.003

EAB) (1725)

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US3512248

Folder: Covid-19 Assessment 19 Apr 2021

Form: Symptom Log (7)

Data signed: (b) (4) 28 Apr 2021 21:04:49

Generated On: 10 Jun 2021 07:56:44

Nasal Congestion

None ☐  
Mild ☒  
Moderate ☐  
Severe ☐  
Not Done ☐

Runny Nose (Rhinorrhea)

None ☐  
Mild ☒  
Moderate ☐  
Severe ☐  
Not Done ☐

Nausea

None ☒  
Mild ☐  
Moderate ☐  
Severe ☐  
Not Done ☐

Vomiting

None ☒  
Mild ☐  
Moderate ☐  
Severe ☐  
Not Done ☐

Diarrhea

None ☒  
Mild ☐  
Moderate ☐  
Severe ☐  
Not Done ☐

Sore Throat

None ☒  
Mild ☐  
Moderate ☐  
Severe ☐  
Not Done ☐

US3512248

Folder: Covid-19 Assessment 19 Apr 2021

Form: Symptom Log (8)

Data signed: (b) (4) 28 Apr 2021 21:04:49

Generated On: 10 Jun 2021 07:56:44

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 19 Apr 2021

Form: Symptom Log (8)

Data signed: (b) (4) 28 Apr 2021 21:04:49

Generated On: 10 Jun 2021 07:56:44

	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 APR 2021
------	-------------

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

O2 Saturation	
---------------	--

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

Temperature	
-------------	--

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

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

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

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

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Folder: Covid-19 Assessment 19 Apr 2021

Form: Symptom Log (8)

Data signed: (b) (4) 28 Apr 2021 21:04:49

Generated On: 10 Jun 2021 07:56:44

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

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Folder: Covid-19 Assessment 19 Apr 2021

Form: Symptom Log (8)

Data signed: (b) (4) 28 Apr 2021 21:04:49

Generated On: 10 Jun 2021 07:56:44

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

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Folder: Covid-19 Assessment 19 Apr 2021

Form: Symptom Log (9)

Data signed: (b) (4) 28 Apr 2021 21:04:49

Generated On: 10 Jun 2021 07:56:44

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 19 Apr 2021

Form: Symptom Log (9)

Data signed: (b) (4) 28 Apr 2021 21:04:49

Generated On: 10 Jun 2021 07:56:44

	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 APR 2021
------	-------------

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

O2 Saturation	99 %
---------------	------

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

Temperature	98.3 F
-------------	--------

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

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

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

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

PRODUCTION RELEASE (v12.003

EAB) (1725)

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Folder: Covid-19 Assessment 19 Apr 2021

Form: Symptom Log (9)

Data signed: (b) (4) 28 Apr 2021 21:04:49

Generated On: 10 Jun 2021 07:56:44

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

US3512248

Folder: Covid-19 Assessment 19 Apr 2021

Form: Symptom Log (9)

Data signed: (b) (4) 28 Apr 2021 21:04:49

Generated On: 10 Jun 2021 07:56:44

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

US3512248

Folder: Covid-19 Assessment 19 Apr 2021

Form: Symptom Log (10)

Data signed: (b) (4) 28 Apr 2021 21:04:49

Generated On: 10 Jun 2021 07:56:44

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"/>

US3512248

Folder: Covid-19 Assessment 19 Apr 2021

Form: Symptom Log (10)

Data signed: (b) (4) 28 Apr 2021 21:04:49

Generated On: 10 Jun 2021 07:56:44

	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 APR 2021	
Assessment Not Done	False	
O2 Saturation	98 %	
O2 Saturation Units	%	
Temperature	98.4 F	
Chills	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Cough	None	<input type="radio"/>
	Mild	<input checked="" type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Shortness of Breath	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Difficulty Breathing	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>

PRODUCTION RELEASE (v12.003  
EAB) (1725)

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US3512248

Folder: Covid-19 Assessment 19 Apr 2021

Form: Symptom Log (10)

Data signed: (b) (4) 28 Apr 2021 21:04:49

Generated On: 10 Jun 2021 07:56:44

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

PRODUCTION RELEASE (v12.003

EAB) (1725)

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US3512248

Folder: Covid-19 Assessment 19 Apr 2021

Form: Symptom Log (10)

Data signed: (b) (4) 28 Apr 2021 21:04:49

Generated On: 10 Jun 2021 07:56:44

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

US3512248

Folder: Covid-19 Assessment 19 Apr 2021

Form: Symptom Log (11)

Data signed: (b) (4) 28 Apr 2021 21:04:49

Generated On: 10 Jun 2021 07:56:44

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 19 Apr 2021

Form: Symptom Log (11)

Data signed: (b) (4) 28 Apr 2021 21:04:49

Generated On: 10 Jun 2021 07:56:44

	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 APR 2021	
Assessment Not Done	False	
O2 Saturation	96 %	
O2 Saturation Units	%	
Temperature	97.8 F	
Chills	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Cough	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Shortness of Breath	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Difficulty Breathing	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>

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Folder: Covid-19 Assessment 19 Apr 2021

Form: Symptom Log (11)

Data signed: (b) (4) 28 Apr 2021 21:04:49

Generated On: 10 Jun 2021 07:56:44

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

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EAB) (1725)

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US3512248

Folder: Covid-19 Assessment 19 Apr 2021

Form: Symptom Log (11)

Data signed: (b) (4) 28 Apr 2021 21:04:49

Generated On: 10 Jun 2021 07:56:44

Nasal Congestion

None ☒  
Mild ☐  
Moderate ☐  
Severe ☐  
Not Done ☐

Runny Nose (Rhinorrhea)

None ☒  
Mild ☐  
Moderate ☐  
Severe ☐  
Not Done ☐

Nausea

None ☒  
Mild ☐  
Moderate ☐  
Severe ☐  
Not Done ☐

Vomiting

None ☒  
Mild ☐  
Moderate ☐  
Severe ☐  
Not Done ☐

Diarrhea

None ☒  
Mild ☐  
Moderate ☐  
Severe ☐  
Not Done ☐

Sore Throat

None ☒  
Mild ☐  
Moderate ☐  
Severe ☐  
Not Done ☐

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Folder: Covid-19 Assessment 19 Apr 2021

Form: Symptom Log (12)

Data signed: (b) (4) 28 Apr 2021 21:04:49

Generated On: 10 Jun 2021 07:56:44

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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Form: Symptom Log (12)

Data signed: (b) (4) 28 Apr 2021 21:04:49

Generated On: 10 Jun 2021 07:56:44

	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 APR 2021
------	-------------

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

O2 Saturation	98 %
---------------	------

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

Temperature	95.8 F
-------------	--------

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

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

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

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

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Folder: Covid-19 Assessment 19 Apr 2021

Form: Symptom Log (12)

Data signed: (b) (4) 28 Apr 2021 21:04:49

Generated On: 10 Jun 2021 07:56:44

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

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Folder: Covid-19 Assessment 19 Apr 2021

Form: Symptom Log (12)

Data signed: (b) (4) 28 Apr 2021 21:04:49

Generated On: 10 Jun 2021 07:56:44

Nasal Congestion

None ☒  
Mild ☐  
Moderate ☐  
Severe ☐  
Not Done ☐

Runny Nose (Rhinorrhea)

None ☒  
Mild ☐  
Moderate ☐  
Severe ☐  
Not Done ☐

Nausea

None ☒  
Mild ☐  
Moderate ☐  
Severe ☐  
Not Done ☐

Vomiting

None ☒  
Mild ☐  
Moderate ☐  
Severe ☐  
Not Done ☐

Diarrhea

None ☒  
Mild ☐  
Moderate ☐  
Severe ☐  
Not Done ☐

Sore Throat

None ☒  
Mild ☐  
Moderate ☐  
Severe ☐  
Not Done ☐

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Folder: Covid-19 Assessment 19 Apr 2021

Form: Symptom Log (13)

Data signed: (b) (4) 28 Apr 2021 21:04:49

Generated On: 10 Jun 2021 07:56:44

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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Form: Symptom Log (13)

Data signed: (b) (4) 28 Apr 2021 21:04:49

Generated On: 10 Jun 2021 07:56:44

	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 APR 2021
------	-------------

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

O2 Saturation	98 %
---------------	------

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

Temperature	97.2 F
-------------	--------

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

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

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

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

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Form: Symptom Log (13)

Data signed: (b) (4) 28 Apr 2021 21:04:49

Generated On: 10 Jun 2021 07:56:44

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

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EAB) (1725)

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Folder: Covid-19 Assessment 19 Apr 2021

Form: Symptom Log (13)

Data signed: (b) (4) 28 Apr 2021 21:04:49

Generated On: 10 Jun 2021 07:56:44

Nasal Congestion

None ☒  
Mild ☐  
Moderate ☐  
Severe ☐  
Not Done ☐

Runny Nose (Rhinorrhea)

None ☒  
Mild ☐  
Moderate ☐  
Severe ☐  
Not Done ☐

Nausea

None ☒  
Mild ☐  
Moderate ☐  
Severe ☐  
Not Done ☐

Vomiting

None ☒  
Mild ☐  
Moderate ☐  
Severe ☐  
Not Done ☐

Diarrhea

None ☒  
Mild ☐  
Moderate ☐  
Severe ☐  
Not Done ☐

Sore Throat

None ☒  
Mild ☐  
Moderate ☐  
Severe ☐  
Not Done ☐

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Folder: Covid-19 Assessment 19 Apr 2021

Form: Symptom Log (14)

Data signed: (b) (4) 28 Apr 2021 21:04:49

Generated On: 10 Jun 2021 07:56:44

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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Form: Symptom Log (14)

Data signed: (b) (4) 28 Apr 2021 21:04:49

Generated On: 10 Jun 2021 07:56:44

	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 APR 2021	
Assessment Not Done	False	
O2 Saturation	98 %	
O2 Saturation Units	%	
Temperature	96.8 F	
Chills	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Cough	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Shortness of Breath	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Difficulty Breathing	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>

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Form: Symptom Log (14)

Data signed: (b) (4) 28 Apr 2021 21:04:49

Generated On: 10 Jun 2021 07:56:44

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

US3512248

Folder: Covid-19 Assessment 19 Apr 2021

Form: Symptom Log (14)

Data signed: (b) (4) 28 Apr 2021 21:04:49

Generated On: 10 Jun 2021 07:56:44

Nasal Congestion

None ☒  
Mild ☐  
Moderate ☐  
Severe ☐  
Not Done ☐

Runny Nose (Rhinorrhea)

None ☒  
Mild ☐  
Moderate ☐  
Severe ☐  
Not Done ☐

Nausea

None ☒  
Mild ☐  
Moderate ☐  
Severe ☐  
Not Done ☐

Vomiting

None ☒  
Mild ☐  
Moderate ☐  
Severe ☐  
Not Done ☐

Diarrhea

None ☒  
Mild ☐  
Moderate ☐  
Severe ☐  
Not Done ☐

Sore Throat

None ☒  
Mild ☐  
Moderate ☐  
Severe ☐  
Not Done ☐

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Folder: Covid-19 Assessment 19 Apr 2021

Form: Symptom Log (15)

Data signed: (b) (4) 28 Apr 2021 21:04:49

Generated On: 10 Jun 2021 07:56:44

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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Form: Symptom Log (15)

Data signed: (b) (4) 28 Apr 2021 21:04:49

Generated On: 10 Jun 2021 07:56:44

	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 APR 2021	
Assessment Not Done	False	
O2 Saturation	98 %	
O2 Saturation Units	%	
Temperature	97.5 F	
Chills	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Cough	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Shortness of Breath	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Difficulty Breathing	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
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Folder: Covid-19 Assessment 19 Apr 2021

Form: Symptom Log (15)

Data signed: (b) (4) 28 Apr 2021 21:04:49

Generated On: 10 Jun 2021 07:56:44

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

PRODUCTION RELEASE (v12.003

EAB) (1725)

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Folder: Covid-19 Assessment 19 Apr 2021

Form: Symptom Log (15)

Data signed: (b) (4) 28 Apr 2021 21:04:49

Generated On: 10 Jun 2021 07:56:44

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

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Form: Symptom Log (16)

Data signed: (b) (4) 28 Apr 2021 21:04:49

Generated On: 10 Jun 2021 07:56:44

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"/>

US3512248

Folder: Covid-19 Assessment 19 Apr 2021

Form: Symptom Log (16)

Data signed: (b) (4) 28 Apr 2021 21:04:49

Generated On: 10 Jun 2021 07:56:44

	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 APR 2021	
Assessment Not Done	False	
O2 Saturation	96 %	
O2 Saturation Units	%	
Temperature	97.8 F	
Chills	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Cough	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Shortness of Breath	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Difficulty Breathing	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>

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Folder: Covid-19 Assessment 19 Apr 2021

Form: Symptom Log (16)

Data signed: (b) (4) 28 Apr 2021 21:04:49

Generated On: 10 Jun 2021 07:56:44

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

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Folder: Covid-19 Assessment 19 Apr 2021

Form: Symptom Log (16)

Data signed: (b) (4) 28 Apr 2021 21:04:49

Generated On: 10 Jun 2021 07:56:44

Nasal Congestion

None ☒  
Mild ☐  
Moderate ☐  
Severe ☐  
Not Done ☐

Runny Nose (Rhinorrhea)

None ☒  
Mild ☐  
Moderate ☐  
Severe ☐  
Not Done ☐

Nausea

None ☒  
Mild ☐  
Moderate ☐  
Severe ☐  
Not Done ☐

Vomiting

None ☒  
Mild ☐  
Moderate ☐  
Severe ☐  
Not Done ☐

Diarrhea

None ☒  
Mild ☐  
Moderate ☐  
Severe ☐  
Not Done ☐

Sore Throat

None ☒  
Mild ☐  
Moderate ☐  
Severe ☐  
Not Done ☐

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Folder: Covid-19 Assessment 19 Apr 2021

Form: COVID Diagnostic Test

Data signed: (b) (4) 26 Apr 2021 15:25:39

Generated On: 10 Jun 2021 07:56:44

Date of Visit 20 APR 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 20 APR 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

CLIA Certified? Yes ☐  
No ☐

COVID-19 Positive (CSA Programming Field Only)

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Folder: Covid-19 Assessment 26 Jan 2021

Form: COVID-19 Contact

Data signed: (b) (4) 12 Feb 2021 22:11:59

Generated On: 10 Jun 2021 07:56:44

Date of Contact	26 JAN 2021
Time of Contact	10:14
Date and Time of Contact (derived)	26 JAN 2021 10:14
Type of Contact	<div>Clinic Visit - Scheduled<input type="checkbox"/></div> <div>Clinical Visit - Unscheduled<input checked="" type="checkbox"/></div> <div>Safety Call<input type="checkbox"/></div> <div>Convalescent Tele-visit<input type="checkbox"/></div>
Has the subject reported symptoms of SARS-COV-2?	<div>Yes<input checked="" type="checkbox"/></div> <div>No<input type="checkbox"/></div>

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Folder: Covid-19 Assessment 26 Jan 2021

Form: Symptom Log (1)

Data signed: (b) (4) 26 Feb 2021 20:02:43

Generated On: 10 Jun 2021 07:56:44

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"/>

US3512248

Folder: Covid-19 Assessment 26 Jan 2021

Form: Symptom Log (1)

Data signed: (b) (4) 26 Feb 2021 20:02:43

Generated On: 10 Jun 2021 07:56:44

	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 JAN 2021
------	-------------

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

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

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

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

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

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

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

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

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EAB) (1725)

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Folder: Covid-19 Assessment 26 Jan 2021

Form: Symptom Log (1)

Data signed: (b) (4) 26 Feb 2021 20:02:43

Generated On: 10 Jun 2021 07:56:44

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

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Folder: Covid-19 Assessment 26 Jan 2021

Form: Symptom Log (1)

Data signed: (b) (4) 26 Feb 2021 20:02:43

Generated On: 10 Jun 2021 07:56:44

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



US3512248

Folder: Covid-19 Assessment 26 Jan 2021

Form: Symptom Log (2)

Data signed: (b) (4) 26 Feb 2021 20:02:43

Generated On: 10 Jun 2021 07:56:44

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"/>

US3512248

Folder: Covid-19 Assessment 26 Jan 2021

Form: Symptom Log (2)

Data signed: (b) (4) 26 Feb 2021 20:02:43

Generated On: 10 Jun 2021 07:56:44

	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 JAN 2021	
Assessment Not Done	False	
O2 Saturation	ND - Not Done	
O2 Saturation Units	%	
Temperature	ND - Not Done	
Chills	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Cough	None	<input type="radio"/>
	Mild	<input checked="" type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Shortness of Breath	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Difficulty Breathing	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>

PRODUCTION RELEASE (v12.003  
EAB) (1725)

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Folder: Covid-19 Assessment 26 Jan 2021

Form: Symptom Log (2)

Data signed: (b) (4) 26 Feb 2021 20:02:43

Generated On: 10 Jun 2021 07:56:44

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

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Folder: Covid-19 Assessment 26 Jan 2021

Form: Symptom Log (2)

Data signed: (b) (4) 26 Feb 2021 20:02:43

Generated On: 10 Jun 2021 07:56:44

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

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Folder: Covid-19 Assessment 26 Jan 2021

Form: Symptom Log (3)

Data signed: (b) (4) 26 Feb 2021 20:02:43

Generated On: 10 Jun 2021 07:56:44

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 26 Jan 2021

Form: Symptom Log (3)

Data signed: (b) (4) 26 Feb 2021 20:02:43

Generated On: 10 Jun 2021 07:56:44

	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 JAN 2021	
Assessment Not Done	False	
O2 Saturation	ND - Not Done	
O2 Saturation Units	%	
Temperature	97.2 F	
Chills	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Cough	None	<input type="radio"/>
	Mild	<input checked="" type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Shortness of Breath	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Difficulty Breathing	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
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EAB) (1725)		

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Folder: Covid-19 Assessment 26 Jan 2021

Form: Symptom Log (3)

Data signed: (b) (4) 26 Feb 2021 20:02:43

Generated On: 10 Jun 2021 07:56:44

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

US3512248

Folder: Covid-19 Assessment 26 Jan 2021

Form: Symptom Log (3)

Data signed: (b) (4) 26 Feb 2021 20:02:43

Generated On: 10 Jun 2021 07:56:44

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



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Folder: Covid-19 Assessment 26 Jan 2021

Form: Symptom Log (4)

Data signed: (b) (4) 26 Feb 2021 20:02:43

Generated On: 10 Jun 2021 07:56:44

Symptom Day

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

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Folder: Covid-19 Assessment 26 Jan 2021

Form: Symptom Log (4)

Data signed: (b) (4) 26 Feb 2021 20:02:43

Generated On: 10 Jun 2021 07:56:44

	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 JAN 2021
------	-------------

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

O2 Saturation	99 %
---------------	------

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

Temperature	97.3 F
-------------	--------

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

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

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

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

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Folder: Covid-19 Assessment 26 Jan 2021

Form: Symptom Log (4)

Data signed: (b) (4) 26 Feb 2021 20:02:43

Generated On: 10 Jun 2021 07:56:44

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

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Form: Symptom Log (4)

Data signed: (b) (4) 26 Feb 2021 20:02:43

Generated On: 10 Jun 2021 07:56:44

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

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Form: Symptom Log (5)

Data signed: (b) (4) 26 Feb 2021 20:02:43

Generated On: 10 Jun 2021 07:56:44

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) 26 Feb 2021 20:02:43

Generated On: 10 Jun 2021 07:56:44

	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 JAN 2021	
Assessment Not Done	False	
O2 Saturation	94 %	
O2 Saturation Units	%	
Temperature	97.5 F	
Chills	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Cough	None	<input type="radio"/>
	Mild	<input checked="" type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Shortness of Breath	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Difficulty Breathing	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>

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Generated On: 10 Jun 2021 07:56:44

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

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Form: Symptom Log (5)

Data signed: (b) (4) 26 Feb 2021 20:02:43

Generated On: 10 Jun 2021 07:56:44

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



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Form: Symptom Log (6)

Data signed: (b) (4) 26 Feb 2021 20:02:43

Generated On: 10 Jun 2021 07:56:44

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) 26 Feb 2021 20:02:43

Generated On: 10 Jun 2021 07:56:44

	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 JAN 2021	
Assessment Not Done	False	
O2 Saturation	97 %	
O2 Saturation Units	%	
Temperature	96.8 F	
Chills	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Cough	None	<input type="radio"/>
	Mild	<input checked="" type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Shortness of Breath	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Difficulty Breathing	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
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Form: Symptom Log (6)

Data signed: (b) (4) 26 Feb 2021 20:02:43

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

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Form: Symptom Log (6)

Data signed: (b) (4) 26 Feb 2021 20:02:43

Generated On: 10 Jun 2021 07:56:44

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

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Form: Symptom Log (7)

Data signed: (b) (4) 26 Feb 2021 20:02:43

Generated On: 10 Jun 2021 07:56:44

Symptom Day

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

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Form: Symptom Log (7)

Data signed: (b) (4) 26 Feb 2021 20:02:43

Generated On: 10 Jun 2021 07:56:44

	Day 33	<input type="checkbox"/>
	Day 34	<input type="checkbox"/>
	Day 35	<input type="checkbox"/>
	Day 36	<input type="checkbox"/>
	Day 37	<input type="checkbox"/>
	Day 38	<input type="checkbox"/>
	Day 39	<input type="checkbox"/>
	Day 40	<input type="checkbox"/>
Date	29 JAN 2021	
Assessment Not Done	False	
O2 Saturation	98 %	
O2 Saturation Units	%	
Temperature	96.2 F	
Chills	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Cough	None	<input type="radio"/>
	Mild	<input checked="" type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Shortness of Breath	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Difficulty Breathing	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>

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

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Form: Symptom Log (7)

Data signed: (b) (4) 26 Feb 2021 20:02:43

Generated On: 10 Jun 2021 07:56:44

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



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Form: Symptom Log (8)

Data signed: (b) (4) 26 Feb 2021 20:02:43

Generated On: 10 Jun 2021 07:56:44

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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Form: Symptom Log (8)

Data signed: (b) (4) 26 Feb 2021 20:02:43

Generated On: 10 Jun 2021 07:56:44

	Day 33	<input type="checkbox"/>
	Day 34	<input type="checkbox"/>
	Day 35	<input type="checkbox"/>
	Day 36	<input type="checkbox"/>
	Day 37	<input type="checkbox"/>
	Day 38	<input type="checkbox"/>
	Day 39	<input type="checkbox"/>
	Day 40	<input type="checkbox"/>
Date	30 JAN 2021	
Assessment Not Done	False	
O2 Saturation	98 %	
O2 Saturation Units	%	
Temperature	96.2 F	
Chills	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Cough	None	<input type="radio"/>
	Mild	<input checked="" type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Shortness of Breath	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Difficulty Breathing	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>

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Data signed: (b) (4) 26 Feb 2021 20:02:43

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

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Form: Symptom Log (8)

Data signed: (b) (4) 26 Feb 2021 20:02:43

Generated On: 10 Jun 2021 07:56:44

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

US3512248

Folder: Covid-19 Assessment 26 Jan 2021

Form: Symptom Log (9)

Data signed: (b) (4) 26 Feb 2021 20:02:43

Generated On: 10 Jun 2021 07:56:44

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"/>

US3512248

Folder: Covid-19 Assessment 26 Jan 2021

Form: Symptom Log (9)

Data signed: (b) (4) 26 Feb 2021 20:02:43

Generated On: 10 Jun 2021 07:56:44

	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	31 JAN 2021
------	-------------

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

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

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

Temperature	97.0 F
-------------	--------

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

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

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

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

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EAB) (1725)

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Folder: Covid-19 Assessment 26 Jan 2021

Form: Symptom Log (9)

Data signed: (b) (4) 26 Feb 2021 20:02:43

Generated On: 10 Jun 2021 07:56:44

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

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Folder: Covid-19 Assessment 26 Jan 2021

Form: Symptom Log (9)

Data signed: (b) (4) 26 Feb 2021 20:02:43

Generated On: 10 Jun 2021 07:56:44

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



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Folder: Covid-19 Assessment 26 Jan 2021

Form: Symptom Log (10)

Data signed: (b) (4) 26 Feb 2021 20:02:43

Generated On: 10 Jun 2021 07:56:44

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 26 Jan 2021

Form: Symptom Log (10)

Data signed: (b) (4) 26 Feb 2021 20:02:43

Generated On: 10 Jun 2021 07:56:44

	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	1 FEB 2021	
Assessment Not Done	False	
O2 Saturation	97 %	
O2 Saturation Units	%	
Temperature	98.1 F	
Chills	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Cough	None	<input type="radio"/>
	Mild	<input checked="" type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Shortness of Breath	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Difficulty Breathing	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>

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Folder: Covid-19 Assessment 26 Jan 2021

Form: Symptom Log (10)

Data signed: (b) (4) 26 Feb 2021 20:02:43

Generated On: 10 Jun 2021 07:56:44

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

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Folder: Covid-19 Assessment 26 Jan 2021

Form: Symptom Log (10)

Data signed: (b) (4) 26 Feb 2021 20:02:43

Generated On: 10 Jun 2021 07:56:44

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

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Folder: Covid-19 Assessment 26 Jan 2021

Form: Symptom Log (11)

Data signed: (b) (4) 26 Feb 2021 20:02:43

Generated On: 10 Jun 2021 07:56:44

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 26 Jan 2021

Form: Symptom Log (11)

Data signed: (b) (4) 26 Feb 2021 20:02:43

Generated On: 10 Jun 2021 07:56:44

	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	False	
O2 Saturation	97 %	
O2 Saturation Units	%	
Temperature	98.2 F	
Chills	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Cough	None	<input type="radio"/>
	Mild	<input checked="" type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Shortness of Breath	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Difficulty Breathing	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
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EAB) (1725)		

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Folder: Covid-19 Assessment 26 Jan 2021

Form: Symptom Log (11)

Data signed: (b) (4) 26 Feb 2021 20:02:43

Generated On: 10 Jun 2021 07:56:44

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

PRODUCTION RELEASE (v12.003

EAB) (1725)

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Folder: Covid-19 Assessment 26 Jan 2021

Form: Symptom Log (11)

Data signed: (b) (4) 26 Feb 2021 20:02:43

Generated On: 10 Jun 2021 07:56:44

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



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Folder: Covid-19 Assessment 26 Jan 2021

Form: Symptom Log (12)

Data signed: (b) (4) 26 Feb 2021 20:02:43

Generated On: 10 Jun 2021 07:56:44

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"/>

US3512248

Folder: Covid-19 Assessment 26 Jan 2021

Form: Symptom Log (12)

Data signed: (b) (4) 26 Feb 2021 20:02:43

Generated On: 10 Jun 2021 07:56:44

	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	False
---------------------	-------

O2 Saturation	94 %
---------------	------

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

Temperature	97.3 F
-------------	--------

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

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

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

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

PRODUCTION RELEASE (v12.003

EAB) (1725)

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Folder: Covid-19 Assessment 26 Jan 2021

Form: Symptom Log (12)

Data signed: (b) (4) 26 Feb 2021 20:02:43

Generated On: 10 Jun 2021 07:56:44

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

US3512248

Folder: Covid-19 Assessment 26 Jan 2021

Form: Symptom Log (12)

Data signed: (b) (4) 26 Feb 2021 20:02:43

Generated On: 10 Jun 2021 07:56:44

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

US3512248

Folder: Covid-19 Assessment 26 Jan 2021

Form: Symptom Log (13)

Data signed: (b) (4) 26 Feb 2021 20:02:43

Generated On: 10 Jun 2021 07:56:44

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"/>

US3512248

Folder: Covid-19 Assessment 26 Jan 2021

Form: Symptom Log (13)

Data signed: (b) (4) 26 Feb 2021 20:02:43

Generated On: 10 Jun 2021 07:56:44

	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	False	
O2 Saturation	97 %	
O2 Saturation Units	%	
Temperature	95.7 F	
Chills	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Cough	None	<input type="radio"/>
	Mild	<input checked="" type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Shortness of Breath	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Difficulty Breathing	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
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EAB) (1725)		

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Folder: Covid-19 Assessment 26 Jan 2021

Form: Symptom Log (13)

Data signed: (b) (4) 26 Feb 2021 20:02:43

Generated On: 10 Jun 2021 07:56:44

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

US3512248

Folder: Covid-19 Assessment 26 Jan 2021

Form: Symptom Log (13)

Data signed: (b) (4) 26 Feb 2021 20:02:43

Generated On: 10 Jun 2021 07:56:44

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



US3512248

Folder: Covid-19 Assessment 26 Jan 2021

Form: Symptom Log (14)

Data signed: (b) (4) 26 Feb 2021 20:02:43

Generated On: 10 Jun 2021 07:56:44

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 26 Jan 2021

Form: Symptom Log (14)

Data signed: (b) (4) 26 Feb 2021 20:02:43

Generated On: 10 Jun 2021 07:56:44

	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	False	
O2 Saturation	97 %	
O2 Saturation Units	%	
Temperature	97.3 F	
Chills	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Cough	None	<input type="radio"/>
	Mild	<input checked="" type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Shortness of Breath	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Difficulty Breathing	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>

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Folder: Covid-19 Assessment 26 Jan 2021

Form: Symptom Log (14)

Data signed: (b) (4) 26 Feb 2021 20:02:43

Generated On: 10 Jun 2021 07:56:44

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

US3512248

Folder: Covid-19 Assessment 26 Jan 2021

Form: Symptom Log (14)

Data signed: (b) (4) 26 Feb 2021 20:02:43

Generated On: 10 Jun 2021 07:56:44

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

US3512248

Folder: Covid-19 Assessment 26 Jan 2021

Form: COVID Diagnostic Test

Data signed: (b) (4) 26 Feb 2021 20:02:43

Generated On: 10 Jun 2021 07:56:44

Date of Visit	26 JAN 2021
Was the Subject Tested For SARS-CoV-2 by RT-PCR?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Did Subject Test Positive For SARS-CoV-2 by RT-PCR?	Yes <input type="radio"/> No <input checked="" type="radio"/>
Date of Test	26 JAN 2021
Type of Test Performed	Nasopharyngeal Swab <input checked="" type="radio"/> Nasal Swab <input type="radio"/> Saliva Test <input type="radio"/> Other <input type="radio"/>
Other, specify	
Was this diagnostic test performed at a lab other than the Study Central Lab?	Yes <input type="radio"/> No <input checked="" type="radio"/>
If yes, provide lab information below	
Lab/ Institution Test Performed	
CLIA Certified?	Yes <input type="radio"/> No <input type="radio"/>
COVID-19 Positive (CSA Programming Field Only)	0

US3512248

Folder: Illness Visit (1)

Form: Saliva Collection

Data signed: (b) (4) 19 Feb 2021 21:27:20

Generated On: 10 Jun 2021 07:56:44

Visit	Was Saliva Collected?	Date of Collection
Day 3	Yes	28 JAN 2021
Day 5	Yes	30 JAN 2021
Day 7	Yes	01 FEB 2021
Day 9	Yes	03 FEB 2021
Day 14	NA (COVID-19 Negative)	
Day 21	NA (COVID-19 Negative)	
Day 28	NA (COVID-19 Negative)	

US3512248

Folder: Illness Visit (2)

Form: Saliva Collection

Data signed: (b) (4) 28 Apr 2021 21:04:49

Generated On: 10 Jun 2021 07:56:44

Visit	Was Saliva Collected?	Date of Collection
Day 3	Yes	22 APR 2021
Day 5	Yes	24 APR 2021
Day 7	Yes	26 APR 2021
Day 9	NA (COVID-19 Negative)	
Day 14	NA (COVID-19 Negative)	
Day 21	NA (COVID-19 Negative)	
Day 28	NA (COVID-19 Negative)	

US3512248

Folder: Illness Visit Day 1 (1)

Form: Visit Date

Data signed: (b) (4) 19 Feb 2021 21:27:20

Generated On: 10 Jun 2021 07:56:44

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	26 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	SICKD1



US3512248

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Data signed: (b) (4) 12 Feb 2021 22:11:59

Generated On: 10 Jun 2021 07:56:44

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (dd MMM yyyy)	26 JAN 2021
Time of assessment (00:00-23:59)	10:31 (24 HR)
Vital Signs Date and Time (derived)	26 JAN 2021 10:31
Height (xxx.x)	71 in
Weight (xxx.x)	231.4 lb
Temperature (xxx.x)	97.5 F
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	65 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	132 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	66 mmHg
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

US3512248

Folder: Illness Visit Day 1 (1)

Form: Physical Examination

Data signed: (b) (4) 12 Feb 2021 22:11:59

Generated On: 10 Jun 2021 07:56:44

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

26 JAN 2021

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

US3512248

Folder: Illness Visit Day 1 (1)

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

Data signed: (b) (4) 12 Feb 2021 22:11:59

Generated On: 10 Jun 2021 07:56:44

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

Yes ☒

No ☐

NA (COVID-19 Negative) ☐

Date of Collection

26 JAN 2021

US3512248

Folder: Illness Visit Day 1 (1)

Form: Visit Date

Data signed: (b) (4) 26 Apr 2021 15:25:39

Generated On: 10 Jun 2021 07:56:44

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

Visit date (dd MMM yyyy)	20 APR 2021
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Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>

Folder OID	SICKD1
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US3512248

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Data signed: (b) (4) 26 Apr 2021 15:25:39

Generated On: 10 Jun 2021 07:56:44

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (dd MMM yyyy)	20 APR 2021
Time of assessment (00:00-23:59)	9:45 (24 HR)
Vital Signs Date and Time (derived)	20 APR 2021 9:45
Height (xxx.x)	71 in
Weight (xxx.x)	231.4 lb
Temperature (xxx.x)	98.3 F
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	86 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	137 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	66 mmHg
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

US3512248

Folder: Illness Visit Day 1 (1)

Form: Physical Examination

Data signed: (b) (4) 26 Apr 2021 15:25:39

Generated On: 10 Jun 2021 07:56:44

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

20 APR 2021

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

US3512248

Folder: Illness Visit Day 1 (1)

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

Data signed: (b) (4) 26 Apr 2021 15:25:39

Generated On: 10 Jun 2021 07:56:44

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

Yes ☒

No ☐

NA (COVID-19 Negative) ☐

Date of Collection

20 APR 2021

US3512248

Folder: Convalescence Visit Day 28 (1)

Form: Visit Date

Data signed: (b) (4) 26 Feb 2021 20:02:43

Generated On: 10 Jun 2021 07:56:44

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 SICKD28



US3512248

Folder: Convalescence Visit Day 28 (1)

Form: Visit Date

Data signed: (b) (4) 28 Apr 2021 21:04:49

Generated On: 10 Jun 2021 07:56:44

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 SICKD28

US3512248

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Data signed: (b) (4) 28 Apr 2021 21:04:49

Generated On: 10 Jun 2021 07:56:44

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) \_\_\_\_\_

US3512248

Folder: Convalescence Visit Day 28 (1)

Form: Physical Examination

Data signed: (b) (4) 28 Apr 2021 21:04:49

Generated On: 10 Jun 2021 07:56:44

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.*

US3512248

Folder: Convalescence Visit Day 28 (1)

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

Data signed: (b) (4) 28 Apr 2021 21:04:49

Generated On: 10 Jun 2021 07:56:44

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

Yes ☐

No ☐

NA (COVID-19 Negative) ☒

Date of Collection

US3512248

Folder: Participant Decision Visit / OL-D1 (1)

Form: Visit Date

Data signed: (b) (4) 12 Feb 2021 22:11:59

Generated On: 10 Jun 2021 07:56:44

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

Visit date (dd MMM yyyy)	20 JAN 2021
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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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US3512248

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Data signed: (b) (4) 19 Mar 2021 20:45:28

Generated On: 10 Jun 2021 07:56:44

Date of updated informed consent ( <i>dd MMM yyyy</i> )	20 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> )	20 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

US3512248

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing

Data signed: (b) (4) 12 Feb 2021 22:11:59

Generated On: 10 Jun 2021 07:56:44

Height	71.0 in
Weight	232.0 lb
BMI (xxx.x)	32.42509

US3512248

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 12 Feb 2021 22:11:59

Generated On: 10 Jun 2021 07:56:44

Height	71.0 in
Weight	232.0 lb
BMI (xxx.x)	32.42509
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)	20 JAN 2021
Time of assessment (00:00-23:59)	13:06 (24 HR)
Vital Signs Date and Time (derived)	20 JAN 2021 13:06
Temperature (xxx.x)	97.5 F
Route of measurement	Oral <input checked="" type="radio"/> Axillary <input type="radio"/> Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	64 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	12 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	126 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	71 mmHg
Diastolic Blood Pressure units	MMHG



US3512248

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 12 Feb 2021 22:11:59

Generated On: 10 Jun 2021 07:56:44

Height	71.0 in
Weight	232.0 lb
BMI (xxx.x)	32.42509
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)	20 JAN 2021
Time of assessment (00:00-23:59)	14:37 (24 HR)
Vital Signs Date and Time (derived)	20 JAN 2021 14:37
Temperature (xxx.x)	97.4 F
Route of measurement	Oral <input checked="" type="radio"/> Axillary <input type="radio"/> Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	65 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	14 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	113 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	59 mmHg
Diastolic Blood Pressure units	MMHG

US3512248

Folder: Participant Decision Visit / OL-D1 (1)

Form: Physical Examination

Data signed: (b) (4) 12 Feb 2021 22:11:59

Generated On: 10 Jun 2021 07:56:44

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Was the physical examination performed?

Yes ☒

No ☐

---

Date of examination (dd MMM yyyy)

20 JAN 2021

---

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

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US3512248

Folder: Participant Decision Visit / OL-D1 (1)

Form: Exposure

Data signed: (b) (4) 12 Feb 2021 22:11:59

Generated On: 10 Jun 2021 07:56:44

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) 20 JAN 2021

What was the treatment time? (00:00-23:59) 13:53 (24 HR)

Treatment Date and Time (derived) 20 JAN 2021 13:53

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

US3512248

Folder: Participant Decision Visit / OL-D1 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 12 Feb 2021 22:11:59

Generated On: 10 Jun 2021 07:56:44

Was the sample collected?

Yes ☒

No ☐

Collection date (dd MMM yyyy)

20 JAN 2021

Collection time (00:00-23:59)

12:53 (24 HR)

Collection date and time (derived)

20 JAN 2021 12:53

US3512248

Folder: Participant Decision Visit / OL-D1 (1)

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Data signed: (b) (4) 12 Feb 2021 22:11:59

Generated On: 10 Jun 2021 07:56:44

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

Collection date (dd MMM yyyy)	20 JAN 2021
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Collection time (00:00 - 23:59)	12:41
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Collection Date and Time (derived)	20 JAN 2021 12:41
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US3512248

Folder: Participant Decision Visit / OL-D1 (1)

Form: Continuing

Data signed: (b) (4) 12 Feb 2021 22:11:59

Generated On: 10 Jun 2021 07:56:44

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3512248

Folder: Safety Call OL-D8 (1)

Form: Safety Call

Data signed: (b) (4) 12 Feb 2021 22:11:59

Generated On: 10 Jun 2021 07:56:44

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

27 JAN 2021

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

*If Contact Not Made, please provide Comments*

US3512248

Folder: Safety Call OL-D8 (1)

Form: Continuing

Data signed: (b) (4) 12 Feb 2021 22:11:59

Generated On: 10 Jun 2021 07:56:44

Is the participant continuing to the next visit?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Continuing Flag	1
OLD29 Placebo Flag	1



US3512248

Folder: OL-D29 (1)

Form: Visit Date

Data signed: (b) (4) 31 Mar 2021 17:34:58

Generated On: 10 Jun 2021 07:56:44

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	25 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	OLD29

US3512248

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 31 Mar 2021 17:34:58

Generated On: 10 Jun 2021 07:56:44

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)	25 MAR 2021
Time of assessment (00:00-23:59)	13:44 (24 HR)
Vital Signs Date and Time (derived)	25 MAR 2021 13:44
Temperature (xxx.x)	97.2 F
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)	142 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	78 mmHg
Diastolic Blood Pressure units	MMHG

US3512248

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 31 Mar 2021 17:34:58

Generated On: 10 Jun 2021 07:56:44

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

US3512248

Folder: OL-D29 (1)

Form: Physical Examination

Data signed: (b) (4) 31 Mar 2021 17:34:58

Generated On: 10 Jun 2021 07:56:44

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

25 MAR 2021

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

US3512248

Folder: OL-D29 (1)

Form: Exposure

Data signed: (b) (4) 31 Mar 2021 17:34:58

Generated On: 10 Jun 2021 07:56:44

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

DUE TO SEPTIC ARTHRITIS IN THE LEFT ELBOW BOTH PI AND PMD ADVISED PT NOT TO HAVE 2ND VACCINE

What was the study treatment? (Unblinded) \_\_\_\_\_

What was the treatment date? (dd MMM yyyy) \_\_\_\_\_

What was the treatment time? (00:00-23:59) \_\_\_\_\_

Treatment Date and Time (derived) \_\_\_\_\_

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

What was the frequency of the study treatment dosing? \_\_\_\_\_

What was the route of administration for the study treatment? \_\_\_\_\_

US3512248

Folder: OL-D29 (1)

Form: Continuing

Data signed: (b) (4) 31 Mar 2021 17:34:58

Generated On: 10 Jun 2021 07:56:44

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3512248

Folder: Safety Call OL-D36 (1)

Form: Safety Call

Data signed: (b) (4) 02 Apr 2021 19:30:26

Generated On: 10 Jun 2021 07:56:44

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

1 APR 2021

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

*If Contact Not Made, please provide Comments*

US3512248

Folder: Safety Call OL-D36 (1)

Form: Continuing

Data signed: (b) (4) 02 Apr 2021 19:30:26

Generated On: 10 Jun 2021 07:56:44

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1



US3512248

Folder: OL-D57 (1)

Form: Visit Date

Data signed: (b) (4) 03 May 2021 15:14:06

Generated On: 10 Jun 2021 07:56:44

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	28 APR 2021
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	OLD57

US3512248

Folder: OL-D57 (1)

Form: Vital Signs

Data signed: (b) (4) 03 May 2021 15:14:06

Generated On: 10 Jun 2021 07:56:44

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) \_\_\_\_\_

US3512248

Folder: OL-D57 (1)

Form: Physical Examination

Data signed: (b) (4) 03 May 2021 15:14:06

Generated On: 10 Jun 2021 07:56:44

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.*

US3512248

Folder: OL-D57 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 03 May 2021 15:14:06

Generated On: 10 Jun 2021 07:56:44

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (dd MMM yyyy)	28 APR 2021
Collection time (00:00-23:59)	12:52 (24 HR)
Collection date and time (derived)	28 APR 2021 12:52

US3512248

Folder: Adverse Events

Form: Adverse Events Summary

Data signed: (b) (4) 12 Feb 2021 22:11:59

Generated On: 10 Jun 2021 07:56:44

---

Did the participant experience any adverse events?

Yes ☒

No ☐

---

If Yes, enter details on the Adverse Events form.

---

US3512248

Folder: Adverse Events

Form: Adverse Events (1)

Data signed: (b) (4) 20 Apr 2021 12:50:37

Generated On: 10 Jun 2021 07:56:44

AEID

Adverse event

RIGHT HIP TROCHANTERIC  
BURSITIS

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)

5 OCT 2020

Start time (00:00-23:59)

AE start date and time (derived)

Ongoing?

Yes ☐

No ☒

If not Ongoing, end date (dd MMM yyyy)

5 OCT 2020

End time (00:00-23:59)

AE End Date and Time (derived)

Severity

Grade 1/Mild ☐

Grade 2/Moderate ☒

Grade 3/Severe ☐

Grade 4 ☐

Is the adverse event serious?

Yes ☐

No ☒

AE is serious due To (check all that apply)

Death

False

Life threatening

False

Requires inpatient or prolongation of existing Hospitalization

False

Hospital Admission Date (dd MMM yyyy)

Hospital Discharge Date (dd MMM yyyy)

Admitted to ICU?

Yes ☐

No ☐

Unknown ☐

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EAB) (1725)

US3512248

Folder: Adverse Events

Form: Adverse Events (1)

Data signed: (b) (4) 20 Apr 2021 12:50:37

Generated On: 10 Jun 2021 07:56:44

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 checked="" type="radio"/> Dose Delayed <input type="radio"/> Investigational Product Withdrawn <input type="radio"/> Not Applicable <input type="radio"/>
Other action taken (check all that apply)	
None	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)	

US3512248

Folder: Adverse Events

Form: Adverse Events (2)

Data signed: (b) (4) 20 Apr 2021 12:50:37

Generated On: 10 Jun 2021 07:56:44

AEID	
Adverse event	HYPERTENSION
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)	17 SEP 2020
Start time (00:00-23:59)	
AE start date and time (derived)	
Ongoing?	Yes <input checked="" type="radio"/> No <input type="radio"/>
If not Ongoing, end date (dd MMM yyyy)	
End time (00:00-23:59)	
AE End Date and Time (derived)	
Severity	Grade 1/Mild <input type="radio"/> Grade 2/Moderate <input checked="" type="radio"/> Grade 3/Severe <input type="radio"/> Grade 4 <input type="radio"/>
Is the adverse event serious?	Yes <input 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 (2)

Data signed: (b) (4) 20 Apr 2021 12:50:37

Generated On: 10 Jun 2021 07:56:44

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 checked="" type="radio"/> Dose Delayed <input type="radio"/> Investigational Product <input type="radio"/> 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 checked="" type="radio"/> Recovered/Resolved <input type="radio"/> Recovered/Resolved with Sequelae <input type="radio"/> Recovering/Resolving <input type="radio"/> Unknown <input type="radio"/>
If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:	
<hr/>	
Narrative	
<hr/>	
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 (3)

Data signed: (b) (4) 20 Apr 2021 12:50:37

Generated On: 10 Jun 2021 07:56:44

AEID

Adverse event

WORSENER RIGHT TEMPLE  
AND LEFT FOREARM ACTINIC  
KERATOSIS

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)

3 FEB 2021

Start time (00:00-23:59)

AE start date and time (derived)

Ongoing?

Yes ☐

No ☒

If not Ongoing, end date (dd MMM yyyy)

3 FEB 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 (3)

Data signed: (b) (4) 20 Apr 2021 12:50:37

Generated On: 10 Jun 2021 07:56:44

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 checked="" type="radio"/> Dose Delayed <input type="radio"/> Investigational Product Withdrawn <input type="radio"/> Not Applicable <input type="radio"/>
Other action taken (check all that apply)	
None	False
Concomitant Medication	False
Concomitant Procedure	True
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)	0
Admitted to ICU Derived (CSA Programming Field Only)	

US3512248

Folder: Adverse Events

Form: Adverse Events (4)

Data signed: (b) (4) 20 Apr 2021 12:50:37

Generated On: 10 Jun 2021 07:56:44

AEID	USA-US065-2021-MRNA-1273-P30 1000005
Adverse event	LEFT ELBOW SEPTIC ARTHRITS
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)	24 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)	12 APR 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)	25 FEB 2021
Hospital Discharge Date (dd MMM yyyy)	26 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 (4)

Data signed: (b) (4) 20 Apr 2021 12:50:37

Generated On: 10 Jun 2021 07:56:44

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 checked="" 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:	SUBJECT DISCONTINUED ALL ASSOCIATED MEDICATIONS BY 05MAR2021 AND AT LAST IN CLINIC VISIT IT WAS NOTED THAT THE REDNESS HAD RESOLVED AND THE SWELLING AND TENDERNESS WAS MOVING TOWARDS RESOLUTION.

US3512248

Folder: Adverse Events

Form: Adverse Events (4)

Data signed: (b) (4) 20 Apr 2021 12:50:37

Generated On: 10 Jun 2021 07:56:44

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[Narrative](#)

FIRST SEEN AT THE CLINICAL SITE ON 2/24/21 WITH WARM, ERYTHEMATOUS LEFT ELBOW.

PARTICIPANT DENIED DECREASES IN RANGE OF MOTION. HE WAS EXAMINED BY DR. KOREN ON 2/24/21 NOTING AN ORAL TEMPERATURE OF 99.5. DR.

KOREN SPOKE TO PARTICIPANTS PCP AND ORDERED 500MG KEFLEX BID FOR 7 DAYS, ADVISED MOIST HEAT TO HIS ARM AND A FOLLOW UP VISIT WITH HIS PCP ON 2/25/21.

PARTICIPANT WAS SEEN BY PCP ON 2/25/21 AND REFERRED TO THE HOSPITAL WHERE HE WAS ADMITTED ON 2/25/21 DUE TO LEFT ELBOW SEPTIC ARTHRITIS. HE WAS GIVEN IV VANCOMYCIN. DISCHARGED ON 02/26/21 ZYVOX 600 MG BID FOR 7 DAYS. CONCERN WAS THAT FINDINGS MAY HAVE BEEN RELATED TO INITIAL BURSITIS WHICH PROGRESSED TO SEPTIC ARTHRITIS.

3/11/2021 AT 11:18, OL-29 VISIT: PARTICIPANTS VITAL SIGNS WERE BP: 131/71 MMHG, HR: 71 B/MIN, ORAL

US3512248

Folder: Adverse Events

Form: Adverse Events (4)

Data signed: (b) (4) 20 Apr 2021 12:50:37

Generated On: 10 Jun 2021 07:56:44

---

TEMPERATURE: 97.7, HEIGHT:  
71 INCHES. WEIGHT: 224.0 LBS.  
PARTICIPANT STILL HAS  
EVIDENCE OF JOINT  
SYMPTOMS OF LEFT ELBOW  
INCLUDING SWELLING,  
ERYTHEMA AND DISCOMFORT.  
SUGGESTED 2 WEEK VACCINE  
DELAY BY INVESTIGATOR OR  
AS DIRECTED BY HIS PCP.

---

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

---

US3512248

Folder: Adverse Events

Form: Adverse Events (5)

Data signed: (b) (4) 20 Apr 2021 12:50:37

Generated On: 10 Jun 2021 07:56:44

AEID	
Adverse event	COVID LIKE-ILLNESS
Was this a medically-attended AE?	Yes <input type="radio"/> No <input checked="" 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)	23 JAN 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)	14 FEB 2021
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	



US3512248

Folder: Adverse Events

Form: Adverse Events (5)

Data signed: (b) (4) 20 Apr 2021 12:50:37

Generated On: 10 Jun 2021 07:56:44

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 checked="" type="radio"/> Dose Delayed <input type="radio"/> Investigational Product <input type="radio"/> 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	
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)	

US3512248

Folder: Adverse Events

Form: Adverse Events (6)

Data signed: (b) (4) 20 Apr 2021 12:50:37

Generated On: 10 Jun 2021 07:56:44

AEID	
Adverse event	
Was this a medically-attended AE?	Yes <input type="checkbox"/> No <input type="checkbox"/>
Was this a Solicited Adverse Reaction?	Yes <input type="checkbox"/> No <input type="checkbox"/>
Is this event a confirmed diagnosis of Symptomatic Covid-19?	Yes <input type="checkbox"/> No <input type="checkbox"/>
Start date (dd MMM yyyy)	
Start time (00:00-23:59)	
AE start date and time (derived)	
Ongoing?	Yes <input type="checkbox"/> No <input type="checkbox"/>
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 type="checkbox"/> Grade 2/Moderate <input type="checkbox"/> Grade 3/Severe <input type="checkbox"/> Grade 4 <input type="checkbox"/>
Is the adverse event serious?	Yes <input type="checkbox"/> No <input type="checkbox"/>
AE is serious due To (check all that apply)	
Death	
Life threatening	
Requires inpatient or prolongation of existing Hospitalization	
Hospital Admission Date (dd MMM yyyy)	
Hospital Discharge Date (dd MMM yyyy)	
Admitted to ICU?	Yes <input type="checkbox"/> No <input type="checkbox"/> Unknown <input type="checkbox"/>
Number of Days in ICU	

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Folder: Adverse Events

Form: Adverse Events (6)

Data signed: (b) (4) 20 Apr 2021 12:50:37

Generated On: 10 Jun 2021 07:56:44

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Data signed: (b) (4) 12 Feb 2021 22:11:59

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---

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

Yes ☒

No ☐

---

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

---

US3512248

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Data signed: (b) (4) 08 Apr 2021 12:06:51

Generated On: 10 Jun 2021 07:56:44

Name of Medication ATORVASTATIN

Prophylaxis Yes ☐  
No ☒

Indication HYPERCHOLESTEROLEMIA

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

Route of administration Oral ☒  
Topical ☐  
Subcutaneous ☐  
Transdermal ☐  
Intraocular ☐

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US3512248

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Data signed: (b) (4) 08 Apr 2021 12:06:51

Generated On: 10 Jun 2021 07:56:44

	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 2006	
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Data signed: (b) (4) 08 Apr 2021 12:06:51

Generated On: 10 Jun 2021 07:56:44

Name of Medication OMEPRAZOLE

Prophylaxis Yes ☐  
No ☒

Indication GASTROESOPHAGEAL REFLUX  
DISEASE

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 ☐

PRODUCTION RELEASE (v12.003  
EAB) (1725)

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Data signed: (b) (4) 08 Apr 2021 12:06:51

Generated On: 10 Jun 2021 07:56:44

	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 JAN 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 (3)

Data signed: (b) (4) 08 Apr 2021 12:06:51

Generated On: 10 Jun 2021 07:56:44

Name of Medication TAMULOSIN

Prophylaxis Yes ☐  
No ☒

Indication BENIGN PROSTATIC  
HYPERPLASIA

Dose per administration 0.4

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 (3)

Data signed: (b) (4) 08 Apr 2021 12:06:51

Generated On: 10 Jun 2021 07:56:44

	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 JAN 2014
Start date completely unknown		False
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)		1
Interval Dosage Unit Number (derived)		1
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Data signed: (b) (4) 08 Apr 2021 12:06:51

Generated On: 10 Jun 2021 07:56:44

Name of Medication SYMBICORT (160MCG/4.5MCG)

Prophylaxis Yes ☐  
No ☒

Indication CHRONIC OBSTRUCTIVE  
PULMONARY DISEASE

Dose per administration 2

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

If dose unit is Other, specify

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

If frequency is Other, specify

Route of administration Oral ☐  
Topical ☐  
Subcutaneous ☐  
Transdermal ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Data signed: (b) (4) 08 Apr 2021 12:06:51

Generated On: 10 Jun 2021 07:56:44

	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 AUG 2020	
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Data signed: (b) (4) 08 Apr 2021 12:06:51

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Name of Medication ALBUTEROL

Prophylaxis Yes ☐  
No ☒

Indication CHRONIC OBSTRUCTIVE  
PULMONARY DISEASE

Dose per administration 90

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) 08 Apr 2021 12:06:51

Generated On: 10 Jun 2021 07:56:44

	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 MAY 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)		
Interval Dosage Unit Number (derived)		
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input type="checkbox"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Data signed: (b) (4) 08 Apr 2021 12:06:51

Generated On: 10 Jun 2021 07:56:44

Name of Medication B12

Prophylaxis Yes ☒  
No ☐

Indication SUPPLEMENT

Dose per administration 1000

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

If dose unit is Other, specify

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

If frequency is Other, specify

Route of administration Oral ☒  
Topical ☐  
Subcutaneous ☐  
Transdermal ☐  
Intraocular ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Data signed: (b) (4) 08 Apr 2021 12:06:51

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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)	UN JAN 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 (7)

Data signed: (b) (4) 08 Apr 2021 12:06:51

Generated On: 10 Jun 2021 07:56:44

Name of Medication OCUVITE PRESERVISION EYE  
VITAMIN AREDS 2 (ZINC 17.4  
MG; VITAMIN C 113 MG;  
VITAMIN E 100 IU; OMEGA-3 250  
MG; LUTEIN 2.5 MG;  
ZEAXANTHIN 2 MG)

Prophylaxis Yes ☒  
No ☐

Indication SUPPLEMENT

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 ☒

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Data signed: (b) (4) 08 Apr 2021 12:06:51

Generated On: 10 Jun 2021 07:56:44

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Data signed: (b) (4) 08 Apr 2021 12:06:51

Generated On: 10 Jun 2021 07:56:44

Name of Medication IBUPROFEN

Prophylaxis Yes ☐  
No ☒

Indication GENERAL ACHES AND PAINS

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 (8)

Data signed: (b) (4) 08 Apr 2021 12:06:51

Generated On: 10 Jun 2021 07:56:44

	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 2006	
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) 08 Apr 2021 12:06:51

Generated On: 10 Jun 2021 07:56:44

Name of Medication ELIQUIS

Prophylaxis Yes ☐  
No ☒

Indication ATRIAL FIBRILLATION

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

Route of administration Oral ☒  
Topical ☐  
Subcutaneous ☐  
Transdermal ☐  
Intraocular ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Data signed: (b) (4) 08 Apr 2021 12:06:51

Generated On: 10 Jun 2021 07:56:44

	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 APR 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)	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 (10)

Data signed: (b) (4) 08 Apr 2021 12:06:51

Generated On: 10 Jun 2021 07:56:44

Name of Medication ASPIRIN

Prophylaxis Yes ☐  
No ☒

Indication CORONARY ARTERY DISEASE

Dose per administration 81

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 (10)

Data signed: (b) (4) 08 Apr 2021 12:06:51

Generated On: 10 Jun 2021 07:56:44

	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 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"/>



US3512248

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Data signed: (b) (4) 08 Apr 2021 12:06:51

Generated On: 10 Jun 2021 07:56:44

Name of Medication MOTRIN

Prophylaxis Yes ☐  
No ☒

Indication LEFT MENISCUS TEAR

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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EAB) (1725)

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US3512248

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Data signed: (b) (4) 08 Apr 2021 12:06:51

Generated On: 10 Jun 2021 07:56:44

	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)		16 JUL 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)		_____
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) 08 Apr 2021 12:06:51

Generated On: 10 Jun 2021 07:56:44

Name of Medication LOSARTAN

Prophylaxis Yes ☐  
No ☒

Indication HYPERTENSION

Dose per administration 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 ☒  
Topical ☐  
Subcutaneous ☐  
Transdermal ☐  
Intraocular ☐

PRODUCTION RELEASE (v12.003

EAB) (1725)

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Data signed: (b) (4) 08 Apr 2021 12:06:51

Generated On: 10 Jun 2021 07:56:44

	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)		17 SEP 2020
Start date completely unknown		False
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)		1
Interval Dosage Unit Number (derived)		1
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Data signed: (b) (4) 08 Apr 2021 12:06:51

Generated On: 10 Jun 2021 07:56:44

Name of Medication	LIDOCAINE 1%
Prophylaxis	Yes <input type="radio"/> No <input checked="" type="radio"/>
Indication	RIGHT HIP TROCHANTERIC BURSITIS
Dose per administration	4
Dose unit	mg <input type="radio"/> ug <input type="radio"/> mL <input type="radio"/> g <input type="radio"/> IU <input type="radio"/> tablet <input type="radio"/> capsule <input type="radio"/> puff <input type="radio"/> Other <input checked="" type="radio"/>
If dose unit is Other, specify	CC
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 type="radio"/> once <input checked="" type="radio"/> unknown <input type="radio"/> other <input type="radio"/>
If frequency is Other, specify	
Route of administration	Oral <input type="radio"/> Topical <input type="radio"/> Subcutaneous <input type="radio"/> Transdermal <input type="radio"/>

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EAB) (1725)

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Data signed: (b) (4) 08 Apr 2021 12:06:51

Generated On: 10 Jun 2021 07:56:44

	Intraocular	<input type="radio"/>
	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	INTRABURSAL	
Start date (dd MMM yyyy)	05 OCT 2020	
Start date completely unknown	False	
Ongoing?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
If not Ongoing, End date (dd MMM yyyy)	5 OCT 2020	
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)		
Interval Dosage Unit Number (derived)		
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input type="radio"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Data signed: (b) (4) 08 Apr 2021 12:06:51

Generated On: 10 Jun 2021 07:56:44

Name of Medication KENALOG

Prophylaxis Yes ☐  
No ☒

Indication RIGHT HIP TROCHANTERIC  
BURSITIS

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 (14)

Data signed: (b) (4) 08 Apr 2021 12:06:51

Generated On: 10 Jun 2021 07:56:44

	Intraocular	<input type="radio"/>
	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	INTRABURSAL	
Start date (dd MMM yyyy)	05 OCT 2020	
Start date completely unknown	False	
Ongoing?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
If not Ongoing, End date (dd MMM yyyy)	5 OCT 2020	
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)		
Interval Dosage Unit Number (derived)		
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input type="radio"/>



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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Data signed: (b) (4) 08 Apr 2021 12:06:51

Generated On: 10 Jun 2021 07:56:44

Name of Medication ROBITUSSIN  
(DEXTROMETHOPHRAN  
GUAIFENESIN 20/200

Prophylaxis Yes ☐  
No ☒

Indication COVID LIKE-ILLNESS

Dose per administration 20/200

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 ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Data signed: (b) (4) 08 Apr 2021 12:06:51

Generated On: 10 Jun 2021 07:56:44

	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)		1 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)		14 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 (16)

Data signed: (b) (4) 08 Apr 2021 12:06:51

Generated On: 10 Jun 2021 07:56:44

Name of Medication KEFLEX

Prophylaxis Yes ☐  
No ☒

Indication LEFT ELBOW SEPTIC  
ARTHRITIS

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 ☐

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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) 08 Apr 2021 12:06:51

Generated On: 10 Jun 2021 07:56:44

	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)	24 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)		3 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 (17)

Data signed: (b) (4) 08 Apr 2021 12:06:51

Generated On: 10 Jun 2021 07:56:44

Name of Medication VANCOMYCIN

Prophylaxis Yes ☐  
No ☒

Indication LEFT ELBOW SEPTIC ARTHRITIS

Dose per administration 1

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

If dose unit is Other, specify GRAM

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 (17)

Data signed: (b) (4) 08 Apr 2021 12:06:51

Generated On: 10 Jun 2021 07:56:44

	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 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)		25 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)		25 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 (18)

Data signed: (b) (4) 08 Apr 2021 12:06:51

Generated On: 10 Jun 2021 07:56:44

Name of Medication ZYVOX

Prophylaxis Yes ☐  
No ☒

Indication LEFT ELBOW SEPTIC ARTHRITIS

Dose per administration 600

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 (18)

Data signed: (b) (4) 08 Apr 2021 12:06:51

Generated On: 10 Jun 2021 07:56:44

	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)	26 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)		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 (19)

Data signed: (b) (4) 08 Apr 2021 12:06:51

Generated On: 10 Jun 2021 07:56:44

Name of Medication B6 VITAMIN

Prophylaxis Yes ☒  
No ☐

Indication DIETARY SUPPLEMENT

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) 08 Apr 2021 12:06:51

Generated On: 10 Jun 2021 07:56:44

	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)	3 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)	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 Procedures (1)

Form: Concomitant Procedures Summary

Data signed: (b) (4) 12 Feb 2021 22:11:59

Generated On: 10 Jun 2021 07:56:44

---

Were any concomitant procedures performed?

Yes ☒

No ☐

---

If yes, please complete Concomitant Procedures form.

---

US3512248

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures

Data signed: (b) (4) 15 Mar 2021 12:52:31

Generated On: 10 Jun 2021 07:56:44

Procedure/Surgery date (dd MMM yyyy)	Procedure/Surgery	Indication	If indication is Other, specify
03 FEB 2021	CRYOTHERAPY	Adverse Event	

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Folder: End of Study (1)

Form: Dosing Discontinuation

Generated On: 10 Jun 2021 07:56:44

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

US3512248

Folder: End of Study (1)

Form: End of Study / Study Discontinuation

Generated On: 10 Jun 2021 07:56:44

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 ☐

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Folder: SAE USA-US065-2021-MRNA-1273-P301000005

Form: Safety Report Form

Data signed: (b) (4) 14 Apr 2021 16:45:45

Generated On: 10 Jun 2021 07:56:44

SAEID	USA-US065-2021-MRNA-1273-P301000005
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input type="radio"/> No <input checked="" type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input checked="" type="radio"/> No <input type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input type="radio"/> No <input checked="" type="radio"/>
Investigator's First Name	MICHAEL
Investigator's Last Name	KOREN
Site Address: Street	
Site Address: City	
Site Address: State	
Site Address: Postal Code	
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	3

US3512248

Folder: SAE USA-US065-2021-MRNA-1273-P301000005

Form: Safety Report Form (1)

Data signed: (b) (4) 14 Apr 2021 16:45:45

Generated On: 10 Jun 2021 07:56:44

SAEID	USA-US065-2021-MRNA-1273-P301000005
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input type="radio"/> No <input checked="" type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input checked="" type="radio"/> No <input type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input type="radio"/> No <input checked="" type="radio"/>
Investigator's First Name	MICHAEL
Investigator's Last Name	KOREN
Site Address: Street	
Site Address: City	
Site Address: State	
Site Address: Postal Code	
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	3
Date of submission (Pre-filled from custom function)	12/MAR/2021 13:32
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



US3512248

Folder: SAE USA-US065-2021-MRNA-1273-P301000005

Form: Safety Report Form (2)

Data signed: (b) (4) 14 Apr 2021 16:45:45

Generated On: 10 Jun 2021 07:56:44

SAEID	USA-US065-2021-MRNA-1273-P301000005
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input type="radio"/> No <input checked="" type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input checked="" type="radio"/> No <input type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input type="radio"/> No <input checked="" type="radio"/>
Investigator's First Name	MICHAEL
Investigator's Last Name	KOREN
Site Address: Street	
Site Address: City	
Site Address: State	
Site Address: Postal Code	
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	3
Date of submission (Pre-filled from custom function)	30/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

US3512248

Folder: SAE USA-US065-2021-MRNA-1273-P301000005

Form: Safety Report Form (3)

Data signed: (b) (4) 14 Apr 2021 16:45:45

Generated On: 10 Jun 2021 07:56:44

SAEID	USA-US065-2021-MRNA-1273-P301000005
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input type="radio"/> No <input checked="" type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input checked="" type="radio"/> No <input type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input type="radio"/> No <input checked="" type="radio"/>
Investigator's First Name	MICHAEL
Investigator's Last Name	KOREN
Site Address: Street	
Site Address: City	
Site Address: State	
Site Address: Postal Code	
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	3
Date of submission (Pre-filled from custom function)	13/APR/2021 08:00
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

US3512248 (Prod: Jacksonville Center for Clinical Research Center)

**US3512248**

**Form: Participant Creation**

**Generated On: 10 Jun 2021 07:56:44**

[Participant ID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 19:43:13
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 22:12:02
User entered 'US3512248'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	10 Sep 2020 15:44:33

**US3512248**

**Folder: Screening**

**Form: Visit Date**

**Generated On: 10 Jun 2021 07:56:44**

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:21:08
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 22:12:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Oct 2020 13:51:13
User entered 'Yes (Y)'	Allison Crain (b) (4) (b) (4)	10 Sep 2020 16:59:28

**US3512248**

**Folder: Screening**

**Form: Visit Date**

**Generated On: 10 Jun 2021 07:56:44**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:21:08
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 22:12:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Oct 2020 13:51:13
User entered '10 SEP 2020'	RWS_ENDPOINT ENDPOINT (b) (4)	10 Sep 2020 15:44:34

**US3512248**

**Folder: Screening**

**Form: Visit Date**

**Generated On: 10 Jun 2021 07:56:44**

[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 10:21:08
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 22:12:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Oct 2020 13:51:13
User entered 'Clinic (Clinic)'	Allison Crain (b) (4) (b) (4)	10 Sep 2020 16:59:28

**US3512248**

**Folder: Screening**

**Form: Visit Date**

**Generated On: 10 Jun 2021 07:56:44**

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:21:08
User entered 'SCRN'	System	10 Sep 2020 16:59:28



US3512248

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 07:56:44

[Date of Birth \(MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:21:08
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 22:12:02
DataPoint Verified.	(b) (4)	(b) (4), (b) (6)
User entered (b) (6) 1943'	RWS_ENDPOINT ENDPOINT (b) (4)	07 Oct 2020 13:51:22
		10 Sep 2020 15:44:35

US3512248

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 07:56:44

[Age](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:21:08
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 22:12:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Oct 2020 13:51:22
User entered '76'	Allison Crain (b) (4) (b) (4)	10 Sep 2020 16:59:46

**US3512248**

**Folder: Screening**

**Form: Demographics**

**Generated On: 10 Jun 2021 07:56:44**

[Age Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:21:08
User entered 'YEARS'	System	10 Sep 2020 16:59:46

**US3512248**

**Folder: Screening**

**Form: Demographics**

**Generated On: 10 Jun 2021 07:56:44**

[Age \(Derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:21:08
User entered '77'	System	10 Sep 2020 17:00:04

**US3512248**

**Folder: Screening**

**Form: Demographics**

**Generated On: 10 Jun 2021 07:56:44**

[Sex](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:21:08
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 22:12:02
DataPoint Verified.	(b) (4)	(b) (4), (b) (6)
User entered 'Male (M)'	Allison Crain (b) (4)	10 Sep 2020 16:59:46
	(b) (4)	

US3512248

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 07:56:44

[Ethnicity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:21:08
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 22:12:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Oct 2020 13:51:22
User entered 'Not Hispanic or Latino (NOT HISPANIC OR LATINO)'	Allison Crain (b) (4) (b) (4)	10 Sep 2020 16:59:46

**US3512248**

**Folder: Screening**

**Form: Demographics**

**Generated On: 10 Jun 2021 07:56:44**

[White](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:21:08
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 22:12:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Oct 2020 13:51:22
User entered 'I'	Allison Crain (b) (4) (b) (4)	10 Sep 2020 16:59:46

US3512248

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 07:56:44

[Black](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:21:08
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 22:12:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Oct 2020 13:51:22
User entered '0'	Allison Crain (b) (4) (b) (4)	10 Sep 2020 16:59:46



**US3512248**

**Folder: Screening**

**Form: Demographics**

**Generated On: 10 Jun 2021 07:56:44**

[Asian](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:21:08
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 22:12:02
DataPoint Verified.	(b) (4)	(b) (4), (b) (6)
User entered '0'	Allison Crain (b) (4)	10 Sep 2020 16:59:46
	(b) (4)	

**US3512248**

**Folder: Screening**

**Form: Demographics**

**Generated On: 10 Jun 2021 07:56:44**

[American Indian or Alaska Native](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:21:08
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 22:12:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Oct 2020 13:51:22
User entered '0'	Allison Crain (b) (4) (b) (4)	10 Sep 2020 16:59:46

**US3512248**

**Folder: Screening**

**Form: Demographics**

**Generated On: 10 Jun 2021 07:56:44**

[Native Hawaiian or other Pacific Islander](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:21:08
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 22:12:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Oct 2020 13:51:22
User entered '0'	Allison Crain (b) (4) (b) (4)	10 Sep 2020 16:59:46

**US3512248**

**Folder: Screening**

**Form: Demographics**

**Generated On: 10 Jun 2021 07:56:44**

[Other](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:21:08
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 22:12:02
DataPoint Verified.	(b) (4)	(b) (4), (b) (6)
User entered '0'	Allison Crain (b) (4)	10 Sep 2020 16:59:46
	(b) (4)	

**US3512248**

**Folder: Screening**

**Form: Demographics**

**Generated On: 10 Jun 2021 07:56:44**

[If race is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:21:08
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 22:12:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Oct 2020 13:51:22
User entered empty.	Allison Crain (b) (4) (b) (4)	10 Sep 2020 16:59:46

**US3512248**

**Folder: Screening**

**Form: Demographics**

**Generated On: 10 Jun 2021 07:56:44**

[Unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:21:08
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 22:12:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Oct 2020 13:51:22
User entered '0'	Allison Crain (b) (4) (b) (4)	10 Sep 2020 16:59:46

**US3512248**

**Folder: Screening**

**Form: Demographics**

**Generated On: 10 Jun 2021 07:56:44**

[Not reported](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:21:08
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 22:12:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Oct 2020 13:51:22
User entered '0'	Allison Crain (b) (4) (b) (4)	10 Sep 2020 16:59:46

US3512248

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 07:56:44

Date of Informed Consent (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:21:08
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 22:12:02
DataPoint Verified.	(b) (4)	(b) (4), (b) (6)
User entered '10 Sep 2020'	Allison Crain (b) (4)	10 Sep 2020 17:00:04
	(b) (4)	



**US3512248**

**Folder: Screening**

**Form: Enrollment**

**Generated On: 10 Jun 2021 07:56:44**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:21:08
User entered 'Sep 2020'	System	10 Sep 2020 17:00:04

**US3512248**

**Folder: Screening**

**Form: Enrollment**

**Generated On: 10 Jun 2021 07:56:44**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:21:08
User entered '2020'	System	10 Sep 2020 17:00:04

**US3512248**

**Folder: Screening**

**Form: Enrollment**

**Generated On: 10 Jun 2021 07:56:44**

[Protocol Version](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:21:08
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 22:12:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Oct 2020 13:51:29
User entered 'Amendment 3 (3)'	Allison Crain (b) (4) (b) (4)	10 Sep 2020 17:00:04

**US3512248**

**Folder: Screening**

**Form: Enrollment**

**Generated On: 10 Jun 2021 07:56:44**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:21:08
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 22:12:02
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	07 Oct 2020 13:51:29
User entered 'Yes (Y)'	Allison Crain (b) (4)	10 Sep 2020 17:00:04
	(b) (4)	

**US3512248**

**Folder: Screening**

**Form: Enrollment**

**Generated On: 10 Jun 2021 07:56:44**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:21:08
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 22:12:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Oct 2020 13:51:29
User entered empty.	Allison Crain (b) (4) (b) (4)	10 Sep 2020 17:00:04

**US3512248**

**Folder: Screening**

**Form: Enrollment**

**Generated On: 10 Jun 2021 07:56:44**

If reason for screen fail is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:21:08
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 22:12:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Oct 2020 13:51:29
User entered empty.	Allison Crain (b) (4) (b) (4)	10 Sep 2020 17:00:04

**US3512248**

**Folder: Screening**

**Form: Enrollment**

**Generated On: 10 Jun 2021 07:56:44**

[Was this participant screened previously?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:21:08
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 22:12:02
DataPoint Verified.	(b) (4)	(b) (4), (b) (6)
	(b) (4), (b) (6)	07 Oct 2020 13:51:29
User entered 'No (N)'	Allison Crain (b) (4)	10 Sep 2020 17:00:04
	(b) (4)	

**US3512248**

**Folder: Screening**

**Form: Enrollment**

**Generated On: 10 Jun 2021 07:56:44**

[If Yes, previous participant number](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:21:08
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 22:12:02
DataPoint Verified.	(b) (4)	07 Oct 2020 13:51:29
User entered empty.	(b) (4), (b) (6)	10 Sep 2020 15:44:34
	RWS_ENDPOINT	
	ENDPOINT (b) (4)	



US3512248

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 07:56:44

[Enrollment Trigger](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:21:08
User entered 'I'	System	10 Sep 2020 17:00:09

**US3512248**

**Folder: Screening**

**Form: Inclusion/Exclusion Criteria Summary**

**Generated On: 10 Jun 2021 07:56:44**

[Did the participant meet all eligibility criteria?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:21:08
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 22:12:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Oct 2020 13:51:39
User entered 'Yes (Y)'	Allison Crain (b) (4) (b) (4)	10 Sep 2020 17:00:09

US3512248

Folder: Screening

Form: Medical History Summary

Generated On: 10 Jun 2021 07:56:44

[Were any significant conditions reported?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:21:08
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 22:12:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Oct 2020 13:51:45
User entered 'Yes (Y)'	Allison Crain (b) (4) (b) (4)	10 Sep 2020 17:14:09

US3512248

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 07:56:44

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:21:08
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 22:12:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Oct 2020 13:51:55
User coded data point as SOC: Immune system disorders, HLGT: Allergic conditions, HLT: Atopic disorders, PT: Seasonal allergy, LLT: Seasonal allergy - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	10 Sep 2020 17:59:47
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	10 Sep 2020 17:59:47
Data point term sent to Coder	System	10 Sep 2020 17:59:01
User entered 'SEASONAL ALLERGIES'	Allison Crain (b) (4) (b) (4)	10 Sep 2020 17:58:59

**US3512248**

**Folder: Screening**

**Form: Medical History (1)**

**Generated On: 10 Jun 2021 07:56:44**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:21:08
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 22:12:02
DataPoint Verified.	(b) (4)	(b) (4), (b) (6)
	(b) (4), (b) (6)	07 Oct 2020 13:51:55
User entered 'UN UNK 1950'	Allison Crain (b) (4)	10 Sep 2020 17:58:59
	(b) (4)	

**US3512248**

**Folder: Screening**

**Form: Medical History (1)**

**Generated On: 10 Jun 2021 07:56:44**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:21:08
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 22:12:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Oct 2020 13:51:55
User entered '0'	Allison Crain (b) (4) (b) (4)	10 Sep 2020 17:58:59

**US3512248**

**Folder: Screening**

**Form: Medical History (1)**

**Generated On: 10 Jun 2021 07:56:44**

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:21:08
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 22:12:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Oct 2020 13:51:55
User entered 'Yes (Y)'	Allison Crain (b) (4) (b) (4)	10 Sep 2020 17:58:59

**US3512248**

**Folder: Screening**

**Form: Medical History (1)**

**Generated On: 10 Jun 2021 07:56:44**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:21:08
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 22:12:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Oct 2020 13:51:55
User entered empty.	Allison Crain (b) (4) (b) (4)	10 Sep 2020 17:58:59



**US3512248**

**Folder: Screening**

**Form: Medical History (1)**

**Generated On: 10 Jun 2021 07:56:44**

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:21:08
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 22:12:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Oct 2020 13:51:55
User entered '0'	Allison Crain (b) (4) (b) (4)	10 Sep 2020 17:58:59

**US3512248**

**Folder: Screening**

**Form: Medical History (1)**

**Generated On: 10 Jun 2021 07:56:44**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:21:08
User entered 'Jan 1950'	System	10 Sep 2020 17:58:59

**US3512248**

**Folder: Screening**

**Form: Medical History (1)**

**Generated On: 10 Jun 2021 07:56:44**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:21:08
User entered '1950'	System	10 Sep 2020 17:58:59

**US3512248**

**Folder: Screening**

**Form: Medical History (1)**

**Generated On: 10 Jun 2021 07:56:44**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:21:08
User entered empty.	System	10 Sep 2020 17:58:59

**US3512248**

**Folder: Screening**

**Form: Medical History (1)**

**Generated On: 10 Jun 2021 07:56:44**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:21:08
User entered empty.	System	10 Sep 2020 17:58:59

US3512248

Folder: Screening

Form: Medical History (2)

Generated On: 10 Jun 2021 07:56:44

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:21:08
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 22:12:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Oct 2020 13:51:55
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) (b) (4)	10 Sep 2020 18:00:51
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	10 Sep 2020 18:00:51
Data point term sent to Coder	System	10 Sep 2020 18:00:07
User entered 'GASTROESOPHAGEAL REFLUX DISEASE'	Allison Crain (b) (4) (b) (4)	10 Sep 2020 17:59:18

**US3512248**

**Folder: Screening**

**Form: Medical History (2)**

**Generated On: 10 Jun 2021 07:56:44**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:21:08
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 22:12:02
DataPoint Verified.	(b) (4)	(b) (4), (b) (6)
	(b) (4), (b) (6)	07 Oct 2020 13:51:55
User entered 'UN UNK 2008'	Allison Crain (b) (4)	10 Sep 2020 17:59:18
	(b) (4)	

**US3512248**

**Folder: Screening**

**Form: Medical History (2)**

**Generated On: 10 Jun 2021 07:56:44**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:21:08
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 22:12:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Oct 2020 13:51:55
User entered '0'	Allison Crain (b) (4) (b) (4)	10 Sep 2020 17:59:18



**US3512248**

**Folder: Screening**

**Form: Medical History (2)**

**Generated On: 10 Jun 2021 07:56:44**

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:21:08
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 22:12:02
DataPoint Verified.	(b) (4)	(b) (4), (b) (6)
	(b) (4), (b) (6)	07 Oct 2020 13:51:55
User entered 'Yes (Y)'	Allison Crain (b) (4)	10 Sep 2020 17:59:18
	(b) (4)	

**US3512248**

**Folder: Screening**

**Form: Medical History (2)**

**Generated On: 10 Jun 2021 07:56:44**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:21:08
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 22:12:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Oct 2020 13:51:55
User entered empty.	Allison Crain (b) (4) (b) (4)	10 Sep 2020 17:59:18

**US3512248**

**Folder: Screening**

**Form: Medical History (2)**

**Generated On: 10 Jun 2021 07:56:44**

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:21:08
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 22:12:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Oct 2020 13:51:55
User entered '0'	Allison Crain (b) (4) (b) (4)	10 Sep 2020 17:59:18

**US3512248**

**Folder: Screening**

**Form: Medical History (2)**

**Generated On: 10 Jun 2021 07:56:44**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:21:08
User entered 'Jan 2008'	System	10 Sep 2020 17:59:18

**US3512248**

**Folder: Screening**

**Form: Medical History (2)**

**Generated On: 10 Jun 2021 07:56:44**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:21:08
User entered '2008'	System	10 Sep 2020 17:59:18

**US3512248**

**Folder: Screening**

**Form: Medical History (2)**

**Generated On: 10 Jun 2021 07:56:44**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:21:08
User entered empty.	System	10 Sep 2020 17:59:18

**US3512248**

**Folder: Screening**

**Form: Medical History (2)**

**Generated On: 10 Jun 2021 07:56:44**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:21:08
User entered empty.	System	10 Sep 2020 17:59:18

US3512248

Folder: Screening

Form: Medical History (3)

Generated On: 10 Jun 2021 07:56:44

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:21:08
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 19:43:23
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 22:12:02
User coded data point as SOC: Gastrointestinal disorders, HLGT: Benign neoplasms gastrointestinal, HLT: Benign neoplasms gastrointestinal (excl oral cavity), PT: Large intestine polyp, LLT: Benign colonic polyp - version MedDRA\\23.0.	Coder Import (b) (4)	08 Oct 2020 23:21:13
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	08 Oct 2020 23:21:13
Data point term sent to Coder	System	08 Oct 2020 16:03:23
DataPoint Un-verified.	Allison Crain (b) (4)	08 Oct 2020 16:02:50
Coding entries removed.	(b) (4)	
	Allison Crain (b) (4)	08 Oct 2020 16:02:50
User entered 'BENIGN COLON POLYPS' reason for change: Data Entry Error	(b) (4)	
	Allison Crain (b) (4)	08 Oct 2020 16:02:50
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	07 Oct 2020 13:51:55
User coded data point as SOC: Gastrointestinal disorders, HLGT: Benign neoplasms gastrointestinal, HLT: Benign neoplasms gastrointestinal (excl oral cavity), PT: Large intestine polyp, LLT: Colonic polyp - version MedDRA\\23.0.	Coder Import (b) (4)	10 Sep 2020 18:00:51
	(b) (4)	
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	10 Sep 2020 18:00:51
Data point term sent to Coder	System	10 Sep 2020 18:00:07
User entered 'COLON POLYPS'	Allison Crain (b) (4)	10 Sep 2020 17:59:35
	(b) (4)	



**US3512248**

**Folder: Screening**

**Form: Medical History (3)**

**Generated On: 10 Jun 2021 07:56:44**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:21:08
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 22:12:02
DataPoint Verified.	(b) (4)	(b) (4), (b) (6)
	(b) (4), (b) (6)	07 Oct 2020 13:51:55
User entered 'UN UNK 2016'	Allison Crain (b) (4)	10 Sep 2020 17:59:35
	(b) (4)	

**US3512248**

**Folder: Screening**

**Form: Medical History (3)**

**Generated On: 10 Jun 2021 07:56:44**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:21:08
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 22:12:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Oct 2020 13:51:55
User entered '0'	Allison Crain (b) (4) (b) (4)	10 Sep 2020 17:59:35

**US3512248**

**Folder: Screening**

**Form: Medical History (3)**

**Generated On: 10 Jun 2021 07:56:44**

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:21:08
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 22:12:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Oct 2020 13:51:55
User entered 'No (N)'	Allison Crain (b) (4) (b) (4)	10 Sep 2020 17:59:35

**US3512248**

**Folder: Screening**

**Form: Medical History (3)**

**Generated On: 10 Jun 2021 07:56:44**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:21:08
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 22:12:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Oct 2020 13:51:55
User entered 'UN UNK 2016'	Allison Crain (b) (4) (b) (4)	10 Sep 2020 17:59:35

**US3512248**

**Folder: Screening**

**Form: Medical History (3)**

**Generated On: 10 Jun 2021 07:56:44**

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:21:08
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 22:12:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Oct 2020 13:51:55
User entered '0'	Allison Crain (b) (4) (b) (4)	10 Sep 2020 17:59:35

**US3512248**

**Folder: Screening**

**Form: Medical History (3)**

**Generated On: 10 Jun 2021 07:56:44**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:21:08
User entered 'Jan 2016'	System	10 Sep 2020 17:59:35

**US3512248**

**Folder: Screening**

**Form: Medical History (3)**

**Generated On: 10 Jun 2021 07:56:44**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:21:08
User entered '2016'	System	10 Sep 2020 17:59:35

**US3512248**

**Folder: Screening**

**Form: Medical History (3)**

**Generated On: 10 Jun 2021 07:56:44**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:21:08
User entered 'Jan 2016'	System	10 Sep 2020 17:59:35



**US3512248**

**Folder: Screening**

**Form: Medical History (3)**

**Generated On: 10 Jun 2021 07:56:44**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:21:08
User entered '2016'	System	10 Sep 2020 17:59:35

US3512248

Folder: Screening

Form: Medical History (4)

Generated On: 10 Jun 2021 07:56:44

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:21:08
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 22:12:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Oct 2020 13:51:55
User coded data point as SOC: Reproductive system and breast disorders, HLG: Prostatic disorders (excl infections and inflammations), HLT: Prostatic signs, symptoms and disorders NEC, PT: Prostatomegaly, LLT: Enlarged prostate - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	10 Sep 2020 18:00:51
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	10 Sep 2020 18:00:51
Data point term sent to Coder	System	10 Sep 2020 18:00:08
User entered 'ENLARGED PROSTATE'	Allison Crain (b) (4) (b) (4)	10 Sep 2020 17:59:47

**US3512248**

**Folder: Screening**

**Form: Medical History (4)**

**Generated On: 10 Jun 2021 07:56:44**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:21:08
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 22:12:02
DataPoint Verified.	(b) (4)	(b) (4), (b) (6)
	(b) (4), (b) (6)	07 Oct 2020 13:51:55
User entered 'UN UNK 2008'	Allison Crain (b) (4)	10 Sep 2020 17:59:47
	(b) (4)	

**US3512248**

**Folder: Screening**

**Form: Medical History (4)**

**Generated On: 10 Jun 2021 07:56:44**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:21:08
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 22:12:02
DataPoint Verified.	(b) (4)	(b) (4), (b) (6)
	(b) (4), (b) (6)	07 Oct 2020 13:51:55
User entered '0'	Allison Crain (b) (4)	10 Sep 2020 17:59:47
	(b) (4)	

**US3512248**

**Folder: Screening**

**Form: Medical History (4)**

**Generated On: 10 Jun 2021 07:56:44**

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:21:08
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 22:12:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Oct 2020 13:51:55
User entered 'Yes (Y)'	Allison Crain (b) (4) (b) (4)	10 Sep 2020 17:59:47

**US3512248**

**Folder: Screening**

**Form: Medical History (4)**

**Generated On: 10 Jun 2021 07:56:44**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:21:08
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 22:12:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Oct 2020 13:51:55
User entered empty.	Allison Crain (b) (4) (b) (4)	10 Sep 2020 17:59:47

**US3512248**

**Folder: Screening**

**Form: Medical History (4)**

**Generated On: 10 Jun 2021 07:56:44**

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:21:08
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 22:12:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Oct 2020 13:51:55
User entered '0'	Allison Crain (b) (4) (b) (4)	10 Sep 2020 17:59:47

**US3512248**

**Folder: Screening**

**Form: Medical History (4)**

**Generated On: 10 Jun 2021 07:56:44**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:21:08
User entered 'Jan 2008'	System	10 Sep 2020 17:59:47



**US3512248**

**Folder: Screening**

**Form: Medical History (4)**

**Generated On: 10 Jun 2021 07:56:44**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:21:08
User entered '2008'	System	10 Sep 2020 17:59:47

**US3512248**

**Folder: Screening**

**Form: Medical History (4)**

**Generated On: 10 Jun 2021 07:56:44**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:21:08
User entered empty.	System	10 Sep 2020 17:59:47

**US3512248**

**Folder: Screening**

**Form: Medical History (4)**

**Generated On: 10 Jun 2021 07:56:44**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:21:08
User entered empty.	System	10 Sep 2020 17:59:47

US3512248

Folder: Screening

Form: Medical History (5)

Generated On: 10 Jun 2021 07:56:44

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:21:08
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 22:12:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Oct 2020 13:51:55
User coded data point as SOC: Reproductive system and breast disorders, HLG: Sexual function and fertility disorders, HLT: Erection and ejaculation conditions and disorders, PT: Erectile dysfunction, LLT: Erectile dysfunction - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	10 Sep 2020 18:00:50
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	10 Sep 2020 18:00:50
Data point term sent to Coder	System	10 Sep 2020 18:00:09
User entered 'ERECTILE DYSFUNCTION'	Allison Crain (b) (4) (b) (4)	10 Sep 2020 18:00:07

**US3512248**

**Folder: Screening**

**Form: Medical History (5)**

**Generated On: 10 Jun 2021 07:56:44**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:21:08
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 22:12:02
DataPoint Verified.	(b) (4)	(b) (4), (b) (6)
	(b) (4), (b) (6)	07 Oct 2020 13:51:55
User entered 'UN UNK 2008'	Allison Crain (b) (4)	10 Sep 2020 18:00:07
	(b) (4)	

**US3512248**

**Folder: Screening**

**Form: Medical History (5)**

**Generated On: 10 Jun 2021 07:56:44**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:21:08
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 22:12:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Oct 2020 13:51:55
User entered '0'	Allison Crain (b) (4) (b) (4)	10 Sep 2020 18:00:07

**US3512248**

**Folder: Screening**

**Form: Medical History (5)**

**Generated On: 10 Jun 2021 07:56:44**

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:21:08
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 22:12:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Oct 2020 13:51:55
User entered 'Yes (Y)'	Allison Crain (b) (4) (b) (4)	10 Sep 2020 18:00:07

**US3512248**

**Folder: Screening**

**Form: Medical History (5)**

**Generated On: 10 Jun 2021 07:56:44**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:21:08
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 22:12:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Oct 2020 13:51:55
User entered empty.	Allison Crain (b) (4) (b) (4)	10 Sep 2020 18:00:07



**US3512248**

**Folder: Screening**

**Form: Medical History (5)**

**Generated On: 10 Jun 2021 07:56:44**

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:21:08
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 22:12:02
DataPoint Verified.	(b) (4)	(b) (4), (b) (6)
	(b) (4), (b) (6)	07 Oct 2020 13:51:55
User entered '0'	Allison Crain (b) (4)	10 Sep 2020 18:00:07
	(b) (4)	

**US3512248**

**Folder: Screening**

**Form: Medical History (5)**

**Generated On: 10 Jun 2021 07:56:44**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:21:08
User entered 'Jan 2008'	System	10 Sep 2020 18:00:07

**US3512248**

**Folder: Screening**

**Form: Medical History (5)**

**Generated On: 10 Jun 2021 07:56:44**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:21:08
User entered '2008'	System	10 Sep 2020 18:00:07

**US3512248**

**Folder: Screening**

**Form: Medical History (5)**

**Generated On: 10 Jun 2021 07:56:44**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:21:08
User entered empty.	System	10 Sep 2020 18:00:07

**US3512248**

**Folder: Screening**

**Form: Medical History (5)**

**Generated On: 10 Jun 2021 07:56:44**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:21:08
User entered empty.	System	10 Sep 2020 18:00:07

US3512248

Folder: Screening

Form: Medical History (6)

Generated On: 10 Jun 2021 07:56:44

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:21:08
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 22:12:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Oct 2020 13:51:55
User coded data point as SOC: Psychiatric disorders, HLGT: Sexual dysfunctions, disturbances and gender identity disorders, HLT: Sexual desire disorders, PT: Libido decreased, LLT: Libido decreased - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	10 Sep 2020 18:01:40
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	10 Sep 2020 18:01:40
Data point term sent to Coder	System	10 Sep 2020 18:01:10
User entered 'LOW LIBIDO'	Allison Crain (b) (4) (b) (4)	10 Sep 2020 18:00:18

**US3512248**

**Folder: Screening**

**Form: Medical History (6)**

**Generated On: 10 Jun 2021 07:56:44**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:21:08
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 22:12:02
DataPoint Verified.	(b) (4)	(b) (4), (b) (6)
	(b) (4), (b) (6)	07 Oct 2020 13:51:55
User entered 'UN UNK 2008'	Allison Crain (b) (4)	10 Sep 2020 18:00:18
	(b) (4)	

**US3512248**

**Folder: Screening**

**Form: Medical History (6)**

**Generated On: 10 Jun 2021 07:56:44**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:21:08
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 22:12:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Oct 2020 13:51:55
User entered '0'	Allison Crain (b) (4) (b) (4)	10 Sep 2020 18:00:18



**US3512248**

**Folder: Screening**

**Form: Medical History (6)**

**Generated On: 10 Jun 2021 07:56:44**

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:21:08
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 22:12:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Oct 2020 13:51:55
User entered 'Yes (Y)'	Allison Crain (b) (4) (b) (4)	10 Sep 2020 18:00:18

**US3512248**

**Folder: Screening**

**Form: Medical History (6)**

**Generated On: 10 Jun 2021 07:56:44**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:21:08
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 22:12:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Oct 2020 13:51:55
User entered empty.	Allison Crain (b) (4) (b) (4)	10 Sep 2020 18:00:18

**US3512248**

**Folder: Screening**

**Form: Medical History (6)**

**Generated On: 10 Jun 2021 07:56:44**

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:21:08
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 22:12:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Oct 2020 13:51:55
User entered '0'	Allison Crain (b) (4) (b) (4)	10 Sep 2020 18:00:18

**US3512248**

**Folder: Screening**

**Form: Medical History (6)**

**Generated On: 10 Jun 2021 07:56:44**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:21:08
User entered 'Jan 2008'	System	10 Sep 2020 18:00:18

**US3512248**

**Folder: Screening**

**Form: Medical History (6)**

**Generated On: 10 Jun 2021 07:56:44**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:21:08
User entered '2008'	System	10 Sep 2020 18:00:18

**US3512248**

**Folder: Screening**

**Form: Medical History (6)**

**Generated On: 10 Jun 2021 07:56:44**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:21:08
User entered empty.	System	10 Sep 2020 18:00:18

**US3512248**

**Folder: Screening**

**Form: Medical History (6)**

**Generated On: 10 Jun 2021 07:56:44**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:21:08
User entered empty.	System	10 Sep 2020 18:00:18

US3512248

Folder: Screening

Form: Medical History (7)

Generated On: 10 Jun 2021 07:56:44

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:21:08
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 22:12:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Oct 2020 13:51:55
User coded data point as SOC: Blood and lymphatic system disorders, HLGT: Anaemias nonhaemolytic and marrow depression, HLT: Anaemias NEC, PT: Anaemia, LLT: Anemia - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	10 Sep 2020 18:01:40
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	10 Sep 2020 18:01:40
Data point term sent to Coder	System	10 Sep 2020 18:01:10
User entered 'ANEMIA'	Allison Crain (b) (4) (b) (4)	10 Sep 2020 18:00:27



**US3512248**

**Folder: Screening**

**Form: Medical History (7)**

**Generated On: 10 Jun 2021 07:56:44**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:21:08
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 22:12:02
DataPoint Verified.	(b) (4)	(b) (4), (b) (6)
	(b) (4), (b) (6)	07 Oct 2020 13:51:55
User entered 'UN UNK 2016'	Allison Crain (b) (4)	10 Sep 2020 18:00:27
	(b) (4)	

**US3512248**

**Folder: Screening**

**Form: Medical History (7)**

**Generated On: 10 Jun 2021 07:56:44**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:21:08
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 22:12:02
DataPoint Verified.	(b) (4)	(b) (4), (b) (6)
	(b) (4), (b) (6)	07 Oct 2020 13:51:55
User entered '0'	Allison Crain (b) (4)	10 Sep 2020 18:00:27
	(b) (4)	

**US3512248**

**Folder: Screening**

**Form: Medical History (7)**

**Generated On: 10 Jun 2021 07:56:44**

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:21:08
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 22:12:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Oct 2020 13:51:55
User entered 'Yes (Y)'	Allison Crain (b) (4) (b) (4)	10 Sep 2020 18:00:27

**US3512248**

**Folder: Screening**

**Form: Medical History (7)**

**Generated On: 10 Jun 2021 07:56:44**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:21:08
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 22:12:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Oct 2020 13:51:55
User entered empty.	Allison Crain (b) (4) (b) (4)	10 Sep 2020 18:00:27

**US3512248**

**Folder: Screening**

**Form: Medical History (7)**

**Generated On: 10 Jun 2021 07:56:44**

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:21:08
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 22:12:02
DataPoint Verified.	(b) (4)	(b) (4), (b) (6)
	(b) (4), (b) (6)	07 Oct 2020 13:51:55
User entered '0'	Allison Crain (b) (4)	10 Sep 2020 18:00:27
	(b) (4)	

**US3512248**

**Folder: Screening**

**Form: Medical History (7)**

**Generated On: 10 Jun 2021 07:56:44**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:21:08
User entered 'Jan 2016'	System	10 Sep 2020 18:00:27

**US3512248**

**Folder: Screening**

**Form: Medical History (7)**

**Generated On: 10 Jun 2021 07:56:44**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:21:08
User entered '2016'	System	10 Sep 2020 18:00:27

**US3512248**

**Folder: Screening**

**Form: Medical History (7)**

**Generated On: 10 Jun 2021 07:56:44**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:21:08
User entered empty.	System	10 Sep 2020 18:00:27



**US3512248**

**Folder: Screening**

**Form: Medical History (7)**

**Generated On: 10 Jun 2021 07:56:44**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:21:08
User entered empty.	System	10 Sep 2020 18:00:27

US3512248

Folder: Screening

Form: Medical History (8)

Generated On: 10 Jun 2021 07:56:44

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:21:08
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 22:12:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Oct 2020 13:51:55
User coded data point as SOC: Eye disorders, HLGT: Anterior eye structural change, deposit and degeneration, HLT: Cataract conditions, PT: Cataract, LLT: Cataracts - version MedDRA\\23.0.	Coder Import (b) (4)	10 Sep 2020 18:01:39
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	10 Sep 2020 18:01:39
Data point term sent to Coder	System	10 Sep 2020 18:01:11
User entered 'CATARACTS'	Allison Crain (b) (4) (b) (4)	10 Sep 2020 18:00:42

US3512248

Folder: Screening

Form: Medical History (8)

Generated On: 10 Jun 2021 07:56:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:21:08
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 22:12:02
DataPoint Verified.	(b) (4)	(b) (4), (b) (6)
	(b) (4), (b) (6)	07 Oct 2020 13:51:55
User entered 'UN UNK 1993'	Allison Crain (b) (4)	10 Sep 2020 18:00:42
	(b) (4)	

**US3512248**

**Folder: Screening**

**Form: Medical History (8)**

**Generated On: 10 Jun 2021 07:56:44**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:21:08
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 22:12:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Oct 2020 13:51:55
User entered '0'	Allison Crain (b) (4) (b) (4)	10 Sep 2020 18:00:42

**US3512248**

**Folder: Screening**

**Form: Medical History (8)**

**Generated On: 10 Jun 2021 07:56:44**

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:21:08
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 22:12:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Oct 2020 13:51:55
User entered 'Yes (Y)'	Allison Crain (b) (4) (b) (4)	10 Sep 2020 18:00:42

**US3512248**

**Folder: Screening**

**Form: Medical History (8)**

**Generated On: 10 Jun 2021 07:56:44**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:21:08
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 22:12:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Oct 2020 13:51:55
User entered empty.	Allison Crain (b) (4) (b) (4)	10 Sep 2020 18:00:42

**US3512248**

**Folder: Screening**

**Form: Medical History (8)**

**Generated On: 10 Jun 2021 07:56:44**

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:21:08
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 22:12:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Oct 2020 13:51:55
User entered '0'	Allison Crain (b) (4) (b) (4)	10 Sep 2020 18:00:42

**US3512248**

**Folder: Screening**

**Form: Medical History (8)**

**Generated On: 10 Jun 2021 07:56:44**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:21:08
User entered 'Jan 1993'	System	10 Sep 2020 18:00:42



**US3512248**

**Folder: Screening**

**Form: Medical History (8)**

**Generated On: 10 Jun 2021 07:56:44**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:21:08
User entered '1993'	System	10 Sep 2020 18:00:42

**US3512248**

**Folder: Screening**

**Form: Medical History (8)**

**Generated On: 10 Jun 2021 07:56:44**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:21:08
User entered empty.	System	10 Sep 2020 18:00:42

**US3512248**

**Folder: Screening**

**Form: Medical History (8)**

**Generated On: 10 Jun 2021 07:56:44**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:21:08
User entered empty.	System	10 Sep 2020 18:00:42

US3512248

Folder: Screening

Form: Medical History (9)

Generated On: 10 Jun 2021 07:56:44

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:21:08
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 22:12:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Oct 2020 13:51:55
User coded data point as SOC: Eye disorders, HLGT: Vision disorders, HLT: Refractive and accommodative disorders, PT: Presbyopia, LLT: Presbyopia - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	10 Sep 2020 18:01:40
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	10 Sep 2020 18:01:40
Data point term sent to Coder	System	10 Sep 2020 18:01:11
User entered 'PRESBYOPIA'	Allison Crain (b) (4) (b) (4)	10 Sep 2020 18:00:53

**US3512248**

**Folder: Screening**

**Form: Medical History (9)**

**Generated On: 10 Jun 2021 07:56:44**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:21:08
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 22:12:02
DataPoint Verified.	(b) (4)	(b) (4), (b) (6)
	(b) (4), (b) (6)	07 Oct 2020 13:51:55
User entered 'UN UNK 1993'	Allison Crain (b) (4)	10 Sep 2020 18:00:53
	(b) (4)	

**US3512248**

**Folder: Screening**

**Form: Medical History (9)**

**Generated On: 10 Jun 2021 07:56:44**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:21:08
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 22:12:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Oct 2020 13:51:55
User entered '0'	Allison Crain (b) (4) (b) (4)	10 Sep 2020 18:00:53

**US3512248**

**Folder: Screening**

**Form: Medical History (9)**

**Generated On: 10 Jun 2021 07:56:44**

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:21:08
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 22:12:02
DataPoint Verified.	(b) (4)	(b) (4), (b) (6)
	(b) (4), (b) (6)	07 Oct 2020 13:51:55
User entered 'Yes (Y)'	Allison Crain (b) (4)	10 Sep 2020 18:00:53
	(b) (4)	

**US3512248**

**Folder: Screening**

**Form: Medical History (9)**

**Generated On: 10 Jun 2021 07:56:44**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:21:08
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 22:12:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Oct 2020 13:51:55
User entered empty.	Allison Crain (b) (4) (b) (4)	10 Sep 2020 18:00:53



**US3512248**

**Folder: Screening**

**Form: Medical History (9)**

**Generated On: 10 Jun 2021 07:56:44**

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:21:08
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 22:12:02
DataPoint Verified.	(b) (4)	(b) (4), (b) (6)
	(b) (4), (b) (6)	07 Oct 2020 13:51:55
User entered '0'	Allison Crain (b) (4)	10 Sep 2020 18:00:53
	(b) (4)	

**US3512248**

**Folder: Screening**

**Form: Medical History (9)**

**Generated On: 10 Jun 2021 07:56:44**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:21:08
User entered 'Jan 1993'	System	10 Sep 2020 18:00:53

**US3512248**

**Folder: Screening**

**Form: Medical History (9)**

**Generated On: 10 Jun 2021 07:56:44**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:21:08
User entered '1993'	System	10 Sep 2020 18:00:53

**US3512248**

**Folder: Screening**

**Form: Medical History (9)**

**Generated On: 10 Jun 2021 07:56:44**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:21:08
User entered empty.	System	10 Sep 2020 18:00:53

**US3512248**

**Folder: Screening**

**Form: Medical History (9)**

**Generated On: 10 Jun 2021 07:56:44**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:21:08
User entered empty.	System	10 Sep 2020 18:00:53

US3512248

Folder: Screening

Form: Medical History (10)

Generated On: 10 Jun 2021 07:56:44

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:21:08
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 22:12:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Oct 2020 13:51:55
User coded data point as SOC: Eye disorders, HLGT: Vision disorders, HLT: Amblyopic vision impairment, PT: Amblyopia, LLT: Amblyopia - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	10 Sep 2020 18:01:40
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	10 Sep 2020 18:01:40
Data point term sent to Coder	System	10 Sep 2020 18:01:12
User entered 'AMBLYOPIA'	Allison Crain (b) (4) (b) (4)	10 Sep 2020 18:01:04

US3512248

Folder: Screening

Form: Medical History (10)

Generated On: 10 Jun 2021 07:56:44

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:21:08
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 22:12:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Oct 2020 13:51:55
User closed query 'Start date is prior to Date of Birth. System Please correct.' (Site from System).		10 Sep 2020 18:02:11
User entered (b) (6) 1943' reason for change: Data Entry Error	Allison Crain (b) (4) (b) (4)	10 Sep 2020 18:02:11
User opened query 'Start date is prior to Date of Birth. Please correct.' (Site from System).	System	10 Sep 2020 18:01:04
User entered 'UN UNK 1943'	Allison Crain (b) (4) (b) (4)	10 Sep 2020 18:01:04

**US3512248**

**Folder: Screening**

**Form: Medical History (10)**

**Generated On: 10 Jun 2021 07:56:44**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:21:08
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 22:12:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Oct 2020 13:51:55
User entered '0'	Allison Crain (b) (4) (b) (4)	10 Sep 2020 18:01:04



**US3512248**

**Folder: Screening**

**Form: Medical History (10)**

**Generated On: 10 Jun 2021 07:56:44**

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:21:08
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 22:12:02
DataPoint Verified.	(b) (4)	(b) (4), (b) (6)
	(b) (4), (b) (6)	07 Oct 2020 13:51:55
User entered 'Yes (Y)'	Allison Crain (b) (4)	10 Sep 2020 18:01:04
	(b) (4)	

**US3512248**

**Folder: Screening**

**Form: Medical History (10)**

**Generated On: 10 Jun 2021 07:56:44**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:21:08
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 22:12:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Oct 2020 13:51:55
User entered empty.	Allison Crain (b) (4) (b) (4)	10 Sep 2020 18:01:04

**US3512248**

**Folder: Screening**

**Form: Medical History (10)**

**Generated On: 10 Jun 2021 07:56:44**

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:21:08
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 22:12:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Oct 2020 13:51:55
User entered '0'	Allison Crain (b) (4) (b) (4)	10 Sep 2020 18:01:04

**US3512248**

**Folder: Screening**

**Form: Medical History (10)**

**Generated On: 10 Jun 2021 07:56:44**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:21:08
User entered (b) (6) 1943'	System	10 Sep 2020 18:02:11
User entered 'Jan 1943'	System	10 Sep 2020 18:01:04

**US3512248**

**Folder: Screening**

**Form: Medical History (10)**

**Generated On: 10 Jun 2021 07:56:44**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:21:08
User entered '1943'	System	10 Sep 2020 18:01:04

**US3512248**

**Folder: Screening**

**Form: Medical History (10)**

**Generated On: 10 Jun 2021 07:56:44**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:21:08
User entered empty.	System	10 Sep 2020 18:01:04

**US3512248**

**Folder: Screening**

**Form: Medical History (10)**

**Generated On: 10 Jun 2021 07:56:44**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:21:08
User entered empty.	System	10 Sep 2020 18:01:04

US3512248

Folder: Screening

Form: Medical History (11)

Generated On: 10 Jun 2021 07:56:44

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:21:08
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 22:12:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Oct 2020 13:51:55
User coded data point as SOC: Nervous system disorders, HLG: Headaches, HLT: Headaches NEC, PT: Headache, LLT: Headache - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	10 Sep 2020 18:05:48
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	10 Sep 2020 18:05:48
Data point term sent to Coder	System	10 Sep 2020 18:04:20
User entered 'HEADACHES' reason for change:	Allison Crain (b) (4)	10 Sep 2020 18:04:02
Data Entry Error	(b) (4)	
Data point term sent to Coder	System	10 Sep 2020 18:02:14
User entered 'HEADACHED'	Allison Crain (b) (4) (b) (4)	10 Sep 2020 18:01:19



**US3512248**

**Folder: Screening**

**Form: Medical History (11)**

**Generated On: 10 Jun 2021 07:56:44**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:21:08
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 22:12:02
DataPoint Verified.	(b) (4)	(b) (4), (b) (6)
User entered 'UN UNK 1945'	Allison Crain (b) (4)	10 Sep 2020 18:01:19
	(b) (4)	

**US3512248**

**Folder: Screening**

**Form: Medical History (11)**

**Generated On: 10 Jun 2021 07:56:44**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:21:08
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 22:12:02
DataPoint Verified.	(b) (4)	(b) (4), (b) (6)
	(b) (4), (b) (6)	07 Oct 2020 13:51:55
User entered '0'	Allison Crain (b) (4)	10 Sep 2020 18:01:19
	(b) (4)	

**US3512248**

**Folder: Screening**

**Form: Medical History (11)**

**Generated On: 10 Jun 2021 07:56:44**

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:21:08
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 22:12:02
DataPoint Verified.	(b) (4)	(b) (4), (b) (6)
	(b) (4), (b) (6)	07 Oct 2020 13:51:55
User entered 'No (N)'	Allison Crain (b) (4)	10 Sep 2020 18:01:19
	(b) (4)	

**US3512248**

**Folder: Screening**

**Form: Medical History (11)**

**Generated On: 10 Jun 2021 07:56:44**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:21:08
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 22:12:02
DataPoint Verified.	(b) (4)	(b) (4), (b) (6)
	(b) (4), (b) (6)	07 Oct 2020 13:51:55
User entered 'UN UNK 1960'	Allison Crain (b) (4)	10 Sep 2020 18:01:19
	(b) (4)	

**US3512248**

**Folder: Screening**

**Form: Medical History (11)**

**Generated On: 10 Jun 2021 07:56:44**

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:21:08
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 22:12:02
DataPoint Verified.	(b) (4)	(b) (4), (b) (6)
	(b) (4), (b) (6)	07 Oct 2020 13:51:55
User entered '0'	Allison Crain (b) (4)	10 Sep 2020 18:01:19
	(b) (4)	

**US3512248**

**Folder: Screening**

**Form: Medical History (11)**

**Generated On: 10 Jun 2021 07:56:44**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:21:08
User entered 'Jan 1945'	System	10 Sep 2020 18:01:19

**US3512248**

**Folder: Screening**

**Form: Medical History (11)**

**Generated On: 10 Jun 2021 07:56:44**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:21:08
User entered '1945'	System	10 Sep 2020 18:01:19

**US3512248**

**Folder: Screening**

**Form: Medical History (11)**

**Generated On: 10 Jun 2021 07:56:44**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:21:08
User entered 'Jan 1960'	System	10 Sep 2020 18:01:19



**US3512248**

**Folder: Screening**

**Form: Medical History (11)**

**Generated On: 10 Jun 2021 07:56:44**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:21:08
User entered '1960'	System	10 Sep 2020 18:01:19

US3512248

Folder: Screening

Form: Medical History (12)

Generated On: 10 Jun 2021 07:56:44

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:21:08
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 22:12:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Oct 2020 13:51:55
User coded data point as SOC: Nervous system disorders, HLG: Headaches, HLT: Migraine headaches, PT: Migraine, LLT: Migraine - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	10 Sep 2020 18:05:48
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	10 Sep 2020 18:05:48
Data point term sent to Coder	System	10 Sep 2020 18:04:20
User entered 'MIGRAINES'	Allison Crain (b) (4) (b) (4)	10 Sep 2020 18:04:19

**US3512248**

**Folder: Screening**

**Form: Medical History (12)**

**Generated On: 10 Jun 2021 07:56:44**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:21:08
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 22:12:02
DataPoint Verified.	(b) (4)	(b) (4), (b) (6)
User entered 'UN UNK 1945'	Allison Crain (b) (4)	10 Sep 2020 18:04:19
	(b) (4)	

**US3512248**

**Folder: Screening**

**Form: Medical History (12)**

**Generated On: 10 Jun 2021 07:56:44**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:21:08
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 22:12:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Oct 2020 13:51:55
User entered '0'	Allison Crain (b) (4) (b) (4)	10 Sep 2020 18:04:19

**US3512248**

**Folder: Screening**

**Form: Medical History (12)**

**Generated On: 10 Jun 2021 07:56:44**

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:21:08
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 22:12:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Oct 2020 13:51:55
User entered 'No (N)'	Allison Crain (b) (4) (b) (4)	10 Sep 2020 18:04:19

**US3512248**

**Folder: Screening**

**Form: Medical History (12)**

**Generated On: 10 Jun 2021 07:56:44**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:21:08
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 22:12:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Oct 2020 13:51:55
User entered 'UN UNK 1960'	Allison Crain (b) (4) (b) (4)	10 Sep 2020 18:04:19

**US3512248**

**Folder: Screening**

**Form: Medical History (12)**

**Generated On: 10 Jun 2021 07:56:44**

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:21:08
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 22:12:02
DataPoint Verified.	(b) (4)	(b) (4), (b) (6)
	(b) (4), (b) (6)	07 Oct 2020 13:51:55
User entered '0'	Allison Crain (b) (4)	10 Sep 2020 18:04:19
	(b) (4)	

**US3512248**

**Folder: Screening**

**Form: Medical History (12)**

**Generated On: 10 Jun 2021 07:56:44**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:21:08
User entered 'Jan 1945'	System	10 Sep 2020 18:04:19



**US3512248**

**Folder: Screening**

**Form: Medical History (12)**

**Generated On: 10 Jun 2021 07:56:44**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:21:08
User entered '1945'	System	10 Sep 2020 18:04:19

**US3512248**

**Folder: Screening**

**Form: Medical History (12)**

**Generated On: 10 Jun 2021 07:56:44**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:21:08
User entered 'Jan 1960'	System	10 Sep 2020 18:04:19

**US3512248**

**Folder: Screening**

**Form: Medical History (12)**

**Generated On: 10 Jun 2021 07:56:44**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:21:08
User entered '1960'	System	10 Sep 2020 18:04:19

US3512248

Folder: Screening

Form: Medical History (13)

Generated On: 10 Jun 2021 07:56:44

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:21:08
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 19:43:23
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 22:12:02
User closed query 'Per DM CLR: Please verify the type of the DIABETIC NEUROPATHY OF THE HANDS (i.e. sensory or motor) and location (bilateral, right, left). Review and update medical history diagnosis as appropriate and ensure update to MHx is reconciled with any corresponding AE or ConMed entries, if applicable.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 05:20:46
' (Site from DM).		
User coded data point as SOC: Nervous system disorders, HLGT: Peripheral neuropathies, HLT: Chronic polyneuropathies, PT: Diabetic neuropathy, LLT: Diabetic neuropathy - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	30 Oct 2020 21:45:04
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	30 Oct 2020 21:45:04
Data point term sent to Coder	System	30 Oct 2020 10:57:45
Query 'Per DM CLR: Please verify the type of the DIABETIC NEUROPATHY OF THE HANDS (i.e. sensory or motor) and location (bilateral, right, left). Review and update medical history diagnosis as appropriate and ensure update to MHx is reconciled with any corresponding AE or ConMed entries, if applicable.	(b) (4), (b) (6)	30 Oct 2020 10:56:53
' answered with 'ok' (Site from DM).		
DataPoint Un-verified.	(b) (4), (b) (6)	30 Oct 2020 10:56:50
Coding entries removed.	(b) (4), (b) (6)	30 Oct 2020 10:56:50
User entered 'DIABETIC NEUROPATHY BILATERAL HANDS' reason for change: Data Entry Error	(b) (4), (b) (6)	30 Oct 2020 10:56:50
User opened query 'Per DM CLR: Please verify the type of the DIABETIC NEUROPATHY OF THE HANDS (i.e. sensory or motor) and location (bilateral, right, left). Review and update medical history diagnosis as appropriate and ensure update to MHx is reconciled with any corresponding AE or ConMed entries, if applicable. ' (Site from DM).	(b) (4), (b) (6)	24 Oct 2020 05:55:26
PRODUCTION RELEASE (v12.003 EAB) (1725)		735 of 3746

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Folder: Screening

Form: Medical History (13)

Generated On: 10 Jun 2021 07:56:44

[Condition](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Oct 2020 13:51:55
User coded data point as SOC: Nervous system disorders, HLGT: Peripheral neuropathies, HLT: Chronic polyneuropathies, PT: Diabetic neuropathy, LLT: Diabetic peripheral neuropathy - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	11 Sep 2020 05:13:48
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	11 Sep 2020 05:13:48
Data point term sent to Coder	System	10 Sep 2020 18:05:21
User entered 'DIABETIC NEUROPATHY OF THE HANDS'	Allison Crain (b) (4) (b) (4)	10 Sep 2020 18:04:51

**US3512248**

**Folder: Screening**

**Form: Medical History (13)**

**Generated On: 10 Jun 2021 07:56:44**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:21:08
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 22:12:02
DataPoint Verified.	(b) (4)	(b) (4), (b) (6)
User entered 'UN UNK 2017'	Allison Crain (b) (4)	10 Sep 2020 18:04:51
	(b) (4)	

**US3512248**

**Folder: Screening**

**Form: Medical History (13)**

**Generated On: 10 Jun 2021 07:56:44**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:21:08
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 22:12:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Oct 2020 13:51:55
User entered '0'	Allison Crain (b) (4) (b) (4)	10 Sep 2020 18:04:51

**US3512248**

**Folder: Screening**

**Form: Medical History (13)**

**Generated On: 10 Jun 2021 07:56:44**

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:21:08
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 22:12:02
DataPoint Verified.	(b) (4)	(b) (4), (b) (6)
	(b) (4), (b) (6)	07 Oct 2020 13:51:55
User entered 'Yes (Y)'	Allison Crain (b) (4)	10 Sep 2020 18:04:51
	(b) (4)	



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**Folder: Screening**

**Form: Medical History (13)**

**Generated On: 10 Jun 2021 07:56:44**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:21:08
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 22:12:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Oct 2020 13:51:55
User entered empty.	Allison Crain (b) (4) (b) (4)	10 Sep 2020 18:04:51

**US3512248**

**Folder: Screening**

**Form: Medical History (13)**

**Generated On: 10 Jun 2021 07:56:44**

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:21:08
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 22:12:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Oct 2020 13:51:55
User entered '0'	Allison Crain (b) (4) (b) (4)	10 Sep 2020 18:04:51

**US3512248**

**Folder: Screening**

**Form: Medical History (13)**

**Generated On: 10 Jun 2021 07:56:44**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:21:08
User entered 'Jan 2017'	System	10 Sep 2020 18:04:51

**US3512248**

**Folder: Screening**

**Form: Medical History (13)**

**Generated On: 10 Jun 2021 07:56:44**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:21:08
User entered '2017'	System	10 Sep 2020 18:04:51

**US3512248**

**Folder: Screening**

**Form: Medical History (13)**

**Generated On: 10 Jun 2021 07:56:44**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:21:08
User entered empty.	System	10 Sep 2020 18:04:51

**US3512248**

**Folder: Screening**

**Form: Medical History (13)**

**Generated On: 10 Jun 2021 07:56:44**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:21:08
User entered empty.	System	10 Sep 2020 18:04:51

US3512248

Folder: Screening

Form: Medical History (14)

Generated On: 10 Jun 2021 07:56:44

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:21:08
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 22:12:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Oct 2020 13:51:55
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) (b) (4)	10 Sep 2020 18:06:51
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	10 Sep 2020 18:06:51
Data point term sent to Coder	System	10 Sep 2020 18:06:23
User entered 'Chronic obstructive pulmonary disease'	Allison Crain (b) (4) (b) (4)	10 Sep 2020 18:05:31

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Folder: Screening

Form: Medical History (14)

Generated On: 10 Jun 2021 07:56:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:21:08
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 22:12:02
DataPoint Verified.	(b) (4)	(b) (4), (b) (6)
User entered 'UN UNK 2003'	Allison Crain (b) (4)	10 Sep 2020 18:05:31
	(b) (4)	



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**Folder: Screening**

**Form: Medical History (14)**

**Generated On: 10 Jun 2021 07:56:44**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:21:08
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 22:12:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Oct 2020 13:51:55
User entered '0'	Allison Crain (b) (4) (b) (4)	10 Sep 2020 18:05:31

**US3512248**

**Folder: Screening**

**Form: Medical History (14)**

**Generated On: 10 Jun 2021 07:56:44**

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:21:08
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 22:12:02
DataPoint Verified.	(b) (4)	(b) (4), (b) (6)
	(b) (4), (b) (6)	07 Oct 2020 13:51:55
User entered 'Yes (Y)'	Allison Crain (b) (4)	10 Sep 2020 18:05:31
	(b) (4)	

**US3512248**

**Folder: Screening**

**Form: Medical History (14)**

**Generated On: 10 Jun 2021 07:56:44**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:21:08
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 22:12:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Oct 2020 13:51:55
User entered empty.	Allison Crain (b) (4) (b) (4)	10 Sep 2020 18:05:31

**US3512248**

**Folder: Screening**

**Form: Medical History (14)**

**Generated On: 10 Jun 2021 07:56:44**

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:21:08
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 22:12:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Oct 2020 13:51:55
User entered '0'	Allison Crain (b) (4) (b) (4)	10 Sep 2020 18:05:31

**US3512248**

**Folder: Screening**

**Form: Medical History (14)**

**Generated On: 10 Jun 2021 07:56:44**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:21:08
User entered 'Jan 2003'	System	10 Sep 2020 18:05:31

**US3512248**

**Folder: Screening**

**Form: Medical History (14)**

**Generated On: 10 Jun 2021 07:56:44**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:21:08
User entered '2003'	System	10 Sep 2020 18:05:31

**US3512248**

**Folder: Screening**

**Form: Medical History (14)**

**Generated On: 10 Jun 2021 07:56:44**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:21:08
User entered empty.	System	10 Sep 2020 18:05:31

**US3512248**

**Folder: Screening**

**Form: Medical History (14)**

**Generated On: 10 Jun 2021 07:56:44**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:21:08
User entered empty.	System	10 Sep 2020 18:05:31



US3512248

Folder: Screening

Form: Medical History (15)

Generated On: 10 Jun 2021 07:56:44

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:21:08
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 19:43:23
User coded data point as SOC: Skin and subcutaneous tissue disorders, HLGT: Cornification and dystrophic skin disorders, HLT: Hyperkeratoses, PT: Hyperkeratosis, LLT: Keratosis - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	30 Mar 2021 12:33:35
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	30 Mar 2021 12:33:35
User signature succeeded.	Michael Koren (b) (4) (b) (4)	19 Mar 2021 20:45:28
Data point term sent to Coder	System	18 Mar 2021 15:41:42
User entered 'KERATOSIS ON BILATERAL ARMS, LEGS, HEAD AND SCALP' reason for change: Data Entry Error	(b) (4), (b) (6)	18 Mar 2021 15:41:09
Data point term sent to Coder	System	17 Mar 2021 17:03:22
DataPoint Un-verified.	(b) (4), (b) (6)	17 Mar 2021 17:03:13
Coding entries removed.	(b) (4), (b) (6)	17 Mar 2021 17:03:13
Signature has been broken.	(b) (4), (b) (6)	17 Mar 2021 17:03:13
User entered 'KERATOSIS ON BILATERAL ARMS, LEGS, Head, and Scalp' reason for change: Data Entry Error	(b) (4), (b) (6)	17 Mar 2021 17:03:13
User signature succeeded.	Michael Koren (b) (4) (b) (4)	12 Feb 2021 22:12:02
DataPoint Verified.	(b) (4), (b) (6)	07 Oct 2020 13:51:55
User coded data point as SOC: Skin and subcutaneous tissue disorders, HLGT: Cornification and dystrophic skin disorders, HLT: Hyperkeratoses, PT: Hyperkeratosis, LLT: Keratosis - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	11 Sep 2020 06:02:45
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	11 Sep 2020 06:02:45
Data point term sent to Coder	System	10 Sep 2020 18:06:24
User entered 'KERATOSIS ON BILATERAL ARMS AND LEGS'	Allison Crain (b) (4) (b) (4)	10 Sep 2020 18:05:58

**US3512248**

**Folder: Screening**

**Form: Medical History (15)**

**Generated On: 10 Jun 2021 07:56:44**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:21:08
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 22:12:02
DataPoint Verified.	(b) (4)	(b) (4), (b) (6)
User entered 'UN UNK 1990'	Allison Crain (b) (4)	10 Sep 2020 18:05:58
	(b) (4)	

**US3512248**

**Folder: Screening**

**Form: Medical History (15)**

**Generated On: 10 Jun 2021 07:56:44**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:21:08
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 22:12:02
DataPoint Verified.	(b) (4)	(b) (4), (b) (6)
	(b) (4), (b) (6)	07 Oct 2020 13:51:55
User entered '0'	Allison Crain (b) (4)	10 Sep 2020 18:05:58
	(b) (4)	

**US3512248**

**Folder: Screening**

**Form: Medical History (15)**

**Generated On: 10 Jun 2021 07:56:44**

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:21:08
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 22:12:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Oct 2020 13:51:55
User entered 'Yes (Y)'	Allison Crain (b) (4) (b) (4)	10 Sep 2020 18:05:58

**US3512248**

**Folder: Screening**

**Form: Medical History (15)**

**Generated On: 10 Jun 2021 07:56:44**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:21:08
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 22:12:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Oct 2020 13:51:55
User entered empty.	Allison Crain (b) (4) (b) (4)	10 Sep 2020 18:05:58

**US3512248**

**Folder: Screening**

**Form: Medical History (15)**

**Generated On: 10 Jun 2021 07:56:44**

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:21:08
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 22:12:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Oct 2020 13:51:55
User entered '0'	Allison Crain (b) (4) (b) (4)	10 Sep 2020 18:05:58

**US3512248**

**Folder: Screening**

**Form: Medical History (15)**

**Generated On: 10 Jun 2021 07:56:44**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:21:08
User entered 'Jan 1990'	System	10 Sep 2020 18:05:58

**US3512248**

**Folder: Screening**

**Form: Medical History (15)**

**Generated On: 10 Jun 2021 07:56:44**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:21:08
User entered '1990'	System	10 Sep 2020 18:05:58



**US3512248**

**Folder: Screening**

**Form: Medical History (15)**

**Generated On: 10 Jun 2021 07:56:44**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:21:08
User entered empty.	System	10 Sep 2020 18:05:58

**US3512248**

**Folder: Screening**

**Form: Medical History (15)**

**Generated On: 10 Jun 2021 07:56:44**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:21:08
User entered empty.	System	10 Sep 2020 18:05:58

US3512248

Folder: Screening

Form: Medical History (16)

Generated On: 10 Jun 2021 07:56:44

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:21:08
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 22:12:02
User coded data point as SOC: Musculoskeletal and connective tissue disorders, HLGT: Joint disorders, HLT: Osteoarthropathies, PT: Osteoarthritis, LLT: Finger osteoarthritis - version MedDRA\\23.0.	Coder Import (b) (4)	23 Nov 2020 14:35:56
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4)	23 Nov 2020 14:35:56
DataPoint Verified.	(b) (4), (b) (6)	07 Oct 2020 13:51:55
Data point term sent to Coder	System	14 Sep 2020 18:36:39
User entered 'OSTEOARTHRITIS OF right FINGERS' reason for change: Data Entry Error	Brenda Anderson (b) (4)	14 Sep 2020 18:36:25
Data point term sent to Coder	System	10 Sep 2020 18:06:25
User entered 'OSTEOARTHRITIS OF FINGERS'	Allison Crain (b) (4)	10 Sep 2020 18:06:17

**US3512248**

**Folder: Screening**

**Form: Medical History (16)**

**Generated On: 10 Jun 2021 07:56:44**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:21:08
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 22:12:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Oct 2020 13:51:55
User entered 'UN UNK 2006'	Allison Crain (b) (4) (b) (4)	10 Sep 2020 18:06:17

**US3512248**

**Folder: Screening**

**Form: Medical History (16)**

**Generated On: 10 Jun 2021 07:56:44**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:21:08
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 22:12:02
DataPoint Verified.	(b) (4)	(b) (4), (b) (6)
	(b) (4), (b) (6)	07 Oct 2020 13:51:55
User entered '0'	Allison Crain (b) (4)	10 Sep 2020 18:06:17
	(b) (4)	

**US3512248**

**Folder: Screening**

**Form: Medical History (16)**

**Generated On: 10 Jun 2021 07:56:44**

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:21:08
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 22:12:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Oct 2020 13:51:55
User entered 'Yes (Y)'	Allison Crain (b) (4) (b) (4)	10 Sep 2020 18:06:17

**US3512248**

**Folder: Screening**

**Form: Medical History (16)**

**Generated On: 10 Jun 2021 07:56:44**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:21:08
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 22:12:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Oct 2020 13:51:55
User entered empty.	Allison Crain (b) (4) (b) (4)	10 Sep 2020 18:06:17

**US3512248**

**Folder: Screening**

**Form: Medical History (16)**

**Generated On: 10 Jun 2021 07:56:44**

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:21:08
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 22:12:02
DataPoint Verified.	(b) (4)	(b) (4), (b) (6)
	(b) (4), (b) (6)	07 Oct 2020 13:51:55
User entered '0'	Allison Crain (b) (4)	10 Sep 2020 18:06:17
	(b) (4)	



**US3512248**

**Folder: Screening**

**Form: Medical History (16)**

**Generated On: 10 Jun 2021 07:56:44**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:21:08
User entered 'Jan 2006'	System	10 Sep 2020 18:06:17

**US3512248**

**Folder: Screening**

**Form: Medical History (16)**

**Generated On: 10 Jun 2021 07:56:44**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:21:08
User entered '2006'	System	10 Sep 2020 18:06:17

**US3512248**

**Folder: Screening**

**Form: Medical History (16)**

**Generated On: 10 Jun 2021 07:56:44**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:21:08
User entered empty.	System	10 Sep 2020 18:06:17

**US3512248**

**Folder: Screening**

**Form: Medical History (16)**

**Generated On: 10 Jun 2021 07:56:44**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:21:08
User entered empty.	System	10 Sep 2020 18:06:17

US3512248

Folder: Screening

Form: Medical History (17)

Generated On: 10 Jun 2021 07:56:44

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:21:08
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 22:12:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Oct 2020 13:51:55
User coded data point as SOC: Musculoskeletal and connective tissue disorders, HLGT: Joint disorders, HLT: Osteoarthropathies, PT: Osteoarthritis, LLT: Ankle osteoarthritis - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	10 Sep 2020 18:08:40
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	10 Sep 2020 18:08:40
Data point term sent to Coder	System	10 Sep 2020 18:07:27
User entered 'OSTEOARTHRITIS OF ANKLE'	Allison Crain (b) (4) (b) (4)	10 Sep 2020 18:06:33

**US3512248**

**Folder: Screening**

**Form: Medical History (17)**

**Generated On: 10 Jun 2021 07:56:44**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:21:08
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 22:12:02
DataPoint Verified.	(b) (4)	(b) (4), (b) (6)
User entered 'UN UNK 2006'	Allison Crain (b) (4)	10 Sep 2020 18:06:33
	(b) (4)	

**US3512248**

**Folder: Screening**

**Form: Medical History (17)**

**Generated On: 10 Jun 2021 07:56:44**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:21:08
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 22:12:02
DataPoint Verified.	(b) (4)	(b) (4), (b) (6)
	(b) (4), (b) (6)	07 Oct 2020 13:51:55
User entered '0'	Allison Crain (b) (4)	10 Sep 2020 18:06:33
	(b) (4)	

**US3512248**

**Folder: Screening**

**Form: Medical History (17)**

**Generated On: 10 Jun 2021 07:56:44**

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:21:08
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 22:12:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Oct 2020 13:51:55
User entered 'Yes (Y)'	Allison Crain (b) (4) (b) (4)	10 Sep 2020 18:06:33



**US3512248**

**Folder: Screening**

**Form: Medical History (17)**

**Generated On: 10 Jun 2021 07:56:44**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:21:08
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 22:12:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Oct 2020 13:51:55
User entered empty.	Allison Crain (b) (4) (b) (4)	10 Sep 2020 18:06:33

**US3512248**

**Folder: Screening**

**Form: Medical History (17)**

**Generated On: 10 Jun 2021 07:56:44**

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:21:08
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 22:12:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Oct 2020 13:51:55
User entered '0'	Allison Crain (b) (4) (b) (4)	10 Sep 2020 18:06:33

**US3512248**

**Folder: Screening**

**Form: Medical History (17)**

**Generated On: 10 Jun 2021 07:56:44**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:21:08
User entered 'Jan 2006'	System	10 Sep 2020 18:06:33

**US3512248**

**Folder: Screening**

**Form: Medical History (17)**

**Generated On: 10 Jun 2021 07:56:44**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:21:08
User entered '2006'	System	10 Sep 2020 18:06:33

**US3512248**

**Folder: Screening**

**Form: Medical History (17)**

**Generated On: 10 Jun 2021 07:56:44**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:21:08
User entered empty.	System	10 Sep 2020 18:06:33

**US3512248**

**Folder: Screening**

**Form: Medical History (17)**

**Generated On: 10 Jun 2021 07:56:44**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:21:08
User entered empty.	System	10 Sep 2020 18:06:33

US3512248

Folder: Screening

Form: Medical History (18)

Generated On: 10 Jun 2021 07:56:44

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:21:08
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 22:12:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Oct 2020 13:51:55
User coded data point as SOC: Musculoskeletal and connective tissue disorders, HLGT: Musculoskeletal and connective tissue disorders NEC, HLT: Musculoskeletal and connective tissue pain and discomfort, PT: Back pain, LLT: Back pain - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	10 Sep 2020 18:08:40
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	10 Sep 2020 18:08:40
Data point term sent to Coder	System	10 Sep 2020 18:07:29
User entered 'BACK PAIN'	Allison Crain (b) (4) (b) (4)	10 Sep 2020 18:06:58

**US3512248**

**Folder: Screening**

**Form: Medical History (18)**

**Generated On: 10 Jun 2021 07:56:44**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:21:08
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 22:12:02
DataPoint Verified.	(b) (4)	(b) (4), (b) (6)
	(b) (4), (b) (6)	07 Oct 2020 13:51:55
User entered 'UN UNK 2000'	Allison Crain (b) (4)	10 Sep 2020 18:06:58
	(b) (4)	



**US3512248**

**Folder: Screening**

**Form: Medical History (18)**

**Generated On: 10 Jun 2021 07:56:44**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:21:08
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 22:12:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Oct 2020 13:51:55
User entered '0'	Allison Crain (b) (4) (b) (4)	10 Sep 2020 18:06:58

**US3512248**

**Folder: Screening**

**Form: Medical History (18)**

**Generated On: 10 Jun 2021 07:56:44**

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:21:08
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 22:12:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Oct 2020 13:51:55
User entered 'Yes (Y)'	Allison Crain (b) (4) (b) (4)	10 Sep 2020 18:06:58

**US3512248**

**Folder: Screening**

**Form: Medical History (18)**

**Generated On: 10 Jun 2021 07:56:44**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:21:08
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 22:12:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Oct 2020 13:51:55
User entered empty.	Allison Crain (b) (4) (b) (4)	10 Sep 2020 18:06:58

**US3512248**

**Folder: Screening**

**Form: Medical History (18)**

**Generated On: 10 Jun 2021 07:56:44**

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:21:08
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 22:12:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Oct 2020 13:51:55
User entered '0'	Allison Crain (b) (4) (b) (4)	10 Sep 2020 18:06:58

**US3512248**

**Folder: Screening**

**Form: Medical History (18)**

**Generated On: 10 Jun 2021 07:56:44**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:21:08
User entered 'Jan 2000'	System	10 Sep 2020 18:06:58

**US3512248**

**Folder: Screening**

**Form: Medical History (18)**

**Generated On: 10 Jun 2021 07:56:44**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:21:08
User entered '2000'	System	10 Sep 2020 18:06:58

**US3512248**

**Folder: Screening**

**Form: Medical History (18)**

**Generated On: 10 Jun 2021 07:56:44**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:21:08
User entered empty.	System	10 Sep 2020 18:06:58

**US3512248**

**Folder: Screening**

**Form: Medical History (18)**

**Generated On: 10 Jun 2021 07:56:44**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:21:08
User entered empty.	System	10 Sep 2020 18:06:58



US3512248

Folder: Screening

Form: Medical History (19)

Generated On: 10 Jun 2021 07:56:44

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:21:08
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 22:12:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Oct 2020 13:51:55
User coded data point as SOC: Injury, poisoning and procedural complications, HLG: Bone and joint injuries, HLT: Limb fractures and dislocations, PT: Lower limb fracture, LLT: Broken leg - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	10 Sep 2020 18:08:39
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	10 Sep 2020 18:08:39
Data point term sent to Coder	System	10 Sep 2020 18:07:29
User entered 'BROKEN RIGHT LEG'	Allison Crain (b) (4) (b) (4)	10 Sep 2020 18:07:15

**US3512248**

**Folder: Screening**

**Form: Medical History (19)**

**Generated On: 10 Jun 2021 07:56:44**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:21:08
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 22:12:02
DataPoint Verified.	(b) (4)	(b) (4), (b) (6)
	(b) (4), (b) (6)	07 Oct 2020 13:51:55
User entered 'UN UNK 1996'	Allison Crain (b) (4)	10 Sep 2020 18:07:15
	(b) (4)	

**US3512248**

**Folder: Screening**

**Form: Medical History (19)**

**Generated On: 10 Jun 2021 07:56:44**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:21:08
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 22:12:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Oct 2020 13:51:55
User entered '0'	Allison Crain (b) (4) (b) (4)	10 Sep 2020 18:07:15

**US3512248**

**Folder: Screening**

**Form: Medical History (19)**

**Generated On: 10 Jun 2021 07:56:44**

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:21:08
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 22:12:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Oct 2020 13:51:55
User entered 'No (N)'	Allison Crain (b) (4) (b) (4)	10 Sep 2020 18:07:15

**US3512248**

**Folder: Screening**

**Form: Medical History (19)**

**Generated On: 10 Jun 2021 07:56:44**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:21:08
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 22:12:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Oct 2020 13:51:55
User entered 'UN UNK 1996'	Allison Crain (b) (4) (b) (4)	10 Sep 2020 18:07:15

**US3512248**

**Folder: Screening**

**Form: Medical History (19)**

**Generated On: 10 Jun 2021 07:56:44**

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:21:08
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 22:12:02
DataPoint Verified.	(b) (4)	(b) (4), (b) (6)
	(b) (4), (b) (6)	07 Oct 2020 13:51:55
User entered '0'	Allison Crain (b) (4)	10 Sep 2020 18:07:15
	(b) (4)	

**US3512248**

**Folder: Screening**

**Form: Medical History (19)**

**Generated On: 10 Jun 2021 07:56:44**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:21:08
User entered 'Jan 1996'	System	10 Sep 2020 18:07:15

**US3512248**

**Folder: Screening**

**Form: Medical History (19)**

**Generated On: 10 Jun 2021 07:56:44**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:21:08
User entered '1996'	System	10 Sep 2020 18:07:15



**US3512248**

**Folder: Screening**

**Form: Medical History (19)**

**Generated On: 10 Jun 2021 07:56:44**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:21:08
User entered 'Jan 1996'	System	10 Sep 2020 18:07:15

**US3512248**

**Folder: Screening**

**Form: Medical History (19)**

**Generated On: 10 Jun 2021 07:56:44**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:21:08
User entered '1996'	System	10 Sep 2020 18:07:15

US3512248

Folder: Screening

Form: Medical History (20)

Generated On: 10 Jun 2021 07:56:44

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:21:08
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 22:12:02
User coded data point as SOC: Surgical and medical procedures, HLGT: Bone and joint therapeutic procedures, HLT: Fracture treatments (excl skull and spine), PT: Fracture treatment, LLT: Fracture repair - version MedDRA\\23.0.	Coder Import (b) (4)	18 Nov 2020 12:34:03
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4)	18 Nov 2020 12:34:03
DataPoint Verified.	(b) (4), (b) (6)	07 Oct 2020 13:51:55
Data point term sent to Coder	System	10 Sep 2020 18:08:40
User entered 'REPAIR OF BROKEN RIGHT LEG'	Allison Crain (b) (4)	10 Sep 2020 18:07:47

**US3512248**

**Folder: Screening**

**Form: Medical History (20)**

**Generated On: 10 Jun 2021 07:56:44**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:21:08
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 22:12:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Oct 2020 13:51:55
User entered 'UN UNK 1996'	Allison Crain (b) (4) (b) (4)	10 Sep 2020 18:07:47

**US3512248**

**Folder: Screening**

**Form: Medical History (20)**

**Generated On: 10 Jun 2021 07:56:44**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:21:08
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 22:12:02
DataPoint Verified.	(b) (4)	(b) (4), (b) (6)
User entered '0'	Allison Crain (b) (4)	10 Sep 2020 18:07:47
	(b) (4)	

**US3512248**

**Folder: Screening**

**Form: Medical History (20)**

**Generated On: 10 Jun 2021 07:56:44**

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:21:08
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 22:12:02
DataPoint Verified.	(b) (4)	(b) (4), (b) (6)
	(b) (4), (b) (6)	07 Oct 2020 13:51:55
User entered 'No (N)'	Allison Crain (b) (4)	10 Sep 2020 18:07:47
	(b) (4)	

**US3512248**

**Folder: Screening**

**Form: Medical History (20)**

**Generated On: 10 Jun 2021 07:56:44**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:21:08
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 22:12:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Oct 2020 13:51:55
User entered 'UN UNK 1996'	Allison Crain (b) (4) (b) (4)	10 Sep 2020 18:07:47

**US3512248**

**Folder: Screening**

**Form: Medical History (20)**

**Generated On: 10 Jun 2021 07:56:44**

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:21:08
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 22:12:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Oct 2020 13:51:55
User entered '0'	Allison Crain (b) (4) (b) (4)	10 Sep 2020 18:07:47



**US3512248**

**Folder: Screening**

**Form: Medical History (20)**

**Generated On: 10 Jun 2021 07:56:44**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:21:08
User entered 'Jan 1996'	System	10 Sep 2020 18:07:47

**US3512248**

**Folder: Screening**

**Form: Medical History (20)**

**Generated On: 10 Jun 2021 07:56:44**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:21:08
User entered '1996'	System	10 Sep 2020 18:07:47

**US3512248**

**Folder: Screening**

**Form: Medical History (20)**

**Generated On: 10 Jun 2021 07:56:44**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:21:08
User entered 'Jan 1996'	System	10 Sep 2020 18:07:47

**US3512248**

**Folder: Screening**

**Form: Medical History (20)**

**Generated On: 10 Jun 2021 07:56:44**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:21:08
User entered '1996'	System	10 Sep 2020 18:07:47

US3512248

Folder: Screening

Form: Medical History (21)

Generated On: 10 Jun 2021 07:56:44

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:21:08
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 22:12:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Oct 2020 13:51:55
User coded data point as SOC: Injury, poisoning and procedural complications, HLGT: Bone and joint injuries, HLT: Limb fractures and dislocations, PT: Upper limb fracture, LLT: Arm fracture - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	10 Sep 2020 18:09:42
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	10 Sep 2020 18:09:42
Data point term sent to Coder	System	10 Sep 2020 18:08:40
User entered 'BROKEN RIGHT ARM'	Allison Crain (b) (4) (b) (4)	10 Sep 2020 18:08:01

**US3512248**

**Folder: Screening**

**Form: Medical History (21)**

**Generated On: 10 Jun 2021 07:56:44**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:21:08
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 22:12:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Oct 2020 13:51:55
User entered 'UN UNK 1996'	Allison Crain (b) (4) (b) (4)	10 Sep 2020 18:08:01

**US3512248**

**Folder: Screening**

**Form: Medical History (21)**

**Generated On: 10 Jun 2021 07:56:44**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:21:08
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 22:12:02
DataPoint Verified.	(b) (4)	(b) (4), (b) (6)
	(b) (4), (b) (6)	07 Oct 2020 13:51:55
User entered '0'	Allison Crain (b) (4)	10 Sep 2020 18:08:01
	(b) (4)	

**US3512248**

**Folder: Screening**

**Form: Medical History (21)**

**Generated On: 10 Jun 2021 07:56:44**

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:21:08
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 22:12:02
DataPoint Verified.	(b) (4)	(b) (4), (b) (6)
	(b) (4), (b) (6)	07 Oct 2020 13:51:55
User entered 'No (N)'	Allison Crain (b) (4)	10 Sep 2020 18:08:01
	(b) (4)	



**US3512248**

**Folder: Screening**

**Form: Medical History (21)**

**Generated On: 10 Jun 2021 07:56:44**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:21:08
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 22:12:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Oct 2020 13:51:55
User entered 'UN UNK 1996'	Allison Crain (b) (4) (b) (4)	10 Sep 2020 18:08:01

**US3512248**

**Folder: Screening**

**Form: Medical History (21)**

**Generated On: 10 Jun 2021 07:56:44**

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:21:08
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 22:12:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Oct 2020 13:51:55
User entered '0'	Allison Crain (b) (4) (b) (4)	10 Sep 2020 18:08:01

**US3512248**

**Folder: Screening**

**Form: Medical History (21)**

**Generated On: 10 Jun 2021 07:56:44**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:21:08
User entered 'Jan 1996'	System	10 Sep 2020 18:08:01

**US3512248**

**Folder: Screening**

**Form: Medical History (21)**

**Generated On: 10 Jun 2021 07:56:44**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:21:08
User entered '1996'	System	10 Sep 2020 18:08:01

**US3512248**

**Folder: Screening**

**Form: Medical History (21)**

**Generated On: 10 Jun 2021 07:56:44**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:21:08
User entered 'Jan 1996'	System	10 Sep 2020 18:08:01

**US3512248**

**Folder: Screening**

**Form: Medical History (21)**

**Generated On: 10 Jun 2021 07:56:44**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:21:08
User entered '1996'	System	10 Sep 2020 18:08:01

US3512248

Folder: Screening

Form: Medical History (22)

Generated On: 10 Jun 2021 07:56:44

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:21:08
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 22:12:02
User coded data point as SOC: Surgical and medical procedures, HLGT: Bone and joint therapeutic procedures, HLT: Fracture treatments (excl skull and spine), PT: Fracture treatment, LLT: Fracture repair - version MedDRA\\23.0.	Coder Import (b) (4)	18 Nov 2020 12:34:04
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4)	18 Nov 2020 12:34:04
DataPoint Verified.	(b) (4), (b) (6)	07 Oct 2020 13:51:55
Data point term sent to Coder	System	10 Sep 2020 18:08:41
User entered 'REPAIR OF BROKEN RIGHT ARM'	Allison Crain (b) (4)	10 Sep 2020 18:08:19

**US3512248**

**Folder: Screening**

**Form: Medical History (22)**

**Generated On: 10 Jun 2021 07:56:44**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:21:08
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 22:12:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Oct 2020 13:51:55
User entered 'UN UNK 1996'	Allison Crain (b) (4) (b) (4)	10 Sep 2020 18:08:19



**US3512248**

**Folder: Screening**

**Form: Medical History (22)**

**Generated On: 10 Jun 2021 07:56:44**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:21:08
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 22:12:02
DataPoint Verified.	(b) (4)	(b) (4), (b) (6)
	(b) (4), (b) (6)	07 Oct 2020 13:51:55
User entered '0'	Allison Crain (b) (4)	10 Sep 2020 18:08:19
	(b) (4)	

**US3512248**

**Folder: Screening**

**Form: Medical History (22)**

**Generated On: 10 Jun 2021 07:56:44**

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:21:08
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 22:12:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Oct 2020 13:51:55
User entered 'No (N)'	Allison Crain (b) (4) (b) (4)	10 Sep 2020 18:08:19

**US3512248**

**Folder: Screening**

**Form: Medical History (22)**

**Generated On: 10 Jun 2021 07:56:44**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:21:08
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 22:12:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Oct 2020 13:51:55
User entered 'UN UNK 1996'	Allison Crain (b) (4) (b) (4)	10 Sep 2020 18:08:19

**US3512248**

**Folder: Screening**

**Form: Medical History (22)**

**Generated On: 10 Jun 2021 07:56:44**

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:21:08
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 22:12:02
DataPoint Verified.	(b) (4)	(b) (4), (b) (6)
	(b) (4), (b) (6)	07 Oct 2020 13:51:55
User entered '0'	Allison Crain (b) (4)	10 Sep 2020 18:08:19
	(b) (4)	

**US3512248**

**Folder: Screening**

**Form: Medical History (22)**

**Generated On: 10 Jun 2021 07:56:44**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:21:08
User entered 'Jan 1996'	System	10 Sep 2020 18:08:19

**US3512248**

**Folder: Screening**

**Form: Medical History (22)**

**Generated On: 10 Jun 2021 07:56:44**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:21:08
User entered '1996'	System	10 Sep 2020 18:08:19

**US3512248**

**Folder: Screening**

**Form: Medical History (22)**

**Generated On: 10 Jun 2021 07:56:44**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:21:08
User entered 'Jan 1996'	System	10 Sep 2020 18:08:19

**US3512248**

**Folder: Screening**

**Form: Medical History (22)**

**Generated On: 10 Jun 2021 07:56:44**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:21:08
User entered '1996'	System	10 Sep 2020 18:08:19



US3512248

Folder: Screening

Form: Medical History (23)

Generated On: 10 Jun 2021 07:56:44

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:21:08
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 22:12:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Oct 2020 13:51:55
User coded data point as SOC: General disorders and administration site conditions, HLGT: General system disorders NEC, HLT: Pain and discomfort NEC, PT: Pain, LLT: General body pain - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	10 Sep 2020 18:09:42
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	10 Sep 2020 18:09:42
Data point term sent to Coder	System	10 Sep 2020 18:08:42
User entered 'GENERAL ACHES AND PAINS'	Allison Crain (b) (4) (b) (4)	10 Sep 2020 18:08:32

**US3512248**

**Folder: Screening**

**Form: Medical History (23)**

**Generated On: 10 Jun 2021 07:56:44**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:21:08
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 22:12:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Oct 2020 13:51:55
User entered 'UN UNK 2006'	Allison Crain (b) (4) (b) (4)	10 Sep 2020 18:08:32

**US3512248**

**Folder: Screening**

**Form: Medical History (23)**

**Generated On: 10 Jun 2021 07:56:44**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:21:08
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 22:12:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Oct 2020 13:51:55
User entered '0'	Allison Crain (b) (4) (b) (4)	10 Sep 2020 18:08:32

**US3512248**

**Folder: Screening**

**Form: Medical History (23)**

**Generated On: 10 Jun 2021 07:56:44**

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:21:08
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 22:12:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Oct 2020 13:51:55
User entered 'Yes (Y)'	Allison Crain (b) (4) (b) (4)	10 Sep 2020 18:08:32

**US3512248**

**Folder: Screening**

**Form: Medical History (23)**

**Generated On: 10 Jun 2021 07:56:44**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:21:08
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 22:12:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Oct 2020 13:51:55
User entered empty.	Allison Crain (b) (4) (b) (4)	10 Sep 2020 18:08:32

**US3512248**

**Folder: Screening**

**Form: Medical History (23)**

**Generated On: 10 Jun 2021 07:56:44**

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:21:08
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 22:12:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Oct 2020 13:51:55
User entered '0'	Allison Crain (b) (4) (b) (4)	10 Sep 2020 18:08:32

**US3512248**

**Folder: Screening**

**Form: Medical History (23)**

**Generated On: 10 Jun 2021 07:56:44**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:21:08
User entered 'Jan 2006'	System	10 Sep 2020 18:08:32

**US3512248**

**Folder: Screening**

**Form: Medical History (23)**

**Generated On: 10 Jun 2021 07:56:44**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:21:08
User entered '2006'	System	10 Sep 2020 18:08:32



**US3512248**

**Folder: Screening**

**Form: Medical History (23)**

**Generated On: 10 Jun 2021 07:56:44**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:21:08
User entered empty.	System	10 Sep 2020 18:08:32

**US3512248**

**Folder: Screening**

**Form: Medical History (23)**

**Generated On: 10 Jun 2021 07:56:44**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:21:08
User entered empty.	System	10 Sep 2020 18:08:32

US3512248

Folder: Screening

Form: Medical History (24)

Generated On: 10 Jun 2021 07:56:44

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:21:08
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 22:12:02
User closed query 'Per DM CLR: Please note that there is no Con Med listed for treatment of this condition and treatment would be expected for this condition. Please review and if applicable add a Con Med or provide an explanation for no medical treatment.' (Site from DM).	(b) (4) (b) (4), (b) (6)	13 Oct 2020 10:27:16
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 'Subject is currently not being treated for this condition. Will add if one is started.' (Site from DM).	Allison Crain (b) (4) (b) (4)	08 Oct 2020 16:00:35
DataPoint Verified.	(b) (4), (b) (6)	07 Oct 2020 13:51:55
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)	02 Oct 2020 09:24:36
User coded data point as SOC: Metabolism and nutrition disorders, HLGT: Glucose metabolism disorders (incl diabetes mellitus), HLT: Hyperglycaemic conditions NEC, PT: Glucose tolerance impaired, LLT: Pre-diabetes - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	10 Sep 2020 18:10:47
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	10 Sep 2020 18:10:47
Data point term sent to Coder	System	10 Sep 2020 18:09:44
User entered 'PRE-DIABETES'	Allison Crain (b) (4) (b) (4)	10 Sep 2020 18:08:44

**US3512248**

**Folder: Screening**

**Form: Medical History (24)**

**Generated On: 10 Jun 2021 07:56:44**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:21:08
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 22:12:02
DataPoint Verified.	(b) (4)	(b) (4), (b) (6)
	(b) (4), (b) (6)	07 Oct 2020 13:51:55
User entered 'UN UNK 2012'	Allison Crain (b) (4)	10 Sep 2020 18:08:44
	(b) (4)	

**US3512248**

**Folder: Screening**

**Form: Medical History (24)**

**Generated On: 10 Jun 2021 07:56:44**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:21:08
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 22:12:02
DataPoint Verified.	(b) (4)	(b) (4), (b) (6)
User entered '0'	Allison Crain (b) (4)	10 Sep 2020 18:08:44
	(b) (4)	

**US3512248**

**Folder: Screening**

**Form: Medical History (24)**

**Generated On: 10 Jun 2021 07:56:44**

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:21:08
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 22:12:02
DataPoint Verified.	(b) (4)	(b) (4), (b) (6)
	(b) (4), (b) (6)	07 Oct 2020 13:51:55
User entered 'Yes (Y)'	Allison Crain (b) (4)	10 Sep 2020 18:08:44
	(b) (4)	

**US3512248**

**Folder: Screening**

**Form: Medical History (24)**

**Generated On: 10 Jun 2021 07:56:44**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:21:08
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 22:12:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Oct 2020 13:51:55
User entered empty.	Allison Crain (b) (4) (b) (4)	10 Sep 2020 18:08:44

**US3512248**

**Folder: Screening**

**Form: Medical History (24)**

**Generated On: 10 Jun 2021 07:56:44**

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:21:08
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 22:12:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Oct 2020 13:51:55
User entered '0'	Allison Crain (b) (4) (b) (4)	10 Sep 2020 18:08:44



**US3512248**

**Folder: Screening**

**Form: Medical History (24)**

**Generated On: 10 Jun 2021 07:56:44**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:21:08
User entered 'Jan 2012'	System	10 Sep 2020 18:08:44

**US3512248**

**Folder: Screening**

**Form: Medical History (24)**

**Generated On: 10 Jun 2021 07:56:44**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:21:08
User entered '2012'	System	10 Sep 2020 18:08:44

**US3512248**

**Folder: Screening**

**Form: Medical History (24)**

**Generated On: 10 Jun 2021 07:56:44**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:21:08
User entered empty.	System	10 Sep 2020 18:08:44

**US3512248**

**Folder: Screening**

**Form: Medical History (24)**

**Generated On: 10 Jun 2021 07:56:44**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:21:08
User entered empty.	System	10 Sep 2020 18:08:44

US3512248

Folder: Screening

Form: Medical History (25)

Generated On: 10 Jun 2021 07:56:44

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:21:08
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 22:12:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Oct 2020 13:51:55
User coded data point as SOC: Metabolism and nutrition disorders, HLGT: Appetite and general nutritional disorders, HLT: General nutritional disorders NEC, PT: Overweight, LLT: Overweight - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	10 Sep 2020 18:10:47
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	10 Sep 2020 18:10:47
Data point term sent to Coder	System	10 Sep 2020 18:09:44
User entered 'OVERWEIGHT'	Allison Crain (b) (4) (b) (4)	10 Sep 2020 18:09:04

**US3512248**

**Folder: Screening**

**Form: Medical History (25)**

**Generated On: 10 Jun 2021 07:56:44**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:21:08
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 22:12:02
DataPoint Verified.	(b) (4)	(b) (4), (b) (6)
	(b) (4), (b) (6)	07 Oct 2020 13:51:55
User entered 'UN UNK 1998'	Allison Crain (b) (4)	10 Sep 2020 18:09:04
	(b) (4)	

**US3512248**

**Folder: Screening**

**Form: Medical History (25)**

**Generated On: 10 Jun 2021 07:56:44**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:21:08
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 22:12:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Oct 2020 13:51:55
User entered '0'	Allison Crain (b) (4) (b) (4)	10 Sep 2020 18:09:04

**US3512248**

**Folder: Screening**

**Form: Medical History (25)**

**Generated On: 10 Jun 2021 07:56:44**

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:21:08
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 22:12:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Oct 2020 13:51:55
User entered 'Yes (Y)'	Allison Crain (b) (4) (b) (4)	10 Sep 2020 18:09:04



**US3512248**

**Folder: Screening**

**Form: Medical History (25)**

**Generated On: 10 Jun 2021 07:56:44**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:21:08
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 22:12:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Oct 2020 13:51:55
User entered empty.	Allison Crain (b) (4) (b) (4)	10 Sep 2020 18:09:04

**US3512248**

**Folder: Screening**

**Form: Medical History (25)**

**Generated On: 10 Jun 2021 07:56:44**

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:21:08
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 22:12:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Oct 2020 13:51:55
User entered '0'	Allison Crain (b) (4) (b) (4)	10 Sep 2020 18:09:04

**US3512248**

**Folder: Screening**

**Form: Medical History (25)**

**Generated On: 10 Jun 2021 07:56:44**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:21:08
User entered 'Jan 1998'	System	10 Sep 2020 18:09:04

**US3512248**

**Folder: Screening**

**Form: Medical History (25)**

**Generated On: 10 Jun 2021 07:56:44**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:21:08
User entered '1998'	System	10 Sep 2020 18:09:04

**US3512248**

**Folder: Screening**

**Form: Medical History (25)**

**Generated On: 10 Jun 2021 07:56:44**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:21:08
User entered empty.	System	10 Sep 2020 18:09:04

**US3512248**

**Folder: Screening**

**Form: Medical History (25)**

**Generated On: 10 Jun 2021 07:56:44**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:21:08
User entered empty.	System	10 Sep 2020 18:09:04

US3512248

Folder: Screening

Form: Medical History (26)

Generated On: 10 Jun 2021 07:56:44

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:21:08
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 22:12:02
User closed query 'Per DM CLR: Please review if this Condition is still ongoing as it was noted that a surgical procedure of CARDIAC ABLATION was performed in UN UNK 2010. Please review and update if appropriate. Otherwise, clarify.' (Site from DM).	(b) (4) (b) (4), (b) (6)	13 Oct 2020 10:28:00
Query 'Per DM CLR: Please review if this Condition is still ongoing as it was noted that a surgical procedure of CARDIAC ABLATION was performed in UN UNK 2010. Please review and update if appropriate. Otherwise, clarify.' answered with 'Cardiac ablation does not cure atrial fibrillation and patient is still on concomitant meds for this condition. Confirmed as is.' (Site from DM).	Allison Crain (b) (4) (b) (4)	08 Oct 2020 16:01:58
DataPoint Verified.	(b) (4), (b) (6)	07 Oct 2020 13:51:55
User opened query 'Per DM CLR: Please review if this Condition is still ongoing as it was noted that a surgical procedure of CARDIAC ABLATION was performed in UN UNK 2010. Please review and update if appropriate. Otherwise, clarify.' (Site from DM).	(b) (4), (b) (6)	02 Oct 2020 09:30:41
User coded data point as SOC: Cardiac disorders, HLT: Cardiac arrhythmias, HLT: Supraventricular arrhythmias, PT: Atrial fibrillation, LLT: Atrial fibrillation - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	10 Sep 2020 18:10:47
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	10 Sep 2020 18:10:47
Data point term sent to Coder	System	10 Sep 2020 18:09:44
User entered 'ATRIAL FIBRILLATION'	Allison Crain (b) (4) (b) (4)	10 Sep 2020 18:09:35

US3512248

Folder: Screening

Form: Medical History (26)

Generated On: 10 Jun 2021 07:56:44

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:21:08
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 19:43:23
User signature succeeded.	Michael Koren (b) (4)	02 Apr 2021 19:30:27
DataPoint Un-verified.	(b) (4)	
	Brenda Anderson (b) (4)	02 Apr 2021 14:07:48
Signature has been broken.	(b) (4)	
	Brenda Anderson (b) (4)	02 Apr 2021 14:07:48
	(b) (4)	
User entered 'UN Apr 2018' reason for change: Per Query Resolution	Brenda Anderson (b) (4)	02 Apr 2021 14:07:48
User signature succeeded.	(b) (4)	
	Michael Koren (b) (4)	12 Feb 2021 22:12:02
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	07 Oct 2020 13:51:55
User entered 'UN Oct 2018'	Allison Crain (b) (4)	10 Sep 2020 18:09:35
	(b) (4)	



**US3512248**

**Folder: Screening**

**Form: Medical History (26)**

**Generated On: 10 Jun 2021 07:56:44**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:21:08
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 22:12:02
DataPoint Verified.	(b) (4)	(b) (4), (b) (6)
	(b) (4), (b) (6)	07 Oct 2020 13:51:55
User entered '0'	Allison Crain (b) (4)	10 Sep 2020 18:09:35
	(b) (4)	

**US3512248**

**Folder: Screening**

**Form: Medical History (26)**

**Generated On: 10 Jun 2021 07:56:44**

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:21:08
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 22:12:02
DataPoint Verified.	(b) (4)	(b) (4), (b) (6)
	(b) (4), (b) (6)	07 Oct 2020 13:51:55
User entered 'Yes (Y)'	Allison Crain (b) (4)	10 Sep 2020 18:09:35
	(b) (4)	

**US3512248**

**Folder: Screening**

**Form: Medical History (26)**

**Generated On: 10 Jun 2021 07:56:44**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:21:08
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 22:12:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Oct 2020 13:51:55
User entered empty.	Allison Crain (b) (4) (b) (4)	10 Sep 2020 18:09:35

**US3512248**

**Folder: Screening**

**Form: Medical History (26)**

**Generated On: 10 Jun 2021 07:56:44**

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:21:08
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 22:12:02
DataPoint Verified.	(b) (4)	(b) (4), (b) (6)
	(b) (4), (b) (6)	07 Oct 2020 13:51:55
User entered '0'	Allison Crain (b) (4)	10 Sep 2020 18:09:35
	(b) (4)	

**US3512248**

**Folder: Screening**

**Form: Medical History (26)**

**Generated On: 10 Jun 2021 07:56:44**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:21:08
User entered 'Apr 2018'	System	02 Apr 2021 14:07:48
User entered 'Oct 2018'	System	10 Sep 2020 18:09:35

**US3512248**

**Folder: Screening**

**Form: Medical History (26)**

**Generated On: 10 Jun 2021 07:56:44**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:21:08
User entered '2018'	System	10 Sep 2020 18:09:35

**US3512248**

**Folder: Screening**

**Form: Medical History (26)**

**Generated On: 10 Jun 2021 07:56:44**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:21:08
User entered empty.	System	10 Sep 2020 18:09:35

**US3512248**

**Folder: Screening**

**Form: Medical History (26)**

**Generated On: 10 Jun 2021 07:56:44**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:21:08
User entered empty.	System	10 Sep 2020 18:09:35



US3512248

Folder: Screening

Form: Medical History (27)

Generated On: 10 Jun 2021 07:56:44

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:21:08
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 22:12:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Oct 2020 13:51:55
User coded data point as SOC: Surgical and medical procedures, HLGT: Cardiac therapeutic procedures, HLT: Cardiac therapeutic procedures NEC, PT: Cardiac ablation, LLT: Cardiac ablation - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	10 Sep 2020 18:11:52
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	10 Sep 2020 18:11:52
Data point term sent to Coder	System	10 Sep 2020 18:10:46
User entered 'CARDIAC ABLATION'	Allison Crain (b) (4) (b) (4)	10 Sep 2020 18:09:53

**US3512248**

**Folder: Screening**

**Form: Medical History (27)**

**Generated On: 10 Jun 2021 07:56:44**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:21:08
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 22:12:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Oct 2020 13:51:55
User entered 'UN Apr 2019'	Allison Crain (b) (4) (b) (4)	10 Sep 2020 18:09:53

**US3512248**

**Folder: Screening**

**Form: Medical History (27)**

**Generated On: 10 Jun 2021 07:56:44**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:21:08
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 22:12:02
DataPoint Verified.	(b) (4)	(b) (4), (b) (6)
	(b) (4), (b) (6)	07 Oct 2020 13:51:55
User entered '0'	Allison Crain (b) (4)	10 Sep 2020 18:09:53
	(b) (4)	

**US3512248**

**Folder: Screening**

**Form: Medical History (27)**

**Generated On: 10 Jun 2021 07:56:44**

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:21:08
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 22:12:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Oct 2020 13:51:55
User entered 'No (N)'	Allison Crain (b) (4) (b) (4)	10 Sep 2020 18:09:53

**US3512248**

**Folder: Screening**

**Form: Medical History (27)**

**Generated On: 10 Jun 2021 07:56:44**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:21:08
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 22:12:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Oct 2020 13:51:55
User entered 'UN Apr 2019'	Allison Crain (b) (4) (b) (4)	10 Sep 2020 18:09:53

**US3512248**

**Folder: Screening**

**Form: Medical History (27)**

**Generated On: 10 Jun 2021 07:56:44**

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:21:08
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 22:12:02
DataPoint Verified.	(b) (4)	(b) (4), (b) (6)
	(b) (4), (b) (6)	07 Oct 2020 13:51:55
User entered '0'	Allison Crain (b) (4)	10 Sep 2020 18:09:53
	(b) (4)	

**US3512248**

**Folder: Screening**

**Form: Medical History (27)**

**Generated On: 10 Jun 2021 07:56:44**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:21:08
User entered 'Apr 2019'	System	10 Sep 2020 18:09:53

**US3512248**

**Folder: Screening**

**Form: Medical History (27)**

**Generated On: 10 Jun 2021 07:56:44**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:21:08
User entered '2019'	System	10 Sep 2020 18:09:53



**US3512248**

**Folder: Screening**

**Form: Medical History (27)**

**Generated On: 10 Jun 2021 07:56:44**

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:21:08
User entered 'Apr 2019'	System	10 Sep 2020 18:09:53

**US3512248**

**Folder: Screening**

**Form: Medical History (27)**

**Generated On: 10 Jun 2021 07:56:44**

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:21:08
User entered '2019'	System	10 Sep 2020 18:09:53

US3512248

Folder: Screening

Form: Medical History (28)

Generated On: 10 Jun 2021 07:56:44

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:21:08
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 22:12:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Oct 2020 13:51:55
User coded data point as SOC: Investigations, HLG: Cardiac and vascular investigations (excl enzyme tests), HLT: Cardiac imaging procedures, PT: Catheterisation cardiac, LLT: Cardiac catheterization - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	11 Sep 2020 05:54:47
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	11 Sep 2020 05:54:47
Data point term sent to Coder	System	10 Sep 2020 18:10:47
User entered 'HEART CAUTERIZATION'	Allison Crain (b) (4) (b) (4)	10 Sep 2020 18:10:17

**US3512248**

**Folder: Screening**

**Form: Medical History (28)**

**Generated On: 10 Jun 2021 07:56:44**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:21:08
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 22:12:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Oct 2020 13:51:55
User entered 'UN UNK 2006'	Allison Crain (b) (4) (b) (4)	10 Sep 2020 18:10:17

**US3512248**

**Folder: Screening**

**Form: Medical History (28)**

**Generated On: 10 Jun 2021 07:56:44**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:21:08
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 22:12:02
DataPoint Verified.	(b) (4)	(b) (4), (b) (6)
	(b) (4), (b) (6)	07 Oct 2020 13:51:55
User entered '0'	Allison Crain (b) (4)	10 Sep 2020 18:10:17
	(b) (4)	

**US3512248**

**Folder: Screening**

**Form: Medical History (28)**

**Generated On: 10 Jun 2021 07:56:44**

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:21:08
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 22:12:02
DataPoint Verified.	(b) (4)	(b) (4), (b) (6)
	(b) (4), (b) (6)	07 Oct 2020 13:51:55
User entered 'No (N)'	Allison Crain (b) (4)	10 Sep 2020 18:10:17
	(b) (4)	

**US3512248**

**Folder: Screening**

**Form: Medical History (28)**

**Generated On: 10 Jun 2021 07:56:44**

[If No, please specify the stop date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:21:08
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 22:12:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Oct 2020 13:51:55
User entered 'UN UNK 2006'	Allison Crain (b) (4) (b) (4)	10 Sep 2020 18:10:17

**US3512248**

**Folder: Screening**

**Form: Medical History (28)**

**Generated On: 10 Jun 2021 07:56:44**

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:21:08
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 22:12:02
DataPoint Verified.	(b) (4)	(b) (4), (b) (6)
	(b) (4), (b) (6)	07 Oct 2020 13:51:55
User entered '0'	Allison Crain (b) (4)	10 Sep 2020 18:10:17
	(b) (4)	



**US3512248**

**Folder: Screening**

**Form: Medical History (28)**

**Generated On: 10 Jun 2021 07:56:44**

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:21:08
User entered 'Jan 2006'	System	10 Sep 2020 18:10:17

**US3512248**

**Folder: Screening**

**Form: Medical History (28)**

**Generated On: 10 Jun 2021 07:56:44**

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:21:08
User entered '2006'	System	10 Sep 2020 18:10:17

**US3512248**

**Folder: Screening**

**Form: Medical History (28)**

**Generated On: 10 Jun 2021 07:56:44**

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:21:08
User entered 'Jan 2006'	System	10 Sep 2020 18:10:17

**US3512248**

**Folder: Screening**

**Form: Medical History (28)**

**Generated On: 10 Jun 2021 07:56:44**

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:21:08
User entered '2006'	System	10 Sep 2020 18:10:17

US3512248

Folder: Screening

Form: Medical History (29)

Generated On: 10 Jun 2021 07:56:44

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:21:08
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 22:12:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Oct 2020 13:51:55
User coded data point as SOC: Cardiac disorders, HLGT: Coronary artery disorders, HLT: Coronary artery disorders NEC, PT: Coronary artery disease, LLT: Coronary artery disease - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	10 Sep 2020 18:11:52
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	10 Sep 2020 18:11:52
Data point term sent to Coder	System	10 Sep 2020 18:10:47
User entered 'CORONARY ARTERY DISEASE'	Allison Crain (b) (4) (b) (4)	10 Sep 2020 18:10:32

**US3512248**

**Folder: Screening**

**Form: Medical History (29)**

**Generated On: 10 Jun 2021 07:56:44**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:21:08
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 22:12:02
DataPoint Verified.	(b) (4)	(b) (4), (b) (6)
User entered 'UN UNK 2008'	Allison Crain (b) (4)	10 Sep 2020 18:10:32
	(b) (4)	

**US3512248**

**Folder: Screening**

**Form: Medical History (29)**

**Generated On: 10 Jun 2021 07:56:44**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:21:08
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 22:12:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Oct 2020 13:51:55
User entered '0'	Allison Crain (b) (4) (b) (4)	10 Sep 2020 18:10:32

**US3512248**

**Folder: Screening**

**Form: Medical History (29)**

**Generated On: 10 Jun 2021 07:56:44**

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:21:08
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 22:12:02
DataPoint Verified.	(b) (4)	(b) (4), (b) (6)
	(b) (4), (b) (6)	07 Oct 2020 13:51:55
User entered 'Yes (Y)'	Allison Crain (b) (4)	10 Sep 2020 18:10:32
	(b) (4)	



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**Folder: Screening**

**Form: Medical History (29)**

**Generated On: 10 Jun 2021 07:56:44**

[If No, please specify the stop date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:21:08
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 22:12:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Oct 2020 13:51:55
User entered empty.	Allison Crain (b) (4) (b) (4)	10 Sep 2020 18:10:32

**US3512248**

**Folder: Screening**

**Form: Medical History (29)**

**Generated On: 10 Jun 2021 07:56:44**

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:21:08
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 22:12:02
DataPoint Verified.	(b) (4)	(b) (4), (b) (6)
	(b) (4), (b) (6)	07 Oct 2020 13:51:55
User entered '0'	Allison Crain (b) (4)	10 Sep 2020 18:10:32
	(b) (4)	

**US3512248**

**Folder: Screening**

**Form: Medical History (29)**

**Generated On: 10 Jun 2021 07:56:44**

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:21:08
User entered 'Jan 2008'	System	10 Sep 2020 18:10:32

**US3512248**

**Folder: Screening**

**Form: Medical History (29)**

**Generated On: 10 Jun 2021 07:56:44**

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:21:08
User entered '2008'	System	10 Sep 2020 18:10:32

**US3512248**

**Folder: Screening**

**Form: Medical History (29)**

**Generated On: 10 Jun 2021 07:56:44**

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:21:08
User entered empty.	System	10 Sep 2020 18:10:32

**US3512248**

**Folder: Screening**

**Form: Medical History (29)**

**Generated On: 10 Jun 2021 07:56:44**

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:21:08
User entered empty.	System	10 Sep 2020 18:10:32

US3512248

Folder: Screening

Form: Medical History (30)

Generated On: 10 Jun 2021 07:56:44

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:21:08
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 22:12:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Oct 2020 13:51:55
User coded data point as SOC: Gastrointestinal disorders, HLGT: Abdominal hernias and other abdominal wall conditions, HLT: Inguinal hernias, PT: Inguinal hernia, LLT: Left inguinal hernia - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	10 Sep 2020 18:12:39
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	10 Sep 2020 18:12:39
Data point term sent to Coder	System	10 Sep 2020 18:11:49
User entered 'LEFT INGUINAL HERNIA'	Allison Crain (b) (4) (b) (4)	10 Sep 2020 18:11:16

US3512248

Folder: Screening

Form: Medical History (30)

Generated On: 10 Jun 2021 07:56:44

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:21:08
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 22:12:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Oct 2020 13:51:55
User closed query 'Start date is missing and Start date is completely unknown has not been checked. Please correct.' (Site from System).	System	14 Sep 2020 18:34:06
User entered 'un Aug 2018' reason for change: Data Entry Error	Brenda Anderson (b) (4) (b) (4)	14 Sep 2020 18:34:06
User opened query 'Start date is missing and Start date is completely unknown has not been checked. Please correct.' (Site from System).	System	10 Sep 2020 18:11:16
User entered empty.	Allison Crain (b) (4) (b) (4)	10 Sep 2020 18:11:16



**US3512248**

**Folder: Screening**

**Form: Medical History (30)**

**Generated On: 10 Jun 2021 07:56:44**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:21:08
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 22:12:02
DataPoint Verified.	(b) (4)	(b) (4), (b) (6)
User entered '0'	Allison Crain (b) (4)	10 Sep 2020 18:11:16
	(b) (4)	

**US3512248**

**Folder: Screening**

**Form: Medical History (30)**

**Generated On: 10 Jun 2021 07:56:44**

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:21:08
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 22:12:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Oct 2020 13:51:55
User entered 'No (N)'	Allison Crain (b) (4) (b) (4)	10 Sep 2020 18:11:16

**US3512248**

**Folder: Screening**

**Form: Medical History (30)**

**Generated On: 10 Jun 2021 07:56:44**

[If No, please specify the stop date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:21:08
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 22:12:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Oct 2020 13:51:55
User entered 'UN Sep 2018'	Allison Crain (b) (4) (b) (4)	10 Sep 2020 18:11:16

**US3512248**

**Folder: Screening**

**Form: Medical History (30)**

**Generated On: 10 Jun 2021 07:56:44**

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:21:08
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 22:12:02
DataPoint Verified.	(b) (4)	(b) (4), (b) (6)
	(b) (4), (b) (6)	07 Oct 2020 13:51:55
User entered '0'	Allison Crain (b) (4)	10 Sep 2020 18:11:16
	(b) (4)	

**US3512248**

**Folder: Screening**

**Form: Medical History (30)**

**Generated On: 10 Jun 2021 07:56:44**

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:21:08
User entered 'Aug 2018'	System	14 Sep 2020 18:34:06
User entered empty.	System	10 Sep 2020 18:11:16

**US3512248**

**Folder: Screening**

**Form: Medical History (30)**

**Generated On: 10 Jun 2021 07:56:44**

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:21:08
User entered '2018'	System	14 Sep 2020 18:34:06
User entered empty.	System	10 Sep 2020 18:11:16

**US3512248**

**Folder: Screening**

**Form: Medical History (30)**

**Generated On: 10 Jun 2021 07:56:44**

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:21:08
User entered 'Sep 2018'	System	10 Sep 2020 18:11:16

**US3512248**

**Folder: Screening**

**Form: Medical History (30)**

**Generated On: 10 Jun 2021 07:56:44**

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:21:08
User entered '2018'	System	10 Sep 2020 18:11:16



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Folder: Screening

Form: Medical History (31)

Generated On: 10 Jun 2021 07:56:44

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:21:08
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 22:12:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Oct 2020 13:51:55
User coded data point as SOC: Surgical and medical procedures, HLG: Gastrointestinal therapeutic procedures, HLT: Hernia repairs, PT: Inguinal hernia repair, LLT: Inguinal hernia repair - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	10 Sep 2020 18:12:41
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	10 Sep 2020 18:12:41
Data point term sent to Coder	System	10 Sep 2020 18:11:51
User entered 'LEFT INGUINAL HERNIA REPAIR'	Allison Crain (b) (4) (b) (4)	10 Sep 2020 18:11:34

**US3512248**

**Folder: Screening**

**Form: Medical History (31)**

**Generated On: 10 Jun 2021 07:56:44**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:21:08
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 22:12:02
DataPoint Verified.	(b) (4)	(b) (4), (b) (6)
User entered 'UN UNK 2017'	Allison Crain (b) (4)	10 Sep 2020 18:11:34
	(b) (4)	

**US3512248**

**Folder: Screening**

**Form: Medical History (31)**

**Generated On: 10 Jun 2021 07:56:44**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:21:08
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 22:12:02
DataPoint Verified.	(b) (4)	(b) (4), (b) (6)
User entered '0'	Allison Crain (b) (4)	10 Sep 2020 18:11:34
	(b) (4)	

**US3512248**

**Folder: Screening**

**Form: Medical History (31)**

**Generated On: 10 Jun 2021 07:56:44**

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:21:08
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 22:12:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Oct 2020 13:51:55
User entered 'No (N)'	Allison Crain (b) (4) (b) (4)	10 Sep 2020 18:11:34

**US3512248**

**Folder: Screening**

**Form: Medical History (31)**

**Generated On: 10 Jun 2021 07:56:44**

[If No, please specify the stop date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:21:08
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 22:12:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Oct 2020 13:51:55
User entered 'UN UNK 2017'	Allison Crain (b) (4) (b) (4)	10 Sep 2020 18:11:34

**US3512248**

**Folder: Screening**

**Form: Medical History (31)**

**Generated On: 10 Jun 2021 07:56:44**

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:21:08
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 22:12:02
DataPoint Verified.	(b) (4)	(b) (4), (b) (6)
	(b) (4), (b) (6)	07 Oct 2020 13:51:55
User entered '0'	Allison Crain (b) (4)	10 Sep 2020 18:11:34
	(b) (4)	

**US3512248**

**Folder: Screening**

**Form: Medical History (31)**

**Generated On: 10 Jun 2021 07:56:44**

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:21:08
User entered 'Jan 2017'	System	10 Sep 2020 18:11:34

**US3512248**

**Folder: Screening**

**Form: Medical History (31)**

**Generated On: 10 Jun 2021 07:56:44**

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:21:08
User entered '2017'	System	10 Sep 2020 18:11:34



**US3512248**

**Folder: Screening**

**Form: Medical History (31)**

**Generated On: 10 Jun 2021 07:56:44**

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:21:08
User entered 'Jan 2017'	System	10 Sep 2020 18:11:34

**US3512248**

**Folder: Screening**

**Form: Medical History (31)**

**Generated On: 10 Jun 2021 07:56:44**

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:21:08
User entered '2017'	System	10 Sep 2020 18:11:34

US3512248

Folder: Screening

Form: Medical History (32)

Generated On: 10 Jun 2021 07:56:44

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:21:08
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 22:12:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Oct 2020 13:51:55
User coded data point as SOC: Surgical and medical procedures, HLG: Gastrointestinal therapeutic procedures, HLT: Hernia repairs, PT: Inguinal hernia repair, LLT: Inguinal hernia repair - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	10 Sep 2020 18:13:43
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	10 Sep 2020 18:13:43
Data point term sent to Coder	System	10 Sep 2020 18:12:52
User entered 'LEFT INGUINAL HERNIA REPAIR'	Allison Crain (b) (4) (b) (4)	10 Sep 2020 18:11:55

**US3512248**

**Folder: Screening**

**Form: Medical History (32)**

**Generated On: 10 Jun 2021 07:56:44**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:21:08
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 22:12:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Oct 2020 13:51:55
User entered 'UN Sep 2018'	Allison Crain (b) (4) (b) (4)	10 Sep 2020 18:11:55

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**Folder: Screening**

**Form: Medical History (32)**

**Generated On: 10 Jun 2021 07:56:44**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:21:08
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 22:12:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Oct 2020 13:51:55
User entered '0'	Allison Crain (b) (4) (b) (4)	10 Sep 2020 18:11:55

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**Folder: Screening**

**Form: Medical History (32)**

**Generated On: 10 Jun 2021 07:56:44**

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:21:08
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 22:12:02
DataPoint Verified.	(b) (4)	(b) (4), (b) (6)
	(b) (4), (b) (6)	07 Oct 2020 13:51:55
User entered 'No (N)'	Allison Crain (b) (4)	10 Sep 2020 18:11:55
	(b) (4)	

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**Folder: Screening**

**Form: Medical History (32)**

**Generated On: 10 Jun 2021 07:56:44**

[If No, please specify the stop date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:21:08
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 22:12:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Oct 2020 13:51:55
User entered 'UN Sep 2018'	Allison Crain (b) (4) (b) (4)	10 Sep 2020 18:11:55

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**Folder: Screening**

**Form: Medical History (32)**

**Generated On: 10 Jun 2021 07:56:44**

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:21:08
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 22:12:02
DataPoint Verified.	(b) (4)	(b) (4), (b) (6)
	(b) (4), (b) (6)	07 Oct 2020 13:51:55
User entered '0'	Allison Crain (b) (4)	10 Sep 2020 18:11:55
	(b) (4)	



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**Folder: Screening**

**Form: Medical History (32)**

**Generated On: 10 Jun 2021 07:56:44**

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:21:08
User entered 'Sep 2018'	System	10 Sep 2020 18:11:55

**US3512248**

**Folder: Screening**

**Form: Medical History (32)**

**Generated On: 10 Jun 2021 07:56:44**

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:21:08
User entered '2018'	System	10 Sep 2020 18:11:55

**US3512248**

**Folder: Screening**

**Form: Medical History (32)**

**Generated On: 10 Jun 2021 07:56:44**

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:21:08
User entered 'Sep 2018'	System	10 Sep 2020 18:11:55

**US3512248**

**Folder: Screening**

**Form: Medical History (32)**

**Generated On: 10 Jun 2021 07:56:44**

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:21:08
User entered '2018'	System	10 Sep 2020 18:11:55

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Folder: Screening

Form: Medical History (33)

Generated On: 10 Jun 2021 07:56:44

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:21:08
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 19:43:23
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 22:12:02
User coded data point as SOC: Injury, poisoning and procedural complications, HLG: Bone and joint injuries, HLT: Limb fractures and dislocations, PT: Patella fracture, LLT: Patella fracture - version MedDRA\\23.0.	Coder Import (b) (4)	16 Nov 2020 19:17:57
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	16 Nov 2020 19:17:57
Data point term sent to Coder	System	16 Nov 2020 19:17:06
User entered 'right patella fracture'	Brenda Anderson (b) (4)	16 Nov 2020 19:16:22
DataPoint activated with code reason code Data required.	Brenda Anderson (b) (4)	16 Nov 2020 19:14:16
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	30 Oct 2020 10:57:11

US3512248

Folder: Screening

Form: Medical History (33)

Generated On: 10 Jun 2021 07:56:44

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:21:08
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 19:43:23
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 22:12:02
User entered '08 Aug 2020'	(b) (4)	
	Brenda Anderson (b) (4)	16 Nov 2020 19:16:22
	(b) (4)	
DataPoint activated with code reason code Data required.	Brenda Anderson (b) (4)	16 Nov 2020 19:14:16
	(b) (4)	
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	30 Oct 2020 10:57:11

US3512248

Folder: Screening

Form: Medical History (33)

Generated On: 10 Jun 2021 07:56:44

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:21:08
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 19:43:23
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 22:12:02
User entered '0'	(b) (4) Brenda Anderson (b) (4)	16 Nov 2020 19:16:22
DataPoint activated with code reason code Data required.	(b) (4) Brenda Anderson (b) (4)	16 Nov 2020 19:14:16
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	30 Oct 2020 10:57:11

US3512248

Folder: Screening

Form: Medical History (33)

Generated On: 10 Jun 2021 07:56:44

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:21:08
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 19:43:23
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 22:12:02
User entered 'Yes (Y)'	(b) (4) Brenda Anderson (b) (4)	16 Nov 2020 19:16:22
DataPoint activated with code reason code Data required.	(b) (4) Brenda Anderson (b) (4)	16 Nov 2020 19:14:16
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	30 Oct 2020 10:57:11



US3512248

Folder: Screening

Form: Medical History (33)

Generated On: 10 Jun 2021 07:56:44

If No, please specify the stop date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:21:08
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 19:43:23
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 22:12:02
User entered empty.	(b) (4)	
	Brenda Anderson (b) (4)	16 Nov 2020 19:16:22
	(b) (4)	
DataPoint activated with code reason code Data required.	Brenda Anderson (b) (4)	16 Nov 2020 19:14:16
	(b) (4)	
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	30 Oct 2020 10:57:11

US3512248

Folder: Screening

Form: Medical History (33)

Generated On: 10 Jun 2021 07:56:44

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:21:08
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 19:43:23
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 22:12:02
User entered '0'	(b) (4) Brenda Anderson (b) (4)	16 Nov 2020 19:16:22
DataPoint activated with code reason code Data required.	(b) (4) Brenda Anderson (b) (4)	16 Nov 2020 19:14:16
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	30 Oct 2020 10:57:11

US3512248

Folder: Screening

Form: Medical History (33)

Generated On: 10 Jun 2021 07:56:44

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:21:08
User entered 'Aug 2020'	System	16 Nov 2020 19:16:22
DataPoint activated with code reason code Data required.	Brenda Anderson (b) (4)	16 Nov 2020 19:14:16
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	30 Oct 2020 10:57:11

US3512248

Folder: Screening

Form: Medical History (33)

Generated On: 10 Jun 2021 07:56:44

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:21:08
User entered '2020'	System	16 Nov 2020 19:16:22
DataPoint activated with code reason code Data required.	Brenda Anderson (b) (4)	16 Nov 2020 19:14:16
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	30 Oct 2020 10:57:11

US3512248

Folder: Screening

Form: Medical History (33)

Generated On: 10 Jun 2021 07:56:44

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:21:08
User entered empty.	System	16 Nov 2020 19:16:22
DataPoint activated with code reason code Data required.	Brenda Anderson (b) (4)	16 Nov 2020 19:14:16
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	30 Oct 2020 10:57:11

US3512248

Folder: Screening

Form: Medical History (33)

Generated On: 10 Jun 2021 07:56:44

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:21:08
User entered empty.	System	16 Nov 2020 19:16:22
DataPoint activated with code reason code Data required.	Brenda Anderson (b) (4)	16 Nov 2020 19:14:16
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	30 Oct 2020 10:57:11

US3512248

Folder: Screening

Form: Medical History (34)

Generated On: 10 Jun 2021 07:56:44

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:21:08
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 22:12:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Oct 2020 13:51:55
User coded data point as SOC: Surgical and medical procedures, HLGT: Male genital tract therapeutic procedures, HLT: Male genital tract therapeutic procedures NEC, PT: Vasectomy, LLT: Vasectomy - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	10 Sep 2020 18:15:20
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	10 Sep 2020 18:15:20
Data point term sent to Coder	System	10 Sep 2020 18:13:54
User entered 'VASECTOMY'	Allison Crain (b) (4) (b) (4)	10 Sep 2020 18:13:04

**US3512248**

**Folder: Screening**

**Form: Medical History (34)**

**Generated On: 10 Jun 2021 07:56:44**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:21:08
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 22:12:02
DataPoint Verified.	(b) (4)	(b) (4), (b) (6)
User entered 'UN UNK 1972'	Allison Crain (b) (4)	10 Sep 2020 18:13:04
	(b) (4)	



**US3512248**

**Folder: Screening**

**Form: Medical History (34)**

**Generated On: 10 Jun 2021 07:56:44**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:21:08
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 22:12:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Oct 2020 13:51:55
User entered '0'	Allison Crain (b) (4) (b) (4)	10 Sep 2020 18:13:04

**US3512248**

**Folder: Screening**

**Form: Medical History (34)**

**Generated On: 10 Jun 2021 07:56:44**

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:21:08
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 22:12:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Oct 2020 13:51:55
User entered 'No (N)'	Allison Crain (b) (4) (b) (4)	10 Sep 2020 18:13:04

**US3512248**

**Folder: Screening**

**Form: Medical History (34)**

**Generated On: 10 Jun 2021 07:56:44**

[If No, please specify the stop date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:21:08
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 22:12:02
DataPoint Verified.	(b) (4)	(b) (4), (b) (6)
	(b) (4), (b) (6)	07 Oct 2020 13:51:55
User entered 'UN UNK 1972'	Allison Crain (b) (4)	10 Sep 2020 18:13:04
	(b) (4)	

**US3512248**

**Folder: Screening**

**Form: Medical History (34)**

**Generated On: 10 Jun 2021 07:56:44**

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:21:08
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 22:12:02
DataPoint Verified.	(b) (4)	(b) (4), (b) (6)
	(b) (4), (b) (6)	07 Oct 2020 13:51:55
User entered '0'	Allison Crain (b) (4)	10 Sep 2020 18:13:04
	(b) (4)	

**US3512248**

**Folder: Screening**

**Form: Medical History (34)**

**Generated On: 10 Jun 2021 07:56:44**

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:21:08
User entered 'Jan 1972'	System	10 Sep 2020 18:13:04

**US3512248**

**Folder: Screening**

**Form: Medical History (34)**

**Generated On: 10 Jun 2021 07:56:44**

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:21:08
User entered '1972'	System	10 Sep 2020 18:13:04

**US3512248**

**Folder: Screening**

**Form: Medical History (34)**

**Generated On: 10 Jun 2021 07:56:44**

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:21:08
User entered 'Jan 1972'	System	10 Sep 2020 18:13:04

**US3512248**

**Folder: Screening**

**Form: Medical History (34)**

**Generated On: 10 Jun 2021 07:56:44**

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:21:08
User entered '1972'	System	10 Sep 2020 18:13:04



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Folder: Screening

Form: Medical History (35)

Generated On: 10 Jun 2021 07:56:44

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:21:08
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 22:12:02
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	07 Oct 2020 13:51:55
User coded data point as SOC: Social circumstances, HLGT: Lifestyle issues, HLT: Tobacco use, PT: Tobacco user, LLT: Smoker - version MedDRA\\23.0.	Coder Import (b) (4)	14 Sep 2020 18:41:50
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	14 Sep 2020 18:41:50
Data point term sent to Coder	System	14 Sep 2020 18:40:54
User entered 'smoker'	Brenda Anderson (b) (4)	14 Sep 2020 18:40:09
	(b) (4)	

**US3512248**

**Folder: Screening**

**Form: Medical History (35)**

**Generated On: 10 Jun 2021 07:56:44**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:21:08
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 22:12:02
DataPoint Verified.	(b) (4)	(b) (4), (b) (6)
		07 Oct 2020 13:51:55
User entered 'un UNK 1963'	Brenda Anderson (b) (4)	14 Sep 2020 18:40:09
	(b) (4)	

**US3512248**

**Folder: Screening**

**Form: Medical History (35)**

**Generated On: 10 Jun 2021 07:56:44**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:21:08
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 22:12:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Oct 2020 13:51:55
User entered '0'	Brenda Anderson (b) (4) (b) (4)	14 Sep 2020 18:40:09

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**Folder: Screening**

**Form: Medical History (35)**

**Generated On: 10 Jun 2021 07:56:44**

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:21:08
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 22:12:02
DataPoint Verified.	(b) (4)	(b) (4), (b) (6)
		07 Oct 2020 13:51:55
User entered 'No (N)'	Brenda Anderson (b) (4)	14 Sep 2020 18:40:09
	(b) (4)	

**US3512248**

**Folder: Screening**

**Form: Medical History (35)**

**Generated On: 10 Jun 2021 07:56:44**

[If No, please specify the stop date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:21:08
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 22:12:02
DataPoint Verified.	(b) (4)	(b) (4), (b) (6)
		07 Oct 2020 13:51:55
User entered 'un UNK 1993'	Brenda Anderson (b) (4)	14 Sep 2020 18:40:09
	(b) (4)	

**US3512248**

**Folder: Screening**

**Form: Medical History (35)**

**Generated On: 10 Jun 2021 07:56:44**

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:21:08
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 22:12:02
DataPoint Verified.	(b) (4)	(b) (4), (b) (6)
		07 Oct 2020 13:51:55
User entered '0'	Brenda Anderson (b) (4)	14 Sep 2020 18:40:09
	(b) (4)	

**US3512248**

**Folder: Screening**

**Form: Medical History (35)**

**Generated On: 10 Jun 2021 07:56:44**

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:21:08
User entered 'Jan 1963'	System	14 Sep 2020 18:40:09

**US3512248**

**Folder: Screening**

**Form: Medical History (35)**

**Generated On: 10 Jun 2021 07:56:44**

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:21:08
User entered '1963'	System	14 Sep 2020 18:40:09



**US3512248**

**Folder: Screening**

**Form: Medical History (35)**

**Generated On: 10 Jun 2021 07:56:44**

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:21:08
User entered 'Jan 1993'	System	14 Sep 2020 18:40:09

**US3512248**

**Folder: Screening**

**Form: Medical History (35)**

**Generated On: 10 Jun 2021 07:56:44**

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:21:08
User entered '1993'	System	14 Sep 2020 18:40:09

US3512248

Folder: Screening

Form: Medical History (36)

Generated On: 10 Jun 2021 07:56:44

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:21:08
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 19:43:23
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 22:12:02
User coded data point as SOC: Metabolism and nutrition disorders, HLGT: Lipid metabolism disorders, HLT: Elevated cholesterol, PT: Hypercholesterolaemia, LLT: Hypercholesterolemia - version MedDRA\\23.0.	(b) (4) Coder Import (b) (4) (b) (4)	05 Nov 2020 22:06:29
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	05 Nov 2020 22:06:29
Data point term sent to Coder	System	05 Nov 2020 21:50:33
User entered 'HYPERCHOLESTEROLEMIA'	Brenda Anderson (b) (4) (b) (4)	05 Nov 2020 21:49:29

US3512248

Folder: Screening

Form: Medical History (36)

Generated On: 10 Jun 2021 07:56:44

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:21:08
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 19:43:23
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 22:12:02
User closed query 'Start date is missing and Start date is completely unknown has not been checked. Please correct.' (Site from System).	(b) (4) System	12 Nov 2020 13:28:54
User entered 'un UNK 2006' reason for change: Data Entry Error	Brenda Anderson (b) (4)	12 Nov 2020 13:28:54
User opened query 'Start date is missing and Start date is completely unknown has not been checked. Please correct.' (Site from System).	(b) (4) System	05 Nov 2020 21:49:29
User entered empty.	Brenda Anderson (b) (4)	05 Nov 2020 21:49:29

**US3512248**

**Folder: Screening**

**Form: Medical History (36)**

**Generated On: 10 Jun 2021 07:56:44**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:21:08
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 19:43:23
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 22:12:02
User entered '0'	(b) (4) Brenda Anderson (b) (4)	05 Nov 2020 21:49:29

**US3512248**

**Folder: Screening**

**Form: Medical History (36)**

**Generated On: 10 Jun 2021 07:56:44**

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:21:08
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 19:43:23
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 22:12:02
User entered 'Yes (Y)'	(b) (4) Brenda Anderson (b) (4)	05 Nov 2020 21:49:29
	(b) (4)	

**US3512248**

**Folder: Screening**

**Form: Medical History (36)**

**Generated On: 10 Jun 2021 07:56:44**

[If No, please specify the stop date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:21:08
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 19:43:23
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 22:12:02
User entered empty.	(b) (4) Brenda Anderson (b) (4)	05 Nov 2020 21:49:29

**US3512248**

**Folder: Screening**

**Form: Medical History (36)**

**Generated On: 10 Jun 2021 07:56:44**

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:21:08
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 19:43:23
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 22:12:02
User entered '0'	(b) (4) Brenda Anderson (b) (4)	05 Nov 2020 21:49:29



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**Folder: Screening**

**Form: Medical History (36)**

**Generated On: 10 Jun 2021 07:56:44**

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:21:08
User entered 'Jan 2006'	System	12 Nov 2020 13:28:54
User entered empty.	System	05 Nov 2020 21:49:29

**US3512248**

**Folder: Screening**

**Form: Medical History (36)**

**Generated On: 10 Jun 2021 07:56:44**

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:21:08
User entered '2006'	System	12 Nov 2020 13:28:54
User entered empty.	System	05 Nov 2020 21:49:29

**US3512248**

**Folder: Screening**

**Form: Medical History (36)**

**Generated On: 10 Jun 2021 07:56:44**

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:21:08
User entered empty.	System	05 Nov 2020 21:49:29

**US3512248**

**Folder: Screening**

**Form: Medical History (36)**

**Generated On: 10 Jun 2021 07:56:44**

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:21:08
User entered empty.	System	05 Nov 2020 21:49:29

US3512248

Folder: Screening

Form: Medical History (38)

Generated On: 10 Jun 2021 07:56:44

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:21:08
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 19:43:23
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 22:12:02
User coded data point as SOC: Injury, poisoning and procedural complications, HLGT: Bone and joint injuries, HLT: Bone and joint injuries NEC, PT: Meniscus injury, LLT: Meniscus tear - version MedDRA\\23.0.	(b) (4) Coder Import (b) (4)	16 Nov 2020 18:59:49
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	16 Nov 2020 18:59:49
Data point term sent to Coder	System	16 Nov 2020 18:58:39
User entered 'left meniscus tear'	Brenda Anderson (b) (4)	16 Nov 2020 18:58:22
	(b) (4)	

**US3512248**

**Folder: Screening**

**Form: Medical History (38)**

**Generated On: 10 Jun 2021 07:56:44**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:21:08
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 19:43:23
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 22:12:02
User entered 'un UNK 2019'	(b) (4) Brenda Anderson (b) (4)	16 Nov 2020 18:58:22

**US3512248**

**Folder: Screening**

**Form: Medical History (38)**

**Generated On: 10 Jun 2021 07:56:44**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:21:08
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 19:43:23
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 22:12:02
User entered '0'	(b) (4) Brenda Anderson (b) (4)	16 Nov 2020 18:58:22

**US3512248**

**Folder: Screening**

**Form: Medical History (38)**

**Generated On: 10 Jun 2021 07:56:44**

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:21:08
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 19:43:23
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 22:12:02
User entered 'Yes (Y)'	(b) (4) Brenda Anderson (b) (4)	16 Nov 2020 18:58:22
	(b) (4)	



**US3512248**

**Folder: Screening**

**Form: Medical History (38)**

**Generated On: 10 Jun 2021 07:56:44**

[If No, please specify the stop date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:21:08
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 19:43:23
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 22:12:02
User entered empty.	(b) (4) Brenda Anderson (b) (4)	16 Nov 2020 18:58:22

**US3512248**

**Folder: Screening**

**Form: Medical History (38)**

**Generated On: 10 Jun 2021 07:56:44**

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:21:08
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 19:43:23
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 22:12:02
User entered '0'	(b) (4) Brenda Anderson (b) (4)	16 Nov 2020 18:58:22
	(b) (4)	

**US3512248**

**Folder: Screening**

**Form: Medical History (38)**

**Generated On: 10 Jun 2021 07:56:44**

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:21:08
User entered 'Jan 2019'	System	16 Nov 2020 18:58:22

**US3512248**

**Folder: Screening**

**Form: Medical History (38)**

**Generated On: 10 Jun 2021 07:56:44**

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:21:08
User entered '2019'	System	16 Nov 2020 18:58:22

**US3512248**

**Folder: Screening**

**Form: Medical History (38)**

**Generated On: 10 Jun 2021 07:56:44**

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:21:08
User entered empty.	System	16 Nov 2020 18:58:22

**US3512248**

**Folder: Screening**

**Form: Medical History (38)**

**Generated On: 10 Jun 2021 07:56:44**

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:21:08
User entered empty.	System	16 Nov 2020 18:58:22

US3512248

Folder: Screening

Form: Medical History (39)

Generated On: 10 Jun 2021 07:56:44

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:21:08
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 19:43:23
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 22:12:02
User coded data point as SOC: Musculoskeletal and connective tissue disorders, HLGT: Joint disorders, HLT: Joint related signs and symptoms, PT: Joint effusion, LLT: Effusion (r) knee - version MedDRA\\23.0.	Coder Import (b) (4)	17 Nov 2020 10:27:55
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4)	17 Nov 2020 10:27:55
Data point term sent to Coder	System	16 Nov 2020 19:18:07
User entered 'right lateral meniscus effusion'	Brenda Anderson (b) (4)	16 Nov 2020 19:17:11

**US3512248**

**Folder: Screening**

**Form: Medical History (39)**

**Generated On: 10 Jun 2021 07:56:44**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:21:08
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 19:43:23
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 22:12:02
User entered '08 Aug 2020'	(b) (4) Brenda Anderson (b) (4)	16 Nov 2020 19:17:11



**US3512248**

**Folder: Screening**

**Form: Medical History (39)**

**Generated On: 10 Jun 2021 07:56:44**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:21:08
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 19:43:23
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 22:12:02
User entered '0'	(b) (4) Brenda Anderson (b) (4)	16 Nov 2020 19:17:11
	(b) (4)	

**US3512248**

**Folder: Screening**

**Form: Medical History (39)**

**Generated On: 10 Jun 2021 07:56:44**

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:21:08
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 19:43:23
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 22:12:02
User entered 'No (N)'	(b) (4) Brenda Anderson (b) (4)	16 Nov 2020 19:17:11

**US3512248**

**Folder: Screening**

**Form: Medical History (39)**

**Generated On: 10 Jun 2021 07:56:44**

[If No, please specify the stop date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:21:08
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 19:43:23
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 22:12:02
User entered '08 Aug 2020'	(b) (4) Brenda Anderson (b) (4)	16 Nov 2020 19:17:11

**US3512248**

**Folder: Screening**

**Form: Medical History (39)**

**Generated On: 10 Jun 2021 07:56:44**

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:21:08
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 19:43:23
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 22:12:02
User entered '0'	(b) (4) Brenda Anderson (b) (4)	16 Nov 2020 19:17:11
	(b) (4)	

**US3512248**

**Folder: Screening**

**Form: Medical History (39)**

**Generated On: 10 Jun 2021 07:56:44**

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:21:08
User entered 'Aug 2020'	System	16 Nov 2020 19:17:11

**US3512248**

**Folder: Screening**

**Form: Medical History (39)**

**Generated On: 10 Jun 2021 07:56:44**

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:21:08
User entered '2020'	System	16 Nov 2020 19:17:11

**US3512248**

**Folder: Screening**

**Form: Medical History (39)**

**Generated On: 10 Jun 2021 07:56:44**

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:21:08
User entered 'Aug 2020'	System	16 Nov 2020 19:17:11

**US3512248**

**Folder: Screening**

**Form: Medical History (39)**

**Generated On: 10 Jun 2021 07:56:44**

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:21:08
User entered '2020'	System	16 Nov 2020 19:17:11



US3512248

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 07:56:44

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:21:08
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 22:12:02
DataPoint Verified.	(b) (4)	(b) (4), (b) (6)
	(b) (4), (b) (6)	07 Oct 2020 13:52:30
User entered 'Yes (Y)'	Allison Crain (b) (4)	10 Sep 2020 17:13:46
	(b) (4)	

US3512248

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 07:56:44

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:21:08
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 22:12:02
DataPoint Verified.	(b) (4)	(b) (4), (b) (6)
	(b) (4), (b) (6)	07 Oct 2020 13:52:30
User entered '10 Sep 2020'	Allison Crain (b) (4)	10 Sep 2020 17:13:46
	(b) (4)	

**US3512248**

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 07:56:44**

[Time of assessment \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:21:08
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 22:12:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Oct 2020 13:52:30
User entered '11:31'	Allison Crain (b) (4) (b) (4)	10 Sep 2020 17:13:46

**US3512248**

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 07:56:44**

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:21:08
User entered '10 Sep 2020 11:31'	System	10 Sep 2020 17:13:46

US3512248

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 07:56:44

[Height \(xxx.x\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:21:08
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 22:12:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Oct 2020 13:52:30
User entered '71' in	Allison Crain (b) (4)	10 Sep 2020 17:13:46
DataPoint set to visible.	(b) (4) System	10 Sep 2020 17:00:09

US3512248

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 07:56:44

[Weight \(xxx.x\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:21:08
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 22:12:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Oct 2020 13:52:30
User entered '231.4' lb	Allison Crain (b) (4)	10 Sep 2020 17:13:46
DataPoint set to visible.	(b) (4) System	10 Sep 2020 17:00:09

**US3512248**

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 07:56:44**

[BMI \(xxx.x\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:21:08
User entered '32.34123'	System	10 Sep 2020 17:13:46
DataPoint set to visible.	System	10 Sep 2020 17:00:09

**US3512248**

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 07:56:44**

[BMI units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:21:08
User entered 'kg/m2'	System	10 Sep 2020 17:13:46
DataPoint set to visible.	System	10 Sep 2020 17:00:09



US3512248

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 07:56:44

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:21:08
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 22:12:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Oct 2020 13:52:30
User entered missing code ND - Not Done.	Allison Crain (b) (4) (b) (4)	10 Sep 2020 17:13:46

US3512248

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 07:56:44

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:21:08
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 22:12:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Oct 2020 13:52:30
User entered empty.	Allison Crain (b) (4) (b) (4)	10 Sep 2020 17:13:46

**US3512248**

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 07:56:44**

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:21:08
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 22:12:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Oct 2020 13:52:30
User entered empty.	Allison Crain (b) (4) (b) (4)	10 Sep 2020 17:13:46

**US3512248**

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 07:56:44**

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:21:08
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 22:12:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Oct 2020 13:52:30
User entered missing code ND - Not Done.	Allison Crain (b) (4) (b) (4)	10 Sep 2020 17:13:46

**US3512248**

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 07:56:44**

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:21:08
User entered 'bpm'	System	10 Sep 2020 17:13:46

US3512248

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 07:56:44

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:21:08
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 22:12:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Oct 2020 13:52:30
User entered missing code ND - Not Done.	Allison Crain (b) (4) (b) (4)	10 Sep 2020 17:13:46

**US3512248**

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 07:56:44**

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:21:08
User entered 'breaths/min'	System	10 Sep 2020 17:13:46

US3512248

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 07:56:44

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:21:08
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 22:12:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Oct 2020 13:52:30
User entered missing code ND - Not Done.	Allison Crain (b) (4) (b) (4)	10 Sep 2020 17:13:46



**US3512248**

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 07:56:44**

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:21:08
User entered 'mmHg'	System	10 Sep 2020 17:13:46

US3512248

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 07:56:44

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:21:08
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 22:12:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Oct 2020 13:52:30
User entered missing code ND - Not Done.	Allison Crain (b) (4) (b) (4)	10 Sep 2020 17:13:46

**US3512248**

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 07:56:44**

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:21:08
User entered 'mmHg'	System	10 Sep 2020 17:13:46

**US3512248**

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 07:56:44**

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:21:08

**US3512248**

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 07:56:44**

[Weight \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:21:08

US3512248

Folder: Screening

Form: Physical Examination

Generated On: 10 Jun 2021 07:56:44

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:21:08
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 22:12:02
DataPoint Verified.	(b) (4)	(b) (4), (b) (6)
	(b) (4), (b) (6)	07 Oct 2020 13:52:38
User entered 'Yes (Y)'	Allison Crain (b) (4)	10 Sep 2020 17:14:02
	(b) (4)	

**US3512248**

**Folder: Screening**

**Form: Physical Examination**

**Generated On: 10 Jun 2021 07:56:44**

**Date of examination (dd MMM yyyy)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:21:08
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 22:12:02
DataPoint Verified.	(b) (4)	(b) (4), (b) (6)
User entered '10 Sep 2020'	Allison Crain (b) (4)	10 Sep 2020 17:14:02
	(b) (4)	

US3512248

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 07:56:44

[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 10:21:08
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 22:12:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Oct 2020 13:52:48
User entered 'No (N)'	Allison Crain (b) (4) (b) (4)	10 Sep 2020 17:58:13



US3512248

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 07:56:44

**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 10:21:08
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 22:12:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Oct 2020 13:52:48
User entered 'No (N)'	Allison Crain (b) (4) (b) (4)	10 Sep 2020 17:58:13

US3512248

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 07:56:44

**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 10:21:08
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 22:12:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Oct 2020 13:52:48
User entered 'No (N)'	Allison Crain (b) (4) (b) (4)	10 Sep 2020 17:58:13

US3512248

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 07:56:44

**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 10:21:08
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 22:12:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Oct 2020 13:52:48
User entered 'No (N)'	Allison Crain (b) (4) (b) (4)	10 Sep 2020 17:58:13

US3512248

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 07:56:44

[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 10:21:08
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 22:12:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Oct 2020 13:52:48
User entered 'No (N)'	Allison Crain (b) (4) (b) (4)	10 Sep 2020 17:58:13

US3512248

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 07:56:44

[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 10:21:08
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 22:12:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Oct 2020 13:52:48
User entered 'No (N)'	Allison Crain (b) (4) (b) (4)	10 Sep 2020 17:58:13

US3512248

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 07:56:44

**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 10:21:08
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 22:12:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Oct 2020 13:52:48
User entered 'No (N)'	Allison Crain (b) (4) (b) (4)	10 Sep 2020 17:58:13

US3512248

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 07:56:44

**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 10:21:08
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 22:12:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Oct 2020 13:52:48
User entered 'No (N)'	Allison Crain (b) (4) (b) (4)	10 Sep 2020 17:58:13

US3512248

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 07:56:44

[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 10:21:08
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 22:12:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Oct 2020 13:52:48
User entered 'No (N)'	Allison Crain (b) (4) (b) (4)	10 Sep 2020 17:58:13



US3512248

Folder: Screening

Form: Risk of Exposure

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**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 10:21:08
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 22:12:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Oct 2020 13:52:48
User entered 'No (N)'	Allison Crain (b) (4) (b) (4)	10 Sep 2020 17:58:13

US3512248

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 07:56:44

**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 10:21:08
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 22:12:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Oct 2020 13:52:48
User entered 'No (N)'	Allison Crain (b) (4) (b) (4)	10 Sep 2020 17:58:13

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Folder: Screening

Form: Risk of Exposure

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[Other](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:21:08
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 22:12:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Oct 2020 13:52:48
User entered 'No (N)'	Allison Crain (b) (4) (b) (4)	10 Sep 2020 17:58:13

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Folder: Screening

Form: Risk of Exposure

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[Specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:21:08
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 22:12:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Oct 2020 13:52:48
User entered empty.	Allison Crain (b) (4) (b) (4)	10 Sep 2020 17:58:13

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Folder: Screening

Form: Risk of Exposure

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No Risk Identified

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:21:08
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 22:12:02
User entered '0'	(b) (4) Allison Crain (b) (4)	10 Sep 2020 17:58:13
	(b) (4)	

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Folder: Screening

Form: Risk of Exposure

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[Resides in Nursing Home or Assisted Living Facility](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:21:08
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 22:12:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Oct 2020 13:52:48
User entered '0'	Allison Crain (b) (4) (b) (4)	10 Sep 2020 17:58:13

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Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 07:56:44

**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 10:21:08
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 22:12:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Oct 2020 13:52:48
User entered '0'	Allison Crain (b) (4) (b) (4)	10 Sep 2020 17:58:13

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Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 07:56:44

[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 10:21:08
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 22:12:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Oct 2020 13:52:48
User entered '0'	Allison Crain (b) (4) (b) (4)	10 Sep 2020 17:58:13



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Folder: Screening

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**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 10:21:08
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 22:12:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Oct 2020 13:52:48
User entered '0'	Allison Crain (b) (4) (b) (4)	10 Sep 2020 17:58:13

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Folder: Screening

Form: Risk of Exposure

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[Resides in a single family home](#) (i.e., detached housing)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:21:08
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 22:12:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Oct 2020 13:52:48
User entered 'I'	Allison Crain (b) (4) (b) (4)	10 Sep 2020 17:58:13

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Folder: Screening

Form: Risk of Exposure

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[Other](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:21:08
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 22:12:02
User entered 'I'	(b) (4) Allison Crain (b) (4) (b) (4)	10 Sep 2020 17:58:13

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Folder: Screening

Form: Risk of Exposure

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[Specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:21:08
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 22:12:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Oct 2020 13:52:48
User entered 'HAS ATTENDED LARGE GROUP EVENTS IN THE PAST FEW WEEKS (CHURCH); PLANS ON ROUTINELY GOING TO PLACES WHERE PEOPLE GATHER(GYM, RESTAURANT, GROCERY STORE); INTERACTS W/>5 PEOPLE OUTSIDE OF THE HOME'	Allison Crain (b) (4) (b) (4)	10 Sep 2020 17:58:13

**US3512248**

**Folder: Visit 1 Day 1**

**Form: Visit Date**

**Generated On: 10 Jun 2021 07:56:44**

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:23:03
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 22:12:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Oct 2020 13:49:08
User entered 'Yes (Y)'	Allison Crain (b) (4) (b) (4)	10 Sep 2020 17:14:17

**US3512248**

**Folder: Visit 1 Day 1**

**Form: Visit Date**

**Generated On: 10 Jun 2021 07:56:44**

[Visit date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:23:03
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 22:12:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Oct 2020 13:49:08
User entered '10 Sep 2020'	Allison Crain (b) (4) (b) (4)	10 Sep 2020 17:14:17

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Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 10 Jun 2021 07:56:44

[Was visit performed at the participant's home or at the clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:23:03
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 22:12:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Oct 2020 13:49:08
User entered 'Clinic (Clinic)'	Allison Crain (b) (4) (b) (4)	10 Sep 2020 17:14:17

**US3512248**

**Folder: Visit 1 Day 1**

**Form: Visit Date**

**Generated On: 10 Jun 2021 07:56:44**

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:23:03
User entered 'VISIT1'	System	10 Sep 2020 17:14:17



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Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 07:56:44

What was the date of randomization? (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:23:03
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 22:12:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Oct 2020 13:49:46
User entered '10 SEP 2020'	RWS_ENDPOINT ENDPOINT (b) (4)	10 Sep 2020 15:49:55

US3512248

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 07:56:44

[What was the participant's randomization number?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:23:03
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 22:12:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Oct 2020 13:49:46
User entered '190352'	RWS_ENDPOINT ENDPOINT (b) (4)	10 Sep 2020 15:49:55

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Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 07:56:44

[In what Cohort was the participant enrolled?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:23:03
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 22:12:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Oct 2020 13:49:46
User entered '>=65 years (3)'	RWS_ENDPOINT ENDPOINT (b) (4)	10 Sep 2020 15:49:55

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Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 07:56:44

Chronic lung disease (eg, emphysema and chronic bronchitis, idiopathic pulmonary fibrosis and cystic fibrosis, or moderate to severe asthma)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:23:03
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 22:12:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Oct 2020 13:49:46
User entered 'No (N)'	Allison Crain (b) (4) (b) (4)	10 Sep 2020 17:14:33

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Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 07:56:44

Significant cardiac disease (eg, heart failure, coronary artery disease, congenital heart disease, cardiomyopathies, and pulmonary hypertension)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:23:03
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 22:12:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Oct 2020 13:49:46
User entered 'No (N)'	Allison Crain (b) (4) (b) (4)	10 Sep 2020 17:14:33

US3512248

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 07:56:44

Severe obesity (body mass index > or = 40kg/m2

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:23:03
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 22:12:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Oct 2020 13:49:46
User entered 'No (N)'	Allison Crain (b) (4) (b) (4)	10 Sep 2020 17:14:33

**US3512248**

**Folder: Visit 1 Day 1**

**Form: Randomization**

**Generated On: 10 Jun 2021 07:56:44**

[Diabetes \(Type I, Type 2, or gestational\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:23:03
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 22:12:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Oct 2020 13:49:46
User entered 'No (N)'	Allison Crain (b) (4) (b) (4)	10 Sep 2020 17:14:33

US3512248

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 07:56:44

[Liver Disease](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:23:03
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 22:12:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Oct 2020 13:49:46
User entered 'No (N)'	Allison Crain (b) (4) (b) (4)	10 Sep 2020 17:14:33



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Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 07:56:44

[Human Immunodeficiency Virus \(HIV\) infection](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:23:03
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 19:43:56
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 22:12:02
User closed query 'Per CDM: This field requires yes or no. Please complete. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	06 Nov 2020 12:11:16
Query 'Per CDM: This field requires yes or no. Please complete. ' answered with 'Completed' (Site from DM).	Allison Crain (b) (4) (b) (4)	04 Nov 2020 18:04:52
User entered 'No (N)'	Allison Crain (b) (4) (b) (4)	04 Nov 2020 18:04:49
User opened query 'Per CDM: This field requires yes or no. Please complete. ' (Site from DM).	(b) (4), (b) (6)	03 Nov 2020 15:03:31
Amendment Manager: DataPoint set to visible.	System	19 Sep 2020 05:59:02
Amendment Manager inserted this DataPoint.	System	19 Sep 2020 05:59:01

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 07:56:44

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:23:03
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 19:43:44
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 22:12:02
User entered missing code ND - Not Done.	Brenda Anderson (b) (4)	10 Dec 2020 21:26:53

US3512248

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 07:56:44

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:23:03
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 19:43:44
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 22:12:02
User entered missing code ND - Not Done.	(b) (4) Brenda Anderson (b) (4)	10 Dec 2020 21:26:53

US3512248

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 07:56:44

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:23:03
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 19:43:44
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 22:12:02
User entered missing code ND - Not Done.	Brenda Anderson (b) (4)	10 Dec 2020 21:26:53

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 07:56:44

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:23:03
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 19:43:44
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 22:12:02
User entered missing code ND - Not Done.	Brenda Anderson (b) (4)	10 Dec 2020 21:26:53

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 07:56:44

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:23:03
User accepted default value 'Pre-Dose (PREDOSE)'	Brenda Anderson (b) (4) (b) (4)	10 Dec 2020 21:26:53

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 07:56:44

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:23:03
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 19:43:44
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 22:12:02
User entered 'Yes (Y)'	Brenda Anderson (b) (4)	10 Dec 2020 21:26:53

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 07:56:44

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:23:03
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 19:43:44
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 22:12:02
User entered '10 Sep 2020'	(b) (4) Brenda Anderson (b) (4) (b) (4)	10 Dec 2020 21:26:53



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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 07:56:44

Time of assessment (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:23:03
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 19:43:44
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 22:12:02
User entered '11:31'	(b) (4) Brenda Anderson (b) (4) (b) (4)	10 Dec 2020 21:26:53

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**Folder: Visit 1 Day 1**

**Form: Vital Signs - Dosing (1)**

**Generated On: 10 Jun 2021 07:56:44**

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:23:03
User entered '10 Sep 2020 11:31'	System	10 Dec 2020 21:26:53

US3512248

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 07:56:44

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:23:03
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 19:43:44
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 22:12:02
User entered '98.7' F	(b) (4) Brenda Anderson (b) (4) (b) (4)	10 Dec 2020 21:26:53

US3512248

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 07:56:44

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:23:03
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 19:43:44
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 22:12:02
User entered 'Oral (Oral)'	(b) (4) Brenda Anderson (b) (4) (b) (4)	10 Dec 2020 21:26:53

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 07:56:44

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:23:03
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 19:43:44
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 22:12:02
User entered empty.	(b) (4) Brenda Anderson (b) (4) (b) (4)	10 Dec 2020 21:26:53

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 07:56:44

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:23:03
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 19:43:44
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 22:12:02
User entered '66'	(b) (4) Brenda Anderson (b) (4) (b) (4)	10 Dec 2020 21:26:53

**US3512248**

**Folder: Visit 1 Day 1**

**Form: Vital Signs - Dosing (1)**

**Generated On: 10 Jun 2021 07:56:44**

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:23:03
User entered 'bpm'	System	10 Dec 2020 21:26:53

US3512248

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 07:56:44

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:23:03
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 19:43:44
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 22:12:02
User entered '13'	(b) (4) Brenda Anderson (b) (4) (b) (4)	10 Dec 2020 21:26:53



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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 07:56:44

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:23:03
User entered 'breaths/min'	System	10 Dec 2020 21:26:53

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 07:56:44

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:23:03
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 19:43:44
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 22:12:02
User entered '152'	(b) (4) Brenda Anderson (b) (4) (b) (4)	10 Dec 2020 21:26:53

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 07:56:44

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:23:03
User entered 'mmHg'	System	10 Dec 2020 21:26:53

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 07:56:44

[Diastolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:23:03
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 19:43:44
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 22:12:02
User entered '83'	(b) (4) Brenda Anderson (b) (4) (b) (4)	10 Dec 2020 21:26:53

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 07:56:44

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:23:03
User entered 'mmHg'	System	10 Dec 2020 21:26:53

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 07:56:44

Height

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:23:03
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 19:43:44
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 22:12:02
User entered missing code ND - Not Done.	(b) (4) Brenda Anderson (b) (4)	10 Dec 2020 21:26:53

US3512248

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 07:56:44

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:23:03
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 19:43:44
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 22:12:02
User entered missing code ND - Not Done.	Brenda Anderson (b) (4)	10 Dec 2020 21:26:53

US3512248

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 07:56:44

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:23:03
User accepted default value 'Post-Dose (POSTDOSE)'	Brenda Anderson (b) (4) (b) (4)	10 Dec 2020 21:26:53



US3512248

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 07:56:44

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:23:03
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 19:43:44
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 22:12:02
User entered 'Yes (Y)'	Brenda Anderson (b) (4)	10 Dec 2020 21:26:53

US3512248

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 07:56:44

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:23:03
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 19:43:44
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 22:12:02
User entered '10 Sep 2020'	(b) (4) Brenda Anderson (b) (4) (b) (4)	10 Dec 2020 21:26:53

**US3512248**

**Folder: Visit 1 Day 1**

**Form: Vital Signs - Dosing (2)**

**Generated On: 10 Jun 2021 07:56:44**

[Time of assessment \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:23:03
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 19:43:44
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 22:12:02
User entered '13:22'	(b) (4) Brenda Anderson (b) (4) (b) (4)	10 Dec 2020 21:26:53

**US3512248**

**Folder: Visit 1 Day 1**

**Form: Vital Signs - Dosing (2)**

**Generated On: 10 Jun 2021 07:56:44**

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:23:03
User entered '10 Sep 2020 13:22'	System	10 Dec 2020 21:26:53

US3512248

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 07:56:44

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:23:03
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 19:43:44
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 22:12:02
User entered '96.8' F	(b) (4) Brenda Anderson (b) (4) (b) (4)	10 Dec 2020 21:26:53

US3512248

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 07:56:44

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:23:03
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 19:43:44
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 22:12:02
User entered 'Oral (Oral)'	(b) (4) Brenda Anderson (b) (4) (b) (4)	10 Dec 2020 21:26:53

US3512248

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 07:56:44

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:23:03
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 19:43:44
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 22:12:02
User entered empty.	(b) (4) Brenda Anderson (b) (4) (b) (4)	10 Dec 2020 21:26:53

US3512248

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 07:56:44

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:23:03
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 19:43:44
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 22:12:02
User entered '78'	(b) (4) Brenda Anderson (b) (4) (b) (4)	10 Dec 2020 21:26:53



**US3512248**

**Folder: Visit 1 Day 1**

**Form: Vital Signs - Dosing (2)**

**Generated On: 10 Jun 2021 07:56:44**

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:23:03
User entered 'bpm'	System	10 Dec 2020 21:26:53

US3512248

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 07:56:44

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:23:03
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 19:43:44
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 22:12:02
User entered '14'	(b) (4) Brenda Anderson (b) (4) (b) (4)	10 Dec 2020 21:26:53

US3512248

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 07:56:44

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:23:03
User entered 'breaths/min'	System	10 Dec 2020 21:26:53

US3512248

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 07:56:44

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:23:03
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 19:43:44
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 22:12:02
Query 'Per CDM: Systolic Blood Pressure is out of range per protocol. Please indicate if CS or NCS and report as AE, if appropriate. ' canceled (Site from DM).	(b) (4) (b) (4), (b) (6)	22 Dec 2020 04:43:17
User opened query 'Per CDM: Systolic Blood Pressure is out of range per protocol. Please indicate if CS or NCS and report as AE, if appropriate. ' (Site from DM).	(b) (4), (b) (6)	22 Dec 2020 04:42:58
User entered '173'	Brenda Anderson (b) (4)	10 Dec 2020 21:26:53

US3512248

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 07:56:44

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:23:03
User entered 'mmHg'	System	10 Dec 2020 21:26:53

US3512248

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 07:56:44

[Diastolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:23:03
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 19:43:44
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 22:12:02
User entered '76'	(b) (4) Brenda Anderson (b) (4) (b) (4)	10 Dec 2020 21:26:53

US3512248

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 07:56:44

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:23:03
User entered 'mmHg'	System	10 Dec 2020 21:26:53

US3512248

Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 10 Jun 2021 07:56:44

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:23:03
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 22:12:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Oct 2020 13:50:16
User entered 'No (N)'	Allison Crain (b) (4) (b) (4)	10 Sep 2020 17:14:48



**US3512248**

**Folder: Visit 1 Day 1**

**Form: Physical Examination**

**Generated On: 10 Jun 2021 07:56:44**

**Date of examination (dd MMM yyyy)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:23:03
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 22:12:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Oct 2020 13:50:16
User entered empty.	Allison Crain (b) (4) (b) (4)	10 Sep 2020 17:14:48

US3512248

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 07:56:44

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:23:03
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 22:12:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Oct 2020 13:50:36
User entered 'Yes (Y)'	Allison Crain (b) (4) (b) (4)	10 Sep 2020 17:24:28

US3512248

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 07:56:44

[If No, reason not given](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:23:03
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 22:12:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Oct 2020 13:50:36
User entered empty.	Allison Crain (b) (4) (b) (4)	10 Sep 2020 17:24:28

US3512248

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 07:56:44

If reason is Physician Decision, Withdrawal of Consent by Participant, Protocol Deviation, or Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:23:03
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 22:12:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Oct 2020 13:50:36
User entered empty.	Allison Crain (b) (4) (b) (4)	10 Sep 2020 17:24:28

**US3512248**

**Folder: Visit 1 Day 1**

**Form: Exposure**

**Generated On: 10 Jun 2021 07:56:44**

[What was the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:23:03
User entered 'MRNA-1273 OR PLACEBO'	System	10 Sep 2020 17:24:28

US3512248

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 07:56:44

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:23:03
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 22:12:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Oct 2020 13:50:36
User entered '10 Sep 2020'	Allison Crain (b) (4) (b) (4)	10 Sep 2020 17:24:28

**US3512248**

**Folder: Visit 1 Day 1**

**Form: Exposure**

**Generated On: 10 Jun 2021 07:56:44**

[What was the treatment time? \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:23:03
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 22:12:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Oct 2020 13:50:36
User entered '12:51'	Allison Crain (b) (4) (b) (4)	10 Sep 2020 17:24:28

**US3512248**

**Folder: Visit 1 Day 1**

**Form: Exposure**

**Generated On: 10 Jun 2021 07:56:44**

[Treatment Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:23:03
User entered '10 Sep 2020 12:51'	System	10 Sep 2020 17:24:28



US3512248

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 07:56:44

[Which arm was used to give treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:23:03
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 22:12:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Oct 2020 13:50:36
User entered 'Left Arm (LEFT ARM)'	Allison Crain (b) (4) (b) (4)	10 Sep 2020 17:24:28

US3512248

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 07:56:44

[What was the frequency of the study treatment dosing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:23:03
DataPoint Verified.	(b) (4), (b) (6)	07 Oct 2020 13:50:36
User entered 'ONCE'	System	10 Sep 2020 17:24:28

US3512248

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 07:56:44

What was the route of administration for the study treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:23:03
User entered 'INTRAMUSCULAR'	System	10 Sep 2020 17:24:28

US3512248

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 07:56:44

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:23:03
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 22:12:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Oct 2020 13:50:45
User entered 'Yes (Y)'	Allison Crain (b) (4) (b) (4)	10 Sep 2020 17:15:07

US3512248

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 07:56:44

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:23:03
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 22:12:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Oct 2020 13:50:45
User entered '10 Sep 2020'	Allison Crain (b) (4) (b) (4)	10 Sep 2020 17:15:07

**US3512248**

**Folder: Visit 1 Day 1**

**Form: Immunogenicity Assessment**

**Generated On: 10 Jun 2021 07:56:44**

[Collection time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:23:03
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 22:12:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Oct 2020 13:50:45
User entered '11:57'	Allison Crain (b) (4) (b) (4)	10 Sep 2020 17:15:07

**US3512248**

**Folder: Visit 1 Day 1**

**Form: Immunogenicity Assessment**

**Generated On: 10 Jun 2021 07:56:44**

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:23:03
User entered '10 Sep 2020 11:57'	System	10 Sep 2020 17:15:07

US3512248

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 10 Jun 2021 07:56:44

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:23:03
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 22:12:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Oct 2020 13:50:53
User entered '10 Sep 2020'	Allison Crain (b) (4) (b) (4)	10 Sep 2020 17:15:19



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Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 10 Jun 2021 07:56:44

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:23:03
User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)'	Allison Crain (b) (4) (b) (4)	10 Sep 2020 17:15:19

US3512248

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 10 Jun 2021 07:56:44

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:23:03
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 22:12:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Oct 2020 13:50:53
User entered 'Yes (Y)'	Allison Crain (b) (4) (b) (4)	10 Sep 2020 17:15:19

US3512248

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 10 Jun 2021 07:56:44

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:23:03
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 22:12:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Oct 2020 13:50:53
User entered '11:47'	Allison Crain (b) (4) (b) (4)	10 Sep 2020 17:15:19

**US3512248**

**Folder: Visit 1 Day 1**

**Form: Central Laboratory - Nasopharyngeal Swab (1)**

**Generated On: 10 Jun 2021 07:56:44**

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:23:03
User entered '10 Sep 2020 11:47'	System	10 Sep 2020 17:15:19

US3512248

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 10 Jun 2021 07:56:44

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:23:03
User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)'	Allison Crain (b) (4) (b) (4)	10 Sep 2020 17:15:19

US3512248

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 10 Jun 2021 07:56:44

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:23:03
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 22:12:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Oct 2020 13:50:53
User entered 'No (N)'	Allison Crain (b) (4) (b) (4)	10 Sep 2020 17:15:19

**US3512248**

**Folder: Visit 1 Day 1**

**Form: Central Laboratory - Nasopharyngeal Swab (2)**

**Generated On: 10 Jun 2021 07:56:44**

[Collection time \(00:00 - 23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:23:03
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 22:12:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Oct 2020 13:50:53
User entered empty.	Allison Crain (b) (4) (b) (4)	10 Sep 2020 17:15:19

**US3512248**

**Folder: Visit 1 Day 1**

**Form: Central Laboratory - Nasopharyngeal Swab (2)**

**Generated On: 10 Jun 2021 07:56:44**

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:23:03
User entered empty.	System	10 Sep 2020 17:15:19



US3512248

Folder: Visit 1 Day 1

Form: Continuing

Generated On: 10 Jun 2021 07:56:44

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:23:03
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 22:12:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Oct 2020 13:51:00
User entered 'Yes (Y)'	Allison Crain (b) (4) (b) (4)	10 Sep 2020 17:15:26

**US3512248**

**Folder: Visit 1 Day 1**

**Form: Continuing**

**Generated On: 10 Jun 2021 07:56:44**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:23:03
User entered 'I'	System	10 Sep 2020 17:15:26

US3512248

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/1)

Generated On: 10 Jun 2021 07:56:44

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:52:02
Data entry locked.	System	10 Sep 2020 17:24:28
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	10 Sep 2020 17:24:28

US3512248

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/1)

Generated On: 10 Jun 2021 07:56:44

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:52:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FCE43EC3-F1E0-47A1-B438-4D694934F821)', Time: '2020-09-10T13:28:45', User OID: 'PatientReportedOutcome (US3512248)', ODM File OID: '974f7931-78d3-4abe-9136-666587ac90f9' User entered 'Yes (Y)'	System	10 Sep 2020 17:29:18
	System	10 Sep 2020 17:29:18

US3512248

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/1)

Generated On: 10 Jun 2021 07:56:44

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:52:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FCE43EC3-F1E0-47A1-B438-4D694934F821)', Time: '2020-09-10T13:28:58', User OID: 'PatientReportedOutcome (US3512248)', ODM File OID: '974f7931-78d3-4abe-9136-666587ac90f9' User entered '96.8'	System	10 Sep 2020 17:29:18
	System	10 Sep 2020 17:29:18

US3512248

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/1)

Generated On: 10 Jun 2021 07:56:44

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:52:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FCE43EC3-F1E0-47A1-B438-4D694934F821)', Time: '2020-09-10T13:29:06', User OID: 'PatientReportedOutcome (US3512248)', ODM File OID: '974f7931-78d3-4abe-9136-666587ac90f9' User entered 'No (N)'	System	10 Sep 2020 17:29:18
	System	10 Sep 2020 17:29:18

**US3512248**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(1/1)**

**Generated On: 10 Jun 2021 07:56:44**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:52:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FCE43EC3-F1E0-47A1-B438-4D694934F821)', Time: '2020-09-10T13:29:16', User OID: 'PatientReportedOutcome (US3512248)', ODM File OID: '974f7931-78d3-4abe-9136-666587ac90f9' User entered '10 Sep 2020 13:29'	System	10 Sep 2020 17:29:18
	System	10 Sep 2020 17:29:18

US3512248

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/1)

Generated On: 10 Jun 2021 07:56:44

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:52:02
User entered '10 Sep 2020 13:11'	System	10 Sep 2020 17:24:28



US3512248

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/1)

Generated On: 10 Jun 2021 07:56:44

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:52:02
User entered '10 Sep 2020 15:41'	System	10 Sep 2020 17:24:28

US3512248

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/2)

Generated On: 10 Jun 2021 07:56:44

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:52:02
Data entry locked.	System	10 Sep 2020 17:24:28
User entered 'Day 1, after vaccination (at home)'	System	10 Sep 2020 17:24:28

**US3512248**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(1/2)**

**Generated On: 10 Jun 2021 07:56:44**

**Was TEMPERATURE taken?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:52:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FCE43EC3-F1E0-47A1-B438-4D694934F821)', Time: '2020-09-10T18:43:07', User OID: 'PatientReportedOutcome (US3512248)', ODM File OID: '51889325-490b-42b9-b305-70b40e413517' User entered 'Yes (Y)'	System	10 Sep 2020 22:44:18
	System	10 Sep 2020 22:44:18

US3512248

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/2)

Generated On: 10 Jun 2021 07:56:44

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:52:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FCE43EC3-F1E0-47A1-B438-4D694934F821)', Time: '2020-09-10T18:43:16', User OID: 'PatientReportedOutcome (US3512248)', ODM File OID: '51889325-490b-42b9-b305-70b40e413517' User entered '97.0'	System	10 Sep 2020 22:44:18
	System	10 Sep 2020 22:44:18

US3512248

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/2)

Generated On: 10 Jun 2021 07:56:44

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:52:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FCE43EC3-F1E0-47A1-B438-4D694934F821)', Time: '2020-09-10T18:43:21', User OID: 'PatientReportedOutcome (US3512248)', ODM File OID: '51889325-490b-42b9-b305-70b40e413517' User entered 'No (N)'	System	10 Sep 2020 22:44:18
	System	10 Sep 2020 22:44:18

**US3512248**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(1/2)**

**Generated On: 10 Jun 2021 07:56:44**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:52:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FCE43EC3-F1E0-47A1-B438-4D694934F821)', Time: '2020-09-10T18:44:15', User OID: 'PatientReportedOutcome (US3512248)', ODM File OID: '51889325-490b-42b9-b305-70b40e413517' User entered '10 Sep 2020 18:44'	System	10 Sep 2020 22:44:18
	System	10 Sep 2020 22:44:18

US3512248

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/2)

Generated On: 10 Jun 2021 07:56:44

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:52:02
User entered '10 Sep 2020 16:36'	System	10 Sep 2020 17:24:28

US3512248

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/2)

Generated On: 10 Jun 2021 07:56:44

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:52:02
User entered '11 Sep 2020 11:59'	System	10 Sep 2020 17:24:28



US3512248

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(2)

Generated On: 10 Jun 2021 07:56:44

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:52:02
Data entry locked.	System	10 Sep 2020 17:24:28
User entered 'Day 2'	System	10 Sep 2020 17:24:28

**US3512248**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(2)**

**Generated On: 10 Jun 2021 07:56:44**

**Was TEMPERATURE taken?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:52:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FCE43EC3-F1E0-47A1-B438-4D694934F821)', Time: '2020-09-11T17:00:19', User OID: 'PatientReportedOutcome (US3512248)', ODM File OID: '71922d9c-bdb1-4c4f-9139-4ac97c0ff0ce' User entered 'Yes (Y)'	System	11 Sep 2020 21:00:40
	System	11 Sep 2020 21:00:40

US3512248

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(2)

Generated On: 10 Jun 2021 07:56:44

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:52:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FCE43EC3-F1E0-47A1-B438-4D694934F821)', Time: '2020-09-11T17:00:28', User OID: 'PatientReportedOutcome (US3512248)', ODM File OID: '71922d9c-bdb1-4c4f-9139-4ac97c0ff0ce' User entered '97.9'	System	11 Sep 2020 21:00:40
	System	11 Sep 2020 21:00:40

US3512248

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(2)

Generated On: 10 Jun 2021 07:56:44

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:52:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FCE43EC3-F1E0-47A1-B438-4D694934F821)', Time: '2020-09-11T17:00:34', User OID: 'PatientReportedOutcome (US3512248)', ODM File OID: '71922d9c-bdb1-4c4f-9139-4ac97c0ff0ce' User entered 'No (N)'	System	11 Sep 2020 21:00:40
	System	11 Sep 2020 21:00:40

**US3512248**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(2)**

**Generated On: 10 Jun 2021 07:56:44**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:52:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FCE43EC3-F1E0-47A1-B438-4D694934F821)', Time: '2020-09-11T17:00:38', User OID: 'PatientReportedOutcome (US3512248)', ODM File OID: '71922d9c-bdb1-4c4f-9139-4ac97c0ff0ce' User entered '11 Sep 2020 17:00'	System	11 Sep 2020 21:00:40
	System	11 Sep 2020 21:00:40

US3512248

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(2)

Generated On: 10 Jun 2021 07:56:44

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:52:02
User entered '11 Sep 2020 12:00'	System	10 Sep 2020 17:24:28

US3512248

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(2)

Generated On: 10 Jun 2021 07:56:44

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:52:02
User entered '12 Sep 2020 11:59'	System	10 Sep 2020 17:24:28

US3512248

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(3)

Generated On: 10 Jun 2021 07:56:44

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:52:02
Data entry locked.	System	10 Sep 2020 17:24:28
User entered 'Day 3'	System	10 Sep 2020 17:24:28



US3512248

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(3)

Generated On: 10 Jun 2021 07:56:44

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:52:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FCE43EC3-F1E0-47A1-B438-4D694934F821)', Time: '2020-09-12T21:01:13', User OID: 'PatientReportedOutcome (US3512248)', ODM File OID: 'e7a7d205-4a14-479a-8bc1-3c098d64a0b0' User entered 'Yes (Y)'	System	13 Sep 2020 01:01:39
	System	13 Sep 2020 01:01:39

US3512248

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(3)

Generated On: 10 Jun 2021 07:56:44

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:52:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FCE43EC3-F1E0-47A1-B438-4D694934F821)', Time: '2020-09-12T21:01:24', User OID: 'PatientReportedOutcome (US3512248)', ODM File OID: 'e7a7d205-4a14-479a-8bc1-3c098d64a0b0' User entered '97.9'	System	13 Sep 2020 01:01:39
	System	13 Sep 2020 01:01:39

US3512248

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(3)

Generated On: 10 Jun 2021 07:56:44

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:52:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FCE43EC3-F1E0-47A1-B438-4D694934F821)', Time: '2020-09-12T21:01:29', User OID: 'PatientReportedOutcome (US3512248)', ODM File OID: 'e7a7d205-4a14-479a-8bc1-3c098d64a0b0' User entered 'No (N)'	System	13 Sep 2020 01:01:39
	System	13 Sep 2020 01:01:39

**US3512248**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(3)**

**Generated On: 10 Jun 2021 07:56:44**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:52:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FCE43EC3-F1E0-47A1-B438-4D694934F821)', Time: '2020-09-12T21:01:38', User OID: 'PatientReportedOutcome (US3512248)', ODM File OID: 'e7a7d205-4a14-479a-8bc1-3c098d64a0b0' User entered '12 Sep 2020 21:01'	System	13 Sep 2020 01:01:39
	System	13 Sep 2020 01:01:39

**US3512248**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(3)**

**Generated On: 10 Jun 2021 07:56:44**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:52:02
User entered '12 Sep 2020 12:00'	System	10 Sep 2020 17:24:28

US3512248

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(3)

Generated On: 10 Jun 2021 07:56:44

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:52:02
User entered '13 Sep 2020 11:59'	System	10 Sep 2020 17:24:28

US3512248

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(4)

Generated On: 10 Jun 2021 07:56:44

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:52:02
Data entry locked.	System	10 Sep 2020 17:24:28
User entered 'Day 4'	System	10 Sep 2020 17:24:28

US3512248

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(4)

Generated On: 10 Jun 2021 07:56:44

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:52:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FCE43EC3-F1E0-47A1-B438-4D694934F821)', Time: '2020-09-13T20:12:13', User OID: 'PatientReportedOutcome (US3512248)', ODM File OID: '527c2da2-a001-4804-8760-27ce405377d9' User entered 'Yes (Y)'	System	14 Sep 2020 00:12:38
	System	14 Sep 2020 00:12:38



US3512248

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(4)

Generated On: 10 Jun 2021 07:56:44

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:52:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FCE43EC3-F1E0-47A1-B438-4D694934F821)', Time: '2020-09-13T20:12:20', User OID: 'PatientReportedOutcome (US3512248)', ODM File OID: '527c2da2-a001-4804-8760-27ce405377d9' User entered '98.6'	System	14 Sep 2020 00:12:38
	System	14 Sep 2020 00:12:38

US3512248

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(4)

Generated On: 10 Jun 2021 07:56:44

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:52:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FCE43EC3-F1E0-47A1-B438-4D694934F821)', Time: '2020-09-13T20:12:25', User OID: 'PatientReportedOutcome (US3512248)', ODM File OID: '527c2da2-a001-4804-8760-27ce405377d9' User entered 'No (N)'	System	14 Sep 2020 00:12:38
	System	14 Sep 2020 00:12:38

**US3512248**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(4)**

**Generated On: 10 Jun 2021 07:56:44**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:52:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FCE43EC3-F1E0-47A1-B438-4D694934F821)', Time: '2020-09-13T20:12:34', User OID: 'PatientReportedOutcome (US3512248)', ODM File OID: '527c2da2-a001-4804-8760-27ce405377d9' User entered '13 Sep 2020 20:12'	System	14 Sep 2020 00:12:38
	System	14 Sep 2020 00:12:38

US3512248

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(4)

Generated On: 10 Jun 2021 07:56:44

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:52:02
User entered '13 Sep 2020 12:00'	System	10 Sep 2020 17:24:28

US3512248

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(4)

Generated On: 10 Jun 2021 07:56:44

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:52:02
User entered '14 Sep 2020 11:59'	System	10 Sep 2020 17:24:28

US3512248

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(5)

Generated On: 10 Jun 2021 07:56:44

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:52:02
Data entry locked.	System	10 Sep 2020 17:24:28
User entered 'Day 5'	System	10 Sep 2020 17:24:28

US3512248

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(5)

Generated On: 10 Jun 2021 07:56:44

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:52:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FCE43EC3-F1E0-47A1-B438-4D694934F821)', Time: '2020-09-14T22:12:39', User OID: 'PatientReportedOutcome (US3512248)', ODM File OID: '874b8af4-6730-44e3-8a94-ea3bce85f4c9' User entered 'Yes (Y)'	System	15 Sep 2020 02:13:17
	System	15 Sep 2020 02:13:17

US3512248

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(5)

Generated On: 10 Jun 2021 07:56:44

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:52:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FCE43EC3-F1E0-47A1-B438-4D694934F821)', Time: '2020-09-14T22:12:53', User OID: 'PatientReportedOutcome (US3512248)', ODM File OID: '874b8af4-6730-44e3-8a94-ea3bce85f4c9' User entered '96.9'	System	15 Sep 2020 02:13:17
	System	15 Sep 2020 02:13:17



US3512248

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(5)

Generated On: 10 Jun 2021 07:56:44

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:52:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FCE43EC3-F1E0-47A1-B438-4D694934F821)', Time: '2020-09-14T22:13:00', User OID: 'PatientReportedOutcome (US3512248)', ODM File OID: '874b8af4-6730-44e3-8a94-ea3bce85f4c9' User entered 'No (N)'	System	15 Sep 2020 02:13:17
	System	15 Sep 2020 02:13:17

**US3512248**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(5)**

**Generated On: 10 Jun 2021 07:56:44**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:52:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FCE43EC3-F1E0-47A1-B438-4D694934F821)', Time: '2020-09-14T22:13:13', User OID: 'PatientReportedOutcome (US3512248)', ODM File OID: '874b8af4-6730-44e3-8a94-ea3bce85f4c9' User entered '14 Sep 2020 22:13'	System	15 Sep 2020 02:13:17
	System	15 Sep 2020 02:13:17

**US3512248**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(5)**

**Generated On: 10 Jun 2021 07:56:44**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:52:02
User entered '14 Sep 2020 12:00'	System	10 Sep 2020 17:24:28

US3512248

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(5)

Generated On: 10 Jun 2021 07:56:44

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:52:02
User entered '15 Sep 2020 11:59'	System	10 Sep 2020 17:24:28

US3512248

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(6)

Generated On: 10 Jun 2021 07:56:44

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:52:02
Data entry locked.	System	10 Sep 2020 17:24:28
User entered 'Day 6'	System	10 Sep 2020 17:24:28

US3512248

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(6)

Generated On: 10 Jun 2021 07:56:44

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:52:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FCE43EC3-F1E0-47A1-B438-4D694934F821)', Time: '2020-09-15T21:27:04', User OID: 'PatientReportedOutcome (US3512248)', ODM File OID: 'cd91b93f-ddd7-4bc2-b3d0-05032614064a' User entered 'Yes (Y)'	System	16 Sep 2020 01:27:26
	System	16 Sep 2020 01:27:26

US3512248

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(6)

Generated On: 10 Jun 2021 07:56:44

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:52:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FCE43EC3-F1E0-47A1-B438-4D694934F821)', Time: '2020-09-15T21:27:11', User OID: 'PatientReportedOutcome (US3512248)', ODM File OID: 'cd91b93f-ddd7-4bc2-b3d0-05032614064a' User entered '97.9'	System	16 Sep 2020 01:27:26
	System	16 Sep 2020 01:27:26

US3512248

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(6)

Generated On: 10 Jun 2021 07:56:44

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:52:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FCE43EC3-F1E0-47A1-B438-4D694934F821)', Time: '2020-09-15T21:27:18', User OID: 'PatientReportedOutcome (US3512248)', ODM File OID: 'cd91b93f-ddd7-4bc2-b3d0-05032614064a' User entered 'No (N)'	System	16 Sep 2020 01:27:26
	System	16 Sep 2020 01:27:26



US3512248

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(6)

Generated On: 10 Jun 2021 07:56:44

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:52:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FCE43EC3-F1E0-47A1-B438-4D694934F821)', Time: '2020-09-15T21:27:25', User OID: 'PatientReportedOutcome (US3512248)', ODM File OID: 'cd91b93f-ddd7-4bc2-b3d0-05032614064a' User entered '15 Sep 2020 21:27'	System	16 Sep 2020 01:27:26
	System	16 Sep 2020 01:27:26

US3512248

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(6)

Generated On: 10 Jun 2021 07:56:44

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:52:02
User entered '15 Sep 2020 12:00'	System	10 Sep 2020 17:24:28

**US3512248**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(6)**

**Generated On: 10 Jun 2021 07:56:44**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:52:02
User entered '16 Sep 2020 11:59'	System	10 Sep 2020 17:24:28

US3512248

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(7)

Generated On: 10 Jun 2021 07:56:44

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:52:02
Data entry locked.	System	10 Sep 2020 17:24:28
User entered 'Day 7'	System	10 Sep 2020 17:24:28

US3512248

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(7)

Generated On: 10 Jun 2021 07:56:44

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:52:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FCE43EC3-F1E0-47A1-B438-4D694934F821)', Time: '2020-09-16T20:32:20', User OID: 'PatientReportedOutcome (US3512248)', ODM File OID: 'eb27581c-69d3-4eb5-bbed-8109b11789da' User entered 'Yes (Y)'	System	17 Sep 2020 00:32:42
	System	17 Sep 2020 00:32:42

US3512248

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(7)

Generated On: 10 Jun 2021 07:56:44

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:52:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FCE43EC3-F1E0-47A1-B438-4D694934F821)', Time: '2020-09-16T20:32:28', User OID: 'PatientReportedOutcome (US3512248)', ODM File OID: 'eb27581c-69d3-4eb5-bbed-8109b11789da' User entered '99.1'	System	17 Sep 2020 00:32:42
	System	17 Sep 2020 00:32:42

US3512248

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(7)

Generated On: 10 Jun 2021 07:56:44

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:52:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FCE43EC3-F1E0-47A1-B438-4D694934F821)', Time: '2020-09-16T20:32:33', User OID: 'PatientReportedOutcome (US3512248)', ODM File OID: 'eb27581c-69d3-4eb5-bbed-8109b11789da' User entered 'No (N)'	System	17 Sep 2020 00:32:42
	System	17 Sep 2020 00:32:42

**US3512248**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(7)**

**Generated On: 10 Jun 2021 07:56:44**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:52:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FCE43EC3-F1E0-47A1-B438-4D694934F821)', Time: '2020-09-16T20:32:38', User OID: 'PatientReportedOutcome (US3512248)', ODM File OID: 'eb27581c-69d3-4eb5-bbed-8109b11789da' User entered '16 Sep 2020 20:32'	System	17 Sep 2020 00:32:42
	System	17 Sep 2020 00:32:42



**US3512248**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(7)**

**Generated On: 10 Jun 2021 07:56:44**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:52:02
User entered '16 Sep 2020 12:00'	System	10 Sep 2020 17:24:28

US3512248

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(7)

Generated On: 10 Jun 2021 07:56:44

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:52:02
User entered '17 Sep 2020 11:59'	System	10 Sep 2020 17:24:28

US3512248

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 10 Jun 2021 07:56:44

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:52:02
Data entry locked.	System	10 Sep 2020 17:24:28
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	10 Sep 2020 17:24:28

US3512248

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 10 Jun 2021 07:56:44

Please record - **PAIN AT INJECTION SITE.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:52:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FCE43EC3-F1E0-47A1-B438-4D694934F821)', Time: '2020-09-10T13:30:18', User OID: 'PatientReportedOutcome (US3512248)', ODM File OID: '90fc2814-4bb9-49c4-85cc-cf3696623ece' User entered 'None (1)'	System	10 Sep 2020 17:31:07
	System	10 Sep 2020 17:31:07

US3512248

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 10 Jun 2021 07:56:44

Is there any **REDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:52:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FCE43EC3-F1E0-47A1-B438-4D694934F821)', Time: '2020-09-10T13:30:24', User OID: 'PatientReportedOutcome (US3512248)', ODM File OID: '90fc2814-4bb9-49c4-85cc-cf3696623ece' User entered 'No (N)'	System	10 Sep 2020 17:31:07
	System	10 Sep 2020 17:31:07

US3512248

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 10 Jun 2021 07:56:44

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:52:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FCE43EC3-F1E0-47A1-B438-4D694934F821)', Time: '2020-09-10T13:30:28', User OID: 'PatientReportedOutcome (US3512248)', ODM File OID: '90fc2814-4bb9-49c4-85cc-cf3696623ece' User entered 'No (N)'	System	10 Sep 2020 17:31:07
	System	10 Sep 2020 17:31:07

US3512248

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 10 Jun 2021 07:56:44

Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:52:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FCE43EC3-F1E0-47A1-B438-4D694934F821)', Time: '2020-09-10T13:30:37', User OID: 'PatientReportedOutcome (US3512248)', ODM File OID: '90fc2814-4bb9-49c4-85cc-cf3696623ece' User entered 'None (1)'	System	10 Sep 2020 17:31:07
	System	10 Sep 2020 17:31:07

**US3512248**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(1/1)**

**Generated On: 10 Jun 2021 07:56:44**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:52:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FCE43EC3-F1E0-47A1-B438-4D694934F821)', Time: '2020-09-10T13:30:46', User OID: 'PatientReportedOutcome (US3512248)', ODM File OID: '90fc2814-4bb9-49c4-85cc-cf3696623ece' User entered '10 Sep 2020 13:30'	System	10 Sep 2020 17:31:07
	System	10 Sep 2020 17:31:07



US3512248

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 10 Jun 2021 07:56:44

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:52:02
User entered '10 Sep 2020 13:11'	System	10 Sep 2020 17:24:28

US3512248

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 10 Jun 2021 07:56:44

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:52:02
User entered '10 Sep 2020 15:41'	System	10 Sep 2020 17:24:28

US3512248

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 10 Jun 2021 07:56:44

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:52:02
Data entry locked.	System	10 Sep 2020 17:24:28
User entered 'Day 1, after vaccination (at home)'	System	10 Sep 2020 17:24:28

US3512248

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 10 Jun 2021 07:56:44

Please record - **PAIN AT INJECTION SITE.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:52:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FCE43EC3-F1E0-47A1-B438-4D694934F821)', Time: '2020-09-10T18:44:29', User OID: 'PatientReportedOutcome (US3512248)', ODM File OID: '609ba9ee-4ff2-4dd8-8796-15441c3ebd07' User entered 'None (1)'	System	10 Sep 2020 22:45:20
	System	10 Sep 2020 22:45:20

US3512248

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 10 Jun 2021 07:56:44

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:52:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FCE43EC3-F1E0-47A1-B438-4D694934F821)', Time: '2020-09-10T18:45:00', User OID: 'PatientReportedOutcome (US3512248)', ODM File OID: '609ba9ee-4ff2-4dd8-8796-15441c3ebd07' User entered 'No (N)'	System	10 Sep 2020 22:45:20
	System	10 Sep 2020 22:45:20

US3512248

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 10 Jun 2021 07:56:44

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:52:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FCE43EC3-F1E0-47A1-B438-4D694934F821)', Time: '2020-09-10T18:45:06', User OID: 'PatientReportedOutcome (US3512248)', ODM File OID: '609ba9ee-4ff2-4dd8-8796-15441c3ebd07' User entered 'No (N)'	System	10 Sep 2020 22:45:20
	System	10 Sep 2020 22:45:20

US3512248

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 10 Jun 2021 07:56:44

Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:52:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FCE43EC3-F1E0-47A1-B438-4D694934F821)', Time: '2020-09-10T18:45:13', User OID: 'PatientReportedOutcome (US3512248)', ODM File OID: '609ba9ee-4ff2-4dd8-8796-15441c3ebd07' User entered 'None (1)'	System	10 Sep 2020 22:45:20
	System	10 Sep 2020 22:45:20

**US3512248**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(1/2)**

**Generated On: 10 Jun 2021 07:56:44**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:52:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FCE43EC3-F1E0-47A1-B438-4D694934F821)', Time: '2020-09-10T18:45:18', User OID: 'PatientReportedOutcome (US3512248)', ODM File OID: '609ba9ee-4ff2-4dd8-8796-15441c3ebd07' User entered '10 Sep 2020 18:45'	System	10 Sep 2020 22:45:20
	System	10 Sep 2020 22:45:20



US3512248

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 10 Jun 2021 07:56:44

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:52:02
User entered '10 Sep 2020 16:36'	System	10 Sep 2020 17:24:28

**US3512248**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(1/2)**

**Generated On: 10 Jun 2021 07:56:44**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:52:02
User entered '11 Sep 2020 11:59'	System	10 Sep 2020 17:24:28

US3512248

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 10 Jun 2021 07:56:44

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:52:02
Data entry locked.	System	10 Sep 2020 17:24:28
User entered 'Day 2'	System	10 Sep 2020 17:24:28

US3512248

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 10 Jun 2021 07:56:44

Please record - **PAIN AT INJECTION SITE.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:52:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FCE43EC3-F1E0-47A1-B438-4D694934F821)', Time: '2020-09-11T17:00:56', User OID: 'PatientReportedOutcome (US3512248)', ODM File OID: '0bf5e4ba-d730-4680-9e6b-906f1543d639'	System	11 Sep 2020 21:01:28
User entered 'None (1)'	System	11 Sep 2020 21:01:28

US3512248

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 10 Jun 2021 07:56:44

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:52:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FCE43EC3-F1E0-47A1-B438-4D694934F821)', Time: '2020-09-11T17:01:01', User OID: 'PatientReportedOutcome (US3512248)', ODM File OID: '0bf5e4ba-d730-4680-9e6b-906f1543d639' User entered 'No (N)'	System	11 Sep 2020 21:01:28
	System	11 Sep 2020 21:01:28

US3512248

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 10 Jun 2021 07:56:44

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:52:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FCE43EC3-F1E0-47A1-B438-4D694934F821)', Time: '2020-09-11T17:01:07', User OID: 'PatientReportedOutcome (US3512248)', ODM File OID: '0bf5e4ba-d730-4680-9e6b-906f1543d639' User entered 'No (N)'	System	11 Sep 2020 21:01:28
	System	11 Sep 2020 21:01:28

US3512248

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 10 Jun 2021 07:56:44

Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:52:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FCE43EC3-F1E0-47A1-B438-4D694934F821)', Time: '2020-09-11T17:01:14', User OID: 'PatientReportedOutcome (US3512248)', ODM File OID: '0bf5e4ba-d730-4680-9e6b-906f1543d639' User entered 'None (1)'	System	11 Sep 2020 21:01:28
	System	11 Sep 2020 21:01:28

**US3512248**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(2)**

**Generated On: 10 Jun 2021 07:56:44**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:52:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FCE43EC3-F1E0-47A1-B438-4D694934F821)', Time: '2020-09-11T17:01:23', User OID: 'PatientReportedOutcome (US3512248)', ODM File OID: '0bf5e4ba-d730-4680-9e6b-906f1543d639' User entered '11 Sep 2020 17:01'	System	11 Sep 2020 21:01:28
	System	11 Sep 2020 21:01:28



**US3512248**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(2)**

**Generated On: 10 Jun 2021 07:56:44**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:52:02
User entered '11 Sep 2020 12:00'	System	10 Sep 2020 17:24:28

**US3512248**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(2)**

**Generated On: 10 Jun 2021 07:56:44**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:52:02
User entered '12 Sep 2020 11:59'	System	10 Sep 2020 17:24:28

US3512248

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 10 Jun 2021 07:56:44

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:52:02
Data entry locked.	System	10 Sep 2020 17:24:28
User entered 'Day 3'	System	10 Sep 2020 17:24:28

US3512248

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 10 Jun 2021 07:56:44

Please record - **PAIN AT INJECTION SITE.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:52:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FCE43EC3-F1E0-47A1-B438-4D694934F821)', Time: '2020-09-12T21:01:53', User OID: 'PatientReportedOutcome (US3512248)', ODM File OID: '6ceb2e82-adaa-48d2-8a39-292dcf9a7e2b' User entered 'Does not interfere with activity (2)'	System	13 Sep 2020 01:02:33
	System	13 Sep 2020 01:02:33

US3512248

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 10 Jun 2021 07:56:44

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:52:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FCE43EC3-F1E0-47A1-B438-4D694934F821)', Time: '2020-09-12T21:01:57', User OID: 'PatientReportedOutcome (US3512248)', ODM File OID: '6ceb2e82-adaa-48d2-8a39-292dcf9a7e2b' User entered 'No (N)'	System	13 Sep 2020 01:02:33
	System	13 Sep 2020 01:02:33

US3512248

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 10 Jun 2021 07:56:44

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:52:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FCE43EC3-F1E0-47A1-B438-4D694934F821)', Time: '2020-09-12T21:02:07', User OID: 'PatientReportedOutcome (US3512248)', ODM File OID: '6ceb2e82-adaa-48d2-8a39-292dcf9a7e2b' User entered 'No (N)'	System	13 Sep 2020 01:02:33
	System	13 Sep 2020 01:02:33

US3512248

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 10 Jun 2021 07:56:44

Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:52:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FCE43EC3-F1E0-47A1-B438-4D694934F821)', Time: '2020-09-12T21:02:16', User OID: 'PatientReportedOutcome (US3512248)', ODM File OID: '6ceb2e82-adaa-48d2-8a39-292dcf9a7e2b' User entered 'None (1)'	System	13 Sep 2020 01:02:33
	System	13 Sep 2020 01:02:33

**US3512248**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(3)**

**Generated On: 10 Jun 2021 07:56:44**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:52:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FCE43EC3-F1E0-47A1-B438-4D694934F821)', Time: '2020-09-12T21:02:26', User OID: 'PatientReportedOutcome (US3512248)', ODM File OID: '6ceb2e82-adaa-48d2-8a39-292dcf9a7e2b' User entered '12 Sep 2020 21:02'	System	13 Sep 2020 01:02:33
	System	13 Sep 2020 01:02:33



**US3512248**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(3)**

**Generated On: 10 Jun 2021 07:56:44**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:52:02
User entered '12 Sep 2020 12:00'	System	10 Sep 2020 17:24:28

**US3512248**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(3)**

**Generated On: 10 Jun 2021 07:56:44**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:52:02
User entered '13 Sep 2020 11:59'	System	10 Sep 2020 17:24:28

US3512248

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 10 Jun 2021 07:56:44

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:52:02
Data entry locked.	System	10 Sep 2020 17:24:28
User entered 'Day 4'	System	10 Sep 2020 17:24:28

US3512248

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 10 Jun 2021 07:56:44

Please record - **PAIN AT INJECTION SITE.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:52:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FCE43EC3-F1E0-47A1-B438-4D694934F821)', Time: '2020-09-13T20:12:48', User OID: 'PatientReportedOutcome (US3512248)', ODM File OID: '615fbe9d-b9b0-456d-a027-dd6208d750d0'	System	14 Sep 2020 00:13:31
User entered 'Does not interfere with activity (2)'	System	14 Sep 2020 00:13:31

US3512248

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 10 Jun 2021 07:56:44

Is there any **REDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:52:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FCE43EC3-F1E0-47A1-B438-4D694934F821)', Time: '2020-09-13T20:12:52', User OID: 'PatientReportedOutcome (US3512248)', ODM File OID: '615fbe9d-b9b0-456d-a027-dd6208d750d0' User entered 'No (N)'	System	14 Sep 2020 00:13:31
	System	14 Sep 2020 00:13:31

US3512248

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 10 Jun 2021 07:56:44

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:52:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FCE43EC3-F1E0-47A1-B438-4D694934F821)', Time: '2020-09-13T20:13:10', User OID: 'PatientReportedOutcome (US3512248)', ODM File OID: '615fbe9d-b9b0-456d-a027-dd6208d750d0' User entered 'No (N)'	System	14 Sep 2020 00:13:31
	System	14 Sep 2020 00:13:31

US3512248

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 10 Jun 2021 07:56:44

Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:52:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FCE43EC3-F1E0-47A1-B438-4D694934F821)', Time: '2020-09-13T20:13:17', User OID: 'PatientReportedOutcome (US3512248)', ODM File OID: '615fbe9d-b9b0-456d-a027-dd6208d750d0' User entered 'None (1)'	System	14 Sep 2020 00:13:31
	System	14 Sep 2020 00:13:31

US3512248

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 10 Jun 2021 07:56:44

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:52:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FCE43EC3-F1E0-47A1-B438-4D694934F821)', Time: '2020-09-13T20:13:28', User OID: 'PatientReportedOutcome (US3512248)', ODM File OID: '615fbe9d-b9b0-456d-a027-dd6208d750d0' User entered '13 Sep 2020 20:13'	System	14 Sep 2020 00:13:31
	System	14 Sep 2020 00:13:31



US3512248

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 10 Jun 2021 07:56:44

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:52:02
User entered '13 Sep 2020 12:00'	System	10 Sep 2020 17:24:28

**US3512248**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(4)**

**Generated On: 10 Jun 2021 07:56:44**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:52:02
User entered '14 Sep 2020 11:59'	System	10 Sep 2020 17:24:28

US3512248

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 10 Jun 2021 07:56:44

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:52:02
Data entry locked.	System	10 Sep 2020 17:24:28
User entered 'Day 5'	System	10 Sep 2020 17:24:28

US3512248

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 10 Jun 2021 07:56:44

Please record - **PAIN AT INJECTION SITE.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:52:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FCE43EC3-F1E0-47A1-B438-4D694934F821)', Time: '2020-09-14T22:14:00', User OID: 'PatientReportedOutcome (US3512248)', ODM File OID: '99bccb52-652b-4c93-b491-89a77b958ebd'	System	15 Sep 2020 02:14:09
User entered 'Does not interfere with activity (2)'	System	15 Sep 2020 02:14:09

US3512248

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 10 Jun 2021 07:56:44

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:52:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FCE43EC3-F1E0-47A1-B438-4D694934F821)', Time: '2020-09-14T22:13:34', User OID: 'PatientReportedOutcome (US3512248)', ODM File OID: '99bccb52-652b-4c93-b491-89a77b958ebd' User entered 'No (N)'	System	15 Sep 2020 02:14:09
	System	15 Sep 2020 02:14:09

US3512248

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 10 Jun 2021 07:56:44

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:52:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FCE43EC3-F1E0-47A1-B438-4D694934F821)', Time: '2020-09-14T22:13:39', User OID: 'PatientReportedOutcome (US3512248)', ODM File OID: '99bccb52-652b-4c93-b491-89a77b958ebd' User entered 'No (N)'	System	15 Sep 2020 02:14:09
	System	15 Sep 2020 02:14:09

US3512248

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 10 Jun 2021 07:56:44

Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:52:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FCE43EC3-F1E0-47A1-B438-4D694934F821)', Time: '2020-09-14T22:13:44', User OID: 'PatientReportedOutcome (US3512248)', ODM File OID: '99bccb52-652b-4c93-b491-89a77b958ebd' User entered 'None (1)'	System	15 Sep 2020 02:14:09
	System	15 Sep 2020 02:14:09

**US3512248**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(5)**

**Generated On: 10 Jun 2021 07:56:44**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:52:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FCE43EC3-F1E0-47A1-B438-4D694934F821)', Time: '2020-09-14T22:14:06', User OID: 'PatientReportedOutcome (US3512248)', ODM File OID: '99bccb52-652b-4c93-b491-89a77b958ebd' User entered '14 Sep 2020 22:14'	System	15 Sep 2020 02:14:09
	System	15 Sep 2020 02:14:09



**US3512248**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(5)**

**Generated On: 10 Jun 2021 07:56:44**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:52:02
User entered '14 Sep 2020 12:00'	System	10 Sep 2020 17:24:28

US3512248

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 10 Jun 2021 07:56:44

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:52:02
User entered '15 Sep 2020 11:59'	System	10 Sep 2020 17:24:28

US3512248

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(6)

Generated On: 10 Jun 2021 07:56:44

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:52:02
Data entry locked.	System	10 Sep 2020 17:24:28
User entered 'Day 6'	System	10 Sep 2020 17:24:28

US3512248

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(6)

Generated On: 10 Jun 2021 07:56:44

Please record - **PAIN AT INJECTION SITE.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:52:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FCE43EC3-F1E0-47A1-B438-4D694934F821)', Time: '2020-09-15T21:27:34', User OID: 'PatientReportedOutcome (US3512248)', ODM File OID: 'f6080dd2-1d6f-4980-9b8c-410f10949a27'	System	16 Sep 2020 01:27:56
User entered 'Does not interfere with activity (2)'	System	16 Sep 2020 01:27:56

US3512248

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(6)

Generated On: 10 Jun 2021 07:56:44

Is there any **REDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:52:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FCE43EC3-F1E0-47A1-B438-4D694934F821)', Time: '2020-09-15T21:27:39', User OID: 'PatientReportedOutcome (US3512248)', ODM File OID: 'f6080dd2-1d6f-4980-9b8c-410f10949a27' User entered 'No (N)'	System	16 Sep 2020 01:27:56
	System	16 Sep 2020 01:27:56

US3512248

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(6)

Generated On: 10 Jun 2021 07:56:44

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:52:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FCE43EC3-F1E0-47A1-B438-4D694934F821)', Time: '2020-09-15T21:27:43', User OID: 'PatientReportedOutcome (US3512248)', ODM File OID: 'f6080dd2-1d6f-4980-9b8c-410f10949a27' User entered 'No (N)'	System	16 Sep 2020 01:27:56
	System	16 Sep 2020 01:27:56

US3512248

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(6)

Generated On: 10 Jun 2021 07:56:44

Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:52:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FCE43EC3-F1E0-47A1-B438-4D694934F821)', Time: '2020-09-15T21:27:49', User OID: 'PatientReportedOutcome (US3512248)', ODM File OID: 'f6080dd2-1d6f-4980-9b8c-410f10949a27'	System	16 Sep 2020 01:27:56
User entered 'None (1)'	System	16 Sep 2020 01:27:56

**US3512248**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(6)**

**Generated On: 10 Jun 2021 07:56:44**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:52:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FCE43EC3-F1E0-47A1-B438-4D694934F821)', Time: '2020-09-15T21:27:53', User OID: 'PatientReportedOutcome (US3512248)', ODM File OID: 'f6080dd2-1d6f-4980-9b8c-410f10949a27'	System	16 Sep 2020 01:27:56
User entered '15 Sep 2020 21:27'	System	16 Sep 2020 01:27:56



**US3512248**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(6)**

**Generated On: 10 Jun 2021 07:56:44**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:52:02
User entered '15 Sep 2020 12:00'	System	10 Sep 2020 17:24:28

US3512248

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(6)

Generated On: 10 Jun 2021 07:56:44

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:52:02
User entered '16 Sep 2020 11:59'	System	10 Sep 2020 17:24:28

US3512248

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 10 Jun 2021 07:56:44

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:52:02
Data entry locked.	System	10 Sep 2020 17:24:28
User entered 'Day 7'	System	10 Sep 2020 17:24:28

US3512248

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 10 Jun 2021 07:56:44

Please record - **PAIN AT INJECTION SITE.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:52:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FCE43EC3-F1E0-47A1-B438-4D694934F821)', Time: '2020-09-16T20:32:47', User OID: 'PatientReportedOutcome (US3512248)', ODM File OID: '2d757dd7-8b6c-46f8-9d86-7a2bf586bcd2'	System	17 Sep 2020 00:33:13
User entered 'None (1)'	System	17 Sep 2020 00:33:13

US3512248

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 10 Jun 2021 07:56:44

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:52:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FCE43EC3-F1E0-47A1-B438-4D694934F821)', Time: '2020-09-16T20:32:51', User OID: 'PatientReportedOutcome (US3512248)', ODM File OID: '2d757dd7-8b6c-46f8-9d86-7a2bf586bcd2' User entered 'No (N)'	System	17 Sep 2020 00:33:13
	System	17 Sep 2020 00:33:13

US3512248

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 10 Jun 2021 07:56:44

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:52:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FCE43EC3-F1E0-47A1-B438-4D694934F821)', Time: '2020-09-16T20:32:55', User OID: 'PatientReportedOutcome (US3512248)', ODM File OID: '2d757dd7-8b6c-46f8-9d86-7a2bf586bcd2' User entered 'No (N)'	System	17 Sep 2020 00:33:13
	System	17 Sep 2020 00:33:13

US3512248

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 10 Jun 2021 07:56:44

Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:52:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FCE43EC3-F1E0-47A1-B438-4D694934F821)', Time: '2020-09-16T20:33:00', User OID: 'PatientReportedOutcome (US3512248)', ODM File OID: '2d757dd7-8b6c-46f8-9d86-7a2bf586bcd2' User entered 'None (1)'	System	17 Sep 2020 00:33:13
	System	17 Sep 2020 00:33:13

**US3512248**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(7)**

**Generated On: 10 Jun 2021 07:56:44**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:52:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FCE43EC3-F1E0-47A1-B438-4D694934F821)', Time: '2020-09-16T20:33:10', User OID: 'PatientReportedOutcome (US3512248)', ODM File OID: '2d757dd7-8b6c-46f8-9d86-7a2bf586bcd2' User entered '16 Sep 2020 20:33'	System	17 Sep 2020 00:33:13
	System	17 Sep 2020 00:33:13



**US3512248**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(7)**

**Generated On: 10 Jun 2021 07:56:44**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:52:02
User entered '16 Sep 2020 12:00'	System	10 Sep 2020 17:24:28

US3512248

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 10 Jun 2021 07:56:44

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:52:02
User entered '17 Sep 2020 11:59'	System	10 Sep 2020 17:24:28

US3512248

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 10 Jun 2021 07:56:44

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:52:02
Data entry locked.	System	10 Sep 2020 17:24:28
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	10 Sep 2020 17:24:28

**US3512248**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(1/1)**

**Generated On: 10 Jun 2021 07:56:44**

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:52:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FCE43EC3-F1E0-47A1-B438-4D694934F821)', Time: '2020-09-10T13:30:58', User OID: 'PatientReportedOutcome (US3512248)', ODM File OID: '127a0f45-21bf-4be1-97d4-31073a12678a' User entered 'None (0)'	System	10 Sep 2020 17:31:55
	System	10 Sep 2020 17:31:55

US3512248

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 10 Jun 2021 07:56:44

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:52:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FCE43EC3-F1E0-47A1-B438-4D694934F821)', Time: '2020-09-10T13:31:04', User OID: 'PatientReportedOutcome (US3512248)', ODM File OID: '127a0f45-21bf-4be1-97d4-31073a12678a' User entered 'None (0)'	System	10 Sep 2020 17:31:55
	System	10 Sep 2020 17:31:55

US3512248

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 10 Jun 2021 07:56:44

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:52:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FCE43EC3-F1E0-47A1-B438-4D694934F821)', Time: '2020-09-10T13:31:09', User OID: 'PatientReportedOutcome (US3512248)', ODM File OID: '127a0f45-21bf-4be1-97d4-31073a12678a' User entered 'None (0)'	System	10 Sep 2020 17:31:55
	System	10 Sep 2020 17:31:55

US3512248

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 10 Jun 2021 07:56:44

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:52:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FCE43EC3-F1E0-47A1-B438-4D694934F821)', Time: '2020-09-10T13:31:13', User OID: 'PatientReportedOutcome (US3512248)', ODM File OID: '127a0f45-21bf-4be1-97d4-31073a12678a' User entered 'None (0)'	System	10 Sep 2020 17:31:55
	System	10 Sep 2020 17:31:55

US3512248

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 10 Jun 2021 07:56:44

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:52:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FCE43EC3-F1E0-47A1-B438-4D694934F821)', Time: '2020-09-10T13:31:17', User OID: 'PatientReportedOutcome (US3512248)', ODM File OID: '127a0f45-21bf-4be1-97d4-31073a12678a' User entered 'None (0)'	System	10 Sep 2020 17:31:55
	System	10 Sep 2020 17:31:55



**US3512248**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(1/1)**

**Generated On: 10 Jun 2021 07:56:44**

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:52:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FCE43EC3-F1E0-47A1-B438-4D694934F821)', Time: '2020-09-10T13:31:21', User OID: 'PatientReportedOutcome (US3512248)', ODM File OID: '127a0f45-21bf-4be1-97d4-31073a12678a' User entered 'None (0)'	System	10 Sep 2020 17:31:55
	System	10 Sep 2020 17:31:55

US3512248

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 10 Jun 2021 07:56:44

Did you receive any **MEDICAL ATTENTION** (doctor visit, other) for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:52:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FCE43EC3-F1E0-47A1-B438-4D694934F821)', Time: '2020-09-10T13:31:36', User OID: 'PatientReportedOutcome (US3512248)', ODM File OID: '127a0f45-21bf-4be1-97d4-31073a12678a' User entered 'No (N)'	System	10 Sep 2020 17:31:55
	System	10 Sep 2020 17:31:55

**US3512248**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(1/1)**

**Generated On: 10 Jun 2021 07:56:44**

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:52:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FCE43EC3-F1E0-47A1-B438-4D694934F821)', Time: '2020-09-10T13:31:51', User OID: 'PatientReportedOutcome (US3512248)', ODM File OID: '127a0f45-21bf-4be1-97d4-31073a12678a' User entered '10 Sep 2020 13:31'	System	10 Sep 2020 17:31:55
	System	10 Sep 2020 17:31:55

US3512248

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 10 Jun 2021 07:56:44

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:52:02
User entered '10 Sep 2020 13:11'	System	10 Sep 2020 17:24:28

US3512248

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 10 Jun 2021 07:56:44

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:52:02
User entered '10 Sep 2020 15:41'	System	10 Sep 2020 17:24:28

US3512248

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 10 Jun 2021 07:56:44

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:52:02
Data entry locked.	System	10 Sep 2020 17:24:28
User entered 'Day 1, after vaccination (at home)'	System	10 Sep 2020 17:24:28

US3512248

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 10 Jun 2021 07:56:44

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:52:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FCE43EC3-F1E0-47A1-B438-4D694934F821)', Time: '2020-09-10T18:45:27', User OID: 'PatientReportedOutcome (US3512248)', ODM File OID: '9c832c1b-493e-4f6d-9ebf-1b1daa2cded5' User entered 'None (0)'	System	10 Sep 2020 22:46:09
	System	10 Sep 2020 22:46:09

US3512248

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 10 Jun 2021 07:56:44

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:52:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FCE43EC3-F1E0-47A1-B438-4D694934F821)', Time: '2020-09-10T18:45:34', User OID: 'PatientReportedOutcome (US3512248)', ODM File OID: '9c832c1b-493e-4f6d-9ebf-1b1daa2cded5' User entered 'None (0)'	System	10 Sep 2020 22:46:09
	System	10 Sep 2020 22:46:09



US3512248

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 10 Jun 2021 07:56:44

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:52:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FCE43EC3-F1E0-47A1-B438-4D694934F821)', Time: '2020-09-10T18:45:39', User OID: 'PatientReportedOutcome (US3512248)', ODM File OID: '9c832c1b-493e-4f6d-9ebf-1b1daa2cded5' User entered 'None (0)'	System	10 Sep 2020 22:46:09
	System	10 Sep 2020 22:46:09

US3512248

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 10 Jun 2021 07:56:44

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:52:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FCE43EC3-F1E0-47A1-B438-4D694934F821)', Time: '2020-09-10T18:45:43', User OID: 'PatientReportedOutcome (US3512248)', ODM File OID: '9c832c1b-493e-4f6d-9ebf-1b1daa2cded5' User entered 'None (0)'	System	10 Sep 2020 22:46:09
	System	10 Sep 2020 22:46:09

**US3512248**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(1/2)**

**Generated On: 10 Jun 2021 07:56:44**

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:52:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FCE43EC3-F1E0-47A1-B438-4D694934F821)', Time: '2020-09-10T18:45:47', User OID: 'PatientReportedOutcome (US3512248)', ODM File OID: '9c832c1b-493e-4f6d-9ebf-1b1daa2cded5' User entered 'None (0)'	System	10 Sep 2020 22:46:09
	System	10 Sep 2020 22:46:09

**US3512248**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(1/2)**

**Generated On: 10 Jun 2021 07:56:44**

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:52:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FCE43EC3-F1E0-47A1-B438-4D694934F821)', Time: '2020-09-10T18:45:51', User OID: 'PatientReportedOutcome (US3512248)', ODM File OID: '9c832c1b-493e-4f6d-9ebf-1b1daa2cded5' User entered 'None (0)'	System	10 Sep 2020 22:46:09
	System	10 Sep 2020 22:46:09

US3512248

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 10 Jun 2021 07:56:44

Did you receive any **MEDICAL ATTENTION** (doctor visit, other) for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:52:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FCE43EC3-F1E0-47A1-B438-4D694934F821)', Time: '2020-09-10T18:45:57', User OID: 'PatientReportedOutcome (US3512248)', ODM File OID: '9c832c1b-493e-4f6d-9ebf-1b1daa2cded5' User entered 'No (N)'	System	10 Sep 2020 22:46:09
	System	10 Sep 2020 22:46:09

**US3512248**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(1/2)**

**Generated On: 10 Jun 2021 07:56:44**

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:52:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FCE43EC3-F1E0-47A1-B438-4D694934F821)', Time: '2020-09-10T18:46:06', User OID: 'PatientReportedOutcome (US3512248)', ODM File OID: '9c832c1b-493e-4f6d-9ebf-1b1daa2cded5' User entered '10 Sep 2020 18:46'	System	10 Sep 2020 22:46:09
	System	10 Sep 2020 22:46:09

**US3512248**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(1/2)**

**Generated On: 10 Jun 2021 07:56:44**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:52:02
User entered '10 Sep 2020 16:36'	System	10 Sep 2020 17:24:28

US3512248

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 10 Jun 2021 07:56:44

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:52:02
User entered '11 Sep 2020 11:59'	System	10 Sep 2020 17:24:28



US3512248

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 10 Jun 2021 07:56:44

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:52:02
Data entry locked.	System	10 Sep 2020 17:24:28
User entered 'Day 2'	System	10 Sep 2020 17:24:28

US3512248

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 10 Jun 2021 07:56:44

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:52:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FCE43EC3-F1E0-47A1-B438-4D694934F821)', Time: '2020-09-11T17:01:35', User OID: 'PatientReportedOutcome (US3512248)', ODM File OID: 'd10ae607-6cb4-4705-a7ff-64c0ac0c648d' User entered 'None (0)'	System	11 Sep 2020 21:02:28
	System	11 Sep 2020 21:02:28

US3512248

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 10 Jun 2021 07:56:44

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:52:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FCE43EC3-F1E0-47A1-B438-4D694934F821)', Time: '2020-09-11T17:01:41', User OID: 'PatientReportedOutcome (US3512248)', ODM File OID: 'd10ae607-6cb4-4705-a7ff-64c0ac0c648d' User entered 'None (0)'	System	11 Sep 2020 21:02:28
	System	11 Sep 2020 21:02:28

US3512248

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 10 Jun 2021 07:56:44

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:52:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FCE43EC3-F1E0-47A1-B438-4D694934F821)', Time: '2020-09-11T17:01:50', User OID: 'PatientReportedOutcome (US3512248)', ODM File OID: 'd10ae607-6cb4-4705-a7ff-64c0ac0c648d' User entered 'None (0)'	System	11 Sep 2020 21:02:28
	System	11 Sep 2020 21:02:28

US3512248

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 10 Jun 2021 07:56:44

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:52:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FCE43EC3-F1E0-47A1-B438-4D694934F821)', Time: '2020-09-11T17:01:59', User OID: 'PatientReportedOutcome (US3512248)', ODM File OID: 'd10ae607-6cb4-4705-a7ff-64c0ac0c648d' User entered 'None (0)'	System	11 Sep 2020 21:02:28
	System	11 Sep 2020 21:02:28

**US3512248**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(2)**

**Generated On: 10 Jun 2021 07:56:44**

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:52:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FCE43EC3-F1E0-47A1-B438-4D694934F821)', Time: '2020-09-11T17:02:05', User OID: 'PatientReportedOutcome (US3512248)', ODM File OID: 'd10ae607-6cb4-4705-a7ff-64c0ac0c648d' User entered 'None (0)'	System	11 Sep 2020 21:02:28
	System	11 Sep 2020 21:02:28

US3512248

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 10 Jun 2021 07:56:44

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:52:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FCE43EC3-F1E0-47A1-B438-4D694934F821)', Time: '2020-09-11T17:02:12', User OID: 'PatientReportedOutcome (US3512248)', ODM File OID: 'd10ae607-6cb4-4705-a7ff-64c0ac0c648d' User entered 'None (0)'	System	11 Sep 2020 21:02:28
	System	11 Sep 2020 21:02:28

US3512248

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 10 Jun 2021 07:56:44

Did you receive any **MEDICAL ATTENTION** (doctor visit, other) for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:52:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FCE43EC3-F1E0-47A1-B438-4D694934F821)', Time: '2020-09-11T17:02:17', User OID: 'PatientReportedOutcome (US3512248)', ODM File OID: 'd10ae607-6cb4-4705-a7ff-64c0ac0c648d' User entered 'No (N)'	System	11 Sep 2020 21:02:28
	System	11 Sep 2020 21:02:28



**US3512248**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(2)**

**Generated On: 10 Jun 2021 07:56:44**

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:52:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FCE43EC3-F1E0-47A1-B438-4D694934F821)', Time: '2020-09-11T17:02:24', User OID: 'PatientReportedOutcome (US3512248)', ODM File OID: 'd10ae607-6cb4-4705-a7ff-64c0ac0c648d' User entered '11 Sep 2020 17:02'	System	11 Sep 2020 21:02:28
	System	11 Sep 2020 21:02:28

**US3512248**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(2)**

**Generated On: 10 Jun 2021 07:56:44**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:52:02
User entered '11 Sep 2020 12:00'	System	10 Sep 2020 17:24:28

**US3512248**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(2)**

**Generated On: 10 Jun 2021 07:56:44**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:52:02
User entered '12 Sep 2020 11:59'	System	10 Sep 2020 17:24:28

US3512248

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 10 Jun 2021 07:56:44

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:52:02
Data entry locked.	System	10 Sep 2020 17:24:28
User entered 'Day 3'	System	10 Sep 2020 17:24:28

**US3512248**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(3)**

**Generated On: 10 Jun 2021 07:56:44**

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:52:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FCE43EC3-F1E0-47A1-B438-4D694934F821)', Time: '2020-09-12T21:02:38', User OID: 'PatientReportedOutcome (US3512248)', ODM File OID: 'eb2786ab-b45a-404f-a1ba-9f4c2acc6995' User entered 'None (0)'	System	13 Sep 2020 01:03:40
	System	13 Sep 2020 01:03:40

US3512248

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 10 Jun 2021 07:56:44

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:52:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FCE43EC3-F1E0-47A1-B438-4D694934F821)', Time: '2020-09-12T21:02:45', User OID: 'PatientReportedOutcome (US3512248)', ODM File OID: 'eb2786ab-b45a-404f-a1ba-9f4c2acc6995' User entered 'None (0)'	System	13 Sep 2020 01:03:40
	System	13 Sep 2020 01:03:40

US3512248

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 10 Jun 2021 07:56:44

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:52:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FCE43EC3-F1E0-47A1-B438-4D694934F821)', Time: '2020-09-12T21:03:07', User OID: 'PatientReportedOutcome (US3512248)', ODM File OID: 'eb2786ab-b45a-404f-a1ba-9f4c2acc6995' User entered 'None (0)'	System	13 Sep 2020 01:03:40
	System	13 Sep 2020 01:03:40

US3512248

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 10 Jun 2021 07:56:44

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:52:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FCE43EC3-F1E0-47A1-B438-4D694934F821)', Time: '2020-09-12T21:03:14', User OID: 'PatientReportedOutcome (US3512248)', ODM File OID: 'eb2786ab-b45a-404f-a1ba-9f4c2acc6995'	System	13 Sep 2020 01:03:40
User entered 'No interference with activity (1)'	System	13 Sep 2020 01:03:40



**US3512248**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(3)**

**Generated On: 10 Jun 2021 07:56:44**

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:52:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FCE43EC3-F1E0-47A1-B438-4D694934F821)', Time: '2020-09-12T21:03:23', User OID: 'PatientReportedOutcome (US3512248)', ODM File OID: 'eb2786ab-b45a-404f-a1ba-9f4c2acc6995' User entered 'None (0)'	System	13 Sep 2020 01:03:40
	System	13 Sep 2020 01:03:40

**US3512248**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(3)**

**Generated On: 10 Jun 2021 07:56:44**

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:52:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FCE43EC3-F1E0-47A1-B438-4D694934F821)', Time: '2020-09-12T21:03:28', User OID: 'PatientReportedOutcome (US3512248)', ODM File OID: 'eb2786ab-b45a-404f-a1ba-9f4c2acc6995' User entered 'None (0)'	System	13 Sep 2020 01:03:40
	System	13 Sep 2020 01:03:40

US3512248

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 10 Jun 2021 07:56:44

Did you receive any **MEDICAL ATTENTION** (doctor visit, other) for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:52:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FCE43EC3-F1E0-47A1-B438-4D694934F821)', Time: '2020-09-12T21:03:34', User OID: 'PatientReportedOutcome (US3512248)', ODM File OID: 'eb2786ab-b45a-404f-a1ba-9f4c2acc6995'	System	13 Sep 2020 01:03:40
User entered 'No (N)'	System	13 Sep 2020 01:03:40

**US3512248**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(3)**

**Generated On: 10 Jun 2021 07:56:44**

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:52:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FCE43EC3-F1E0-47A1-B438-4D694934F821)', Time: '2020-09-12T21:03:38', User OID: 'PatientReportedOutcome (US3512248)', ODM File OID: 'eb2786ab-b45a-404f-a1ba-9f4c2acc6995' User entered '12 Sep 2020 21:03'	System	13 Sep 2020 01:03:40
	System	13 Sep 2020 01:03:40

**US3512248**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(3)**

**Generated On: 10 Jun 2021 07:56:44**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:52:02
User entered '12 Sep 2020 12:00'	System	10 Sep 2020 17:24:28

**US3512248**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(3)**

**Generated On: 10 Jun 2021 07:56:44**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:52:02
User entered '13 Sep 2020 11:59'	System	10 Sep 2020 17:24:28

US3512248

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 10 Jun 2021 07:56:44

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:52:02
Data entry locked.	System	10 Sep 2020 17:24:28
User entered 'Day 4'	System	10 Sep 2020 17:24:28

**US3512248**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(4)**

**Generated On: 10 Jun 2021 07:56:44**

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:52:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FCE43EC3-F1E0-47A1-B438-4D694934F821)', Time: '2020-09-13T20:13:36', User OID: 'PatientReportedOutcome (US3512248)', ODM File OID: '377b8c13-c42f-43e4-b2a3-a9ae8959216e' User entered 'No interference with activity (1)'	System	14 Sep 2020 00:14:45
	System	14 Sep 2020 00:14:45



US3512248

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 10 Jun 2021 07:56:44

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:52:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FCE43EC3-F1E0-47A1-B438-4D694934F821)', Time: '2020-09-13T20:13:41', User OID: 'PatientReportedOutcome (US3512248)', ODM File OID: '377b8c13-c42f-43e4-b2a3-a9ae8959216e' User entered 'None (0)'	System	14 Sep 2020 00:14:45
	System	14 Sep 2020 00:14:45

US3512248

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 10 Jun 2021 07:56:44

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:52:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FCE43EC3-F1E0-47A1-B438-4D694934F821)', Time: '2020-09-13T20:13:58', User OID: 'PatientReportedOutcome (US3512248)', ODM File OID: '377b8c13-c42f-43e4-b2a3-a9ae8959216e' User entered 'None (0)'	System	14 Sep 2020 00:14:45
	System	14 Sep 2020 00:14:45

US3512248

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 10 Jun 2021 07:56:44

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:52:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FCE43EC3-F1E0-47A1-B438-4D694934F821)', Time: '2020-09-13T20:14:03', User OID: 'PatientReportedOutcome (US3512248)', ODM File OID: '377b8c13-c42f-43e4-b2a3-a9ae8959216e' User entered 'No interference with activity (1)'	System	14 Sep 2020 00:14:45
	System	14 Sep 2020 00:14:45

**US3512248**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(4)**

**Generated On: 10 Jun 2021 07:56:44**

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:52:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FCE43EC3-F1E0-47A1-B438-4D694934F821)', Time: '2020-09-13T20:14:08', User OID: 'PatientReportedOutcome (US3512248)', ODM File OID: '377b8c13-c42f-43e4-b2a3-a9ae8959216e' User entered 'None (0)'	System	14 Sep 2020 00:14:45
	System	14 Sep 2020 00:14:45

**US3512248**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(4)**

**Generated On: 10 Jun 2021 07:56:44**

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:52:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FCE43EC3-F1E0-47A1-B438-4D694934F821)', Time: '2020-09-13T20:14:16', User OID: 'PatientReportedOutcome (US3512248)', ODM File OID: '377b8c13-c42f-43e4-b2a3-a9ae8959216e' User entered 'None (0)'	System	14 Sep 2020 00:14:45
	System	14 Sep 2020 00:14:45

US3512248

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 10 Jun 2021 07:56:44

Did you receive any **MEDICAL ATTENTION** (doctor visit, other) for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:52:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FCE43EC3-F1E0-47A1-B438-4D694934F821)', Time: '2020-09-13T20:14:21', User OID: 'PatientReportedOutcome (US3512248)', ODM File OID: '377b8c13-c42f-43e4-b2a3-a9ae8959216e' User entered 'No (N)'	System	14 Sep 2020 00:14:45
	System	14 Sep 2020 00:14:45

**US3512248**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(4)**

**Generated On: 10 Jun 2021 07:56:44**

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:52:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FCE43EC3-F1E0-47A1-B438-4D694934F821)', Time: '2020-09-13T20:14:43', User OID: 'PatientReportedOutcome (US3512248)', ODM File OID: '377b8c13-c42f-43e4-b2a3-a9ae8959216e' User entered '13 Sep 2020 20:14'	System	14 Sep 2020 00:14:45
	System	14 Sep 2020 00:14:45

**US3512248**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(4)**

**Generated On: 10 Jun 2021 07:56:44**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:52:02
User entered '13 Sep 2020 12:00'	System	10 Sep 2020 17:24:28



**US3512248**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(4)**

**Generated On: 10 Jun 2021 07:56:44**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:52:02
User entered '14 Sep 2020 11:59'	System	10 Sep 2020 17:24:28

US3512248

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 10 Jun 2021 07:56:44

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:52:02
Data entry locked.	System	10 Sep 2020 17:24:28
User entered 'Day 5'	System	10 Sep 2020 17:24:28

**US3512248**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(5)**

**Generated On: 10 Jun 2021 07:56:44**

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:52:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FCE43EC3-F1E0-47A1-B438-4D694934F821)', Time: '2020-09-14T22:14:15', User OID: 'PatientReportedOutcome (US3512248)', ODM File OID: 'fb65b3f7-0f00-4039-926e-ef9a3441135f' User entered 'No interference with activity (1)'	System	15 Sep 2020 02:15:28
	System	15 Sep 2020 02:15:28

**US3512248**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(5)**

**Generated On: 10 Jun 2021 07:56:44**

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:52:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FCE43EC3-F1E0-47A1-B438-4D694934F821)', Time: '2020-09-14T22:14:20', User OID: 'PatientReportedOutcome (US3512248)', ODM File OID: 'fb65b3f7-0f00-4039-926e-ef9a3441135f' User entered 'None (0)'	System	15 Sep 2020 02:15:28
	System	15 Sep 2020 02:15:28

US3512248

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 10 Jun 2021 07:56:44

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:52:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FCE43EC3-F1E0-47A1-B438-4D694934F821)', Time: '2020-09-14T22:14:33', User OID: 'PatientReportedOutcome (US3512248)', ODM File OID: 'fb65b3f7-0f00-4039-926e-ef9a3441135f' User entered 'None (0)'	System	15 Sep 2020 02:15:28
	System	15 Sep 2020 02:15:28

**US3512248**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(5)**

**Generated On: 10 Jun 2021 07:56:44**

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:52:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FCE43EC3-F1E0-47A1-B438-4D694934F821)', Time: '2020-09-14T22:14:38', User OID: 'PatientReportedOutcome (US3512248)', ODM File OID: 'fb65b3f7-0f00-4039-926e-ef9a3441135f' User entered 'No interference with activity (1)'	System	15 Sep 2020 02:15:28
	System	15 Sep 2020 02:15:28

**US3512248**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(5)**

**Generated On: 10 Jun 2021 07:56:44**

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:52:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FCE43EC3-F1E0-47A1-B438-4D694934F821)', Time: '2020-09-14T22:14:43', User OID: 'PatientReportedOutcome (US3512248)', ODM File OID: 'fb65b3f7-0f00-4039-926e-ef9a3441135f' User entered 'None (0)'	System	15 Sep 2020 02:15:28
	System	15 Sep 2020 02:15:28

**US3512248**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(5)**

**Generated On: 10 Jun 2021 07:56:44**

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:52:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FCE43EC3-F1E0-47A1-B438-4D694934F821)', Time: '2020-09-14T22:14:47', User OID: 'PatientReportedOutcome (US3512248)', ODM File OID: 'fb65b3f7-0f00-4039-926e-ef9a3441135f' User entered 'None (0)'	System	15 Sep 2020 02:15:28
	System	15 Sep 2020 02:15:28



US3512248

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 10 Jun 2021 07:56:44

Did you receive any **MEDICAL ATTENTION** (doctor visit, other) for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:52:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FCE43EC3-F1E0-47A1-B438-4D694934F821)', Time: '2020-09-14T22:14:51', User OID: 'PatientReportedOutcome (US3512248)', ODM File OID: 'fb65b3f7-0f00-4039-926e-ef9a3441135f' User entered 'No (N)'	System	15 Sep 2020 02:15:28
	System	15 Sep 2020 02:15:28

**US3512248**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(5)**

**Generated On: 10 Jun 2021 07:56:44**

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:52:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FCE43EC3-F1E0-47A1-B438-4D694934F821)', Time: '2020-09-14T22:15:25', User OID: 'PatientReportedOutcome (US3512248)', ODM File OID: 'fb65b3f7-0f00-4039-926e-ef9a3441135f' User entered '14 Sep 2020 22:15'	System	15 Sep 2020 02:15:28
	System	15 Sep 2020 02:15:28

**US3512248**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(5)**

**Generated On: 10 Jun 2021 07:56:44**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:52:02
User entered '14 Sep 2020 12:00'	System	10 Sep 2020 17:24:28

**US3512248**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(5)**

**Generated On: 10 Jun 2021 07:56:44**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:52:02
User entered '15 Sep 2020 11:59'	System	10 Sep 2020 17:24:28

US3512248

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 10 Jun 2021 07:56:44

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:52:02
Data entry locked.	System	10 Sep 2020 17:24:28
User entered 'Day 6'	System	10 Sep 2020 17:24:28

**US3512248**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(6)**

**Generated On: 10 Jun 2021 07:56:44**

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:52:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FCE43EC3-F1E0-47A1-B438-4D694934F821)', Time: '2020-09-15T21:28:07', User OID: 'PatientReportedOutcome (US3512248)', ODM File OID: 'ff39e4d8-08d6-4c4f-abee-9b6fa09c800b' User entered 'None (0)'	System	16 Sep 2020 01:29:08
	System	16 Sep 2020 01:29:08

**US3512248**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(6)**

**Generated On: 10 Jun 2021 07:56:44**

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:52:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FCE43EC3-F1E0-47A1-B438-4D694934F821)', Time: '2020-09-15T21:28:11', User OID: 'PatientReportedOutcome (US3512248)', ODM File OID: 'ff39e4d8-08d6-4c4f-abee-9b6fa09c800b' User entered 'None (0)'	System	16 Sep 2020 01:29:08
	System	16 Sep 2020 01:29:08

US3512248

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 10 Jun 2021 07:56:44

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:52:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FCE43EC3-F1E0-47A1-B438-4D694934F821)', Time: '2020-09-15T21:28:28', User OID: 'PatientReportedOutcome (US3512248)', ODM File OID: 'ff39e4d8-08d6-4c4f-abee-9b6fa09c800b' User entered 'None (0)'	System	16 Sep 2020 01:29:08
	System	16 Sep 2020 01:29:08



US3512248

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 10 Jun 2021 07:56:44

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:52:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FCE43EC3-F1E0-47A1-B438-4D694934F821)', Time: '2020-09-15T21:28:33', User OID: 'PatientReportedOutcome (US3512248)', ODM File OID: 'ff39e4d8-08d6-4c4f-abee-9b6fa09c800b' User entered 'No interference with activity (1)'	System	16 Sep 2020 01:29:08
	System	16 Sep 2020 01:29:08

**US3512248**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(6)**

**Generated On: 10 Jun 2021 07:56:44**

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:52:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FCE43EC3-F1E0-47A1-B438-4D694934F821)', Time: '2020-09-15T21:28:37', User OID: 'PatientReportedOutcome (US3512248)', ODM File OID: 'ff39e4d8-08d6-4c4f-abee-9b6fa09c800b' User entered 'None (0)'	System	16 Sep 2020 01:29:08
	System	16 Sep 2020 01:29:08

**US3512248**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(6)**

**Generated On: 10 Jun 2021 07:56:44**

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:52:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FCE43EC3-F1E0-47A1-B438-4D694934F821)', Time: '2020-09-15T21:28:44', User OID: 'PatientReportedOutcome (US3512248)', ODM File OID: 'ff39e4d8-08d6-4c4f-abee-9b6fa09c800b' User entered 'None (0)'	System	16 Sep 2020 01:29:08
	System	16 Sep 2020 01:29:08

US3512248

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 10 Jun 2021 07:56:44

Did you receive any **MEDICAL ATTENTION** (doctor visit, other) for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:52:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FCE43EC3-F1E0-47A1-B438-4D694934F821)', Time: '2020-09-15T21:28:48', User OID: 'PatientReportedOutcome (US3512248)', ODM File OID: 'ff39e4d8-08d6-4c4f-abee-9b6fa09c800b' User entered 'No (N)'	System	16 Sep 2020 01:29:08
	System	16 Sep 2020 01:29:08

**US3512248**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(6)**

**Generated On: 10 Jun 2021 07:56:44**

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:52:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FCE43EC3-F1E0-47A1-B438-4D694934F821)', Time: '2020-09-15T21:29:07', User OID: 'PatientReportedOutcome (US3512248)', ODM File OID: 'ff39e4d8-08d6-4c4f-abee-9b6fa09c800b' User entered '15 Sep 2020 21:29'	System	16 Sep 2020 01:29:08
	System	16 Sep 2020 01:29:08

**US3512248**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(6)**

**Generated On: 10 Jun 2021 07:56:44**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:52:02
User entered '15 Sep 2020 12:00'	System	10 Sep 2020 17:24:28

**US3512248**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(6)**

**Generated On: 10 Jun 2021 07:56:44**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:52:02
User entered '16 Sep 2020 11:59'	System	10 Sep 2020 17:24:28

US3512248

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 10 Jun 2021 07:56:44

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:52:02
Data entry locked.	System	10 Sep 2020 17:24:28
User entered 'Day 7'	System	10 Sep 2020 17:24:28



**US3512248**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(7)**

**Generated On: 10 Jun 2021 07:56:44**

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:52:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FCE43EC3-F1E0-47A1-B438-4D694934F821)', Time: '2020-09-16T20:33:18', User OID: 'PatientReportedOutcome (US3512248)', ODM File OID: '0c2304a6-0dae-41b5-84b5-886b52df47e0' User entered 'None (0)'	System	17 Sep 2020 00:34:02
	System	17 Sep 2020 00:34:02

**US3512248**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(7)**

**Generated On: 10 Jun 2021 07:56:44**

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:52:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FCE43EC3-F1E0-47A1-B438-4D694934F821)', Time: '2020-09-16T20:33:23', User OID: 'PatientReportedOutcome (US3512248)', ODM File OID: '0c2304a6-0dae-41b5-84b5-886b52df47e0' User entered 'None (0)'	System	17 Sep 2020 00:34:02
	System	17 Sep 2020 00:34:02

US3512248

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 10 Jun 2021 07:56:44

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:52:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FCE43EC3-F1E0-47A1-B438-4D694934F821)', Time: '2020-09-16T20:33:30', User OID: 'PatientReportedOutcome (US3512248)', ODM File OID: '0c2304a6-0dae-41b5-84b5-886b52df47e0' User entered 'None (0)'	System	17 Sep 2020 00:34:02
	System	17 Sep 2020 00:34:02

US3512248

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 10 Jun 2021 07:56:44

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:52:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FCE43EC3-F1E0-47A1-B438-4D694934F821)', Time: '2020-09-16T20:33:35', User OID: 'PatientReportedOutcome (US3512248)', ODM File OID: '0c2304a6-0dae-41b5-84b5-886b52df47e0'	System	17 Sep 2020 00:34:02
User entered 'No interference with activity (1)'	System	17 Sep 2020 00:34:02

**US3512248**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(7)**

**Generated On: 10 Jun 2021 07:56:44**

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:52:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FCE43EC3-F1E0-47A1-B438-4D694934F821)', Time: '2020-09-16T20:33:40', User OID: 'PatientReportedOutcome (US3512248)', ODM File OID: '0c2304a6-0dae-41b5-84b5-886b52df47e0' User entered 'None (0)'	System	17 Sep 2020 00:34:02
	System	17 Sep 2020 00:34:02

**US3512248**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(7)**

**Generated On: 10 Jun 2021 07:56:44**

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:52:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FCE43EC3-F1E0-47A1-B438-4D694934F821)', Time: '2020-09-16T20:33:44', User OID: 'PatientReportedOutcome (US3512248)', ODM File OID: '0c2304a6-0dae-41b5-84b5-886b52df47e0' User entered 'None (0)'	System	17 Sep 2020 00:34:02
	System	17 Sep 2020 00:34:02

US3512248

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 10 Jun 2021 07:56:44

Did you receive any **MEDICAL ATTENTION** (doctor visit, other) for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:52:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FCE43EC3-F1E0-47A1-B438-4D694934F821)', Time: '2020-09-16T20:33:49', User OID: 'PatientReportedOutcome (US3512248)', ODM File OID: '0c2304a6-0dae-41b5-84b5-886b52df47e0' User entered 'No (N)'	System	17 Sep 2020 00:34:02
	System	17 Sep 2020 00:34:02

**US3512248**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(7)**

**Generated On: 10 Jun 2021 07:56:44**

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:52:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FCE43EC3-F1E0-47A1-B438-4D694934F821)', Time: '2020-09-16T20:33:53', User OID: 'PatientReportedOutcome (US3512248)', ODM File OID: '0c2304a6-0dae-41b5-84b5-886b52df47e0' User entered '16 Sep 2020 20:33'	System	17 Sep 2020 00:34:02
	System	17 Sep 2020 00:34:02



**US3512248**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(7)**

**Generated On: 10 Jun 2021 07:56:44**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:52:02
User entered '16 Sep 2020 12:00'	System	10 Sep 2020 17:24:28

**US3512248**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(7)**

**Generated On: 10 Jun 2021 07:56:44**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:52:02
User entered '17 Sep 2020 11:59'	System	10 Sep 2020 17:24:28

US3512248

Folder: Diary Dose 1 (1)

Form: JointsAche\_Day(8)

Generated On: 10 Jun 2021 07:56:44

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:52:02
Data entry locked.	System	16 Sep 2020 01:29:08
User entered 'Day 8'	System	16 Sep 2020 01:29:08

US3512248

Folder: Diary Dose 1 (1)

Form: JointsAche\_Day(8)

Generated On: 10 Jun 2021 07:56:44

Select one response below to indicate the intensity of your **JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:52:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FCE43EC3-F1E0-47A1-B438-4D694934F821)', Time: '2020-09-17T20:53:02', User OID: 'PatientReportedOutcome (US3512248)', ODM File OID: 'a1ed0c35-7ae0-4c80-a2e8-ae3215117b57'	System	18 Sep 2020 00:53:19
User entered 'No interference with activity (1)'	System	18 Sep 2020 00:53:19

**US3512248**

**Folder: Diary Dose 1 (1)**

**Form: JointsAche\_Day(8)**

**Generated On: 10 Jun 2021 07:56:44**

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:52:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FCE43EC3-F1E0-47A1-B438-4D694934F821)', Time: '2020-09-17T20:53:13', User OID: 'PatientReportedOutcome (US3512248)', ODM File OID: 'a1ed0c35-7ae0-4c80-a2e8-ae3215117b57'	System	18 Sep 2020 00:53:19
User entered '17 Sep 2020 20:53'	System	18 Sep 2020 00:53:19

**US3512248**

**Folder: Diary Dose 1 (1)**

**Form: JointsAche\_Day(8)**

**Generated On: 10 Jun 2021 07:56:44**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:52:02
User entered '17 Sep 2020 12:00'	System	16 Sep 2020 01:29:08

**US3512248**

**Folder: Diary Dose 1 (1)**

**Form: JointsAche\_Day(8)**

**Generated On: 10 Jun 2021 07:56:44**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:52:02
User entered '18 Sep 2020 11:59'	System	16 Sep 2020 01:29:08

**US3512248**

**Folder: Diary Dose 1 (1)**

**Form: JointsAche\_Day(9)**

**Generated On: 10 Jun 2021 07:56:44**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:52:02
Data entry locked.	System	17 Sep 2020 00:34:02
User entered 'Day 9'	System	17 Sep 2020 00:34:02



US3512248

Folder: Diary Dose 1 (1)

Form: JointsAche\_Day(9)

Generated On: 10 Jun 2021 07:56:44

Select one response below to indicate the intensity of your **JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:52:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FCE43EC3-F1E0-47A1-B438-4D694934F821)', Time: '2020-09-18T21:43:13', User OID: 'PatientReportedOutcome (US3512248)', ODM File OID: 'd544a04b-2ecf-4c25-8583-bf84eeb4ec5c' User entered 'None (0)'	System	19 Sep 2020 01:43:24
	System	19 Sep 2020 01:43:24

**US3512248**

**Folder: Diary Dose 1 (1)**

**Form: JointsAche\_Day(9)**

**Generated On: 10 Jun 2021 07:56:44**

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:52:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FCE43EC3-F1E0-47A1-B438-4D694934F821)', Time: '2020-09-18T21:43:22', User OID: 'PatientReportedOutcome (US3512248)', ODM File OID: 'd544a04b-2ecf-4c25-8583-bf84eeb4ec5c' User entered '18 Sep 2020 21:43'	System	19 Sep 2020 01:43:24
	System	19 Sep 2020 01:43:24

**US3512248**

**Folder: Diary Dose 1 (1)**

**Form: JointsAche\_Day(9)**

**Generated On: 10 Jun 2021 07:56:44**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:52:02
User entered '18 Sep 2020 12:00'	System	17 Sep 2020 00:34:02

**US3512248**

**Folder: Diary Dose 1 (1)**

**Form: JointsAche\_Day(9)**

**Generated On: 10 Jun 2021 07:56:44**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:52:02
User entered '19 Sep 2020 11:59'	System	17 Sep 2020 00:34:02

US3512248

Folder: Diary Dose 1 (1)

Form: Medical Attention\_Day(8)

Generated On: 10 Jun 2021 07:56:44

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:52:02
Data entry locked.	System	16 Sep 2020 01:27:56
User entered 'Day 8'	System	16 Sep 2020 01:27:56

US3512248

Folder: Diary Dose 1 (1)

Form: Medical Attention\_Day(8)

Generated On: 10 Jun 2021 07:56:44

Did you receive any **MEDICAL ATTENTION** (doctor visit, other) for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:52:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FCE43EC3-F1E0-47A1-B438-4D694934F821)', Time: '2020-09-17T20:53:21', User OID: 'PatientReportedOutcome (US3512248)', ODM File OID: '47a23491-2e2c-403e-8aff-2ba83d7c4346' User entered 'No (N)'	System	18 Sep 2020 00:53:27
	System	18 Sep 2020 00:53:27

**US3512248**

**Folder: Diary Dose 1 (1)**

**Form: Medical Attention\_Day(8)**

**Generated On: 10 Jun 2021 07:56:44**

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:52:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FCE43EC3-F1E0-47A1-B438-4D694934F821)', Time: '2020-09-17T20:53:24', User OID: 'PatientReportedOutcome (US3512248)', ODM File OID: '47a23491-2e2c-403e-8aff-2ba83d7c4346' User entered '17 Sep 2020 20:53'	System	18 Sep 2020 00:53:27
	System	18 Sep 2020 00:53:27

US3512248

Folder: Diary Dose 1 (1)

Form: Medical Attention\_Day(8)

Generated On: 10 Jun 2021 07:56:44

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:52:02
User entered '17 Sep 2020 12:00'	System	16 Sep 2020 01:27:56



**US3512248**

**Folder: Diary Dose 1 (1)**

**Form: Medical Attention\_Day(8)**

**Generated On: 10 Jun 2021 07:56:44**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:52:02
User entered '18 Sep 2020 11:59'	System	16 Sep 2020 01:27:56

**US3512248**

**Folder: Diary Dose 1 (1)**

**Form: Medical Attention\_Day(9)**

**Generated On: 10 Jun 2021 07:56:44**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:52:02
Data entry locked.	System	17 Sep 2020 00:34:02
User entered 'Day 9'	System	17 Sep 2020 00:34:02

US3512248

Folder: Diary Dose 1 (1)

Form: Medical Attention\_Day(9)

Generated On: 10 Jun 2021 07:56:44

Did you receive any **MEDICAL ATTENTION** (doctor visit, other) for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:52:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FCE43EC3-F1E0-47A1-B438-4D694934F821)', Time: '2020-09-18T21:43:28', User OID: 'PatientReportedOutcome (US3512248)', ODM File OID: '5987679b-9dd0-4056-848c-b8988c7597bd' User entered 'No (N)'	System	19 Sep 2020 01:43:35
	System	19 Sep 2020 01:43:35

**US3512248**

**Folder: Diary Dose 1 (1)**

**Form: Medical Attention\_Day(9)**

**Generated On: 10 Jun 2021 07:56:44**

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:52:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FCE43EC3-F1E0-47A1-B438-4D694934F821)', Time: '2020-09-18T21:43:31', User OID: 'PatientReportedOutcome (US3512248)', ODM File OID: '5987679b-9dd0-4056-848c-b8988c7597bd' User entered '18 Sep 2020 21:43'	System	19 Sep 2020 01:43:35
	System	19 Sep 2020 01:43:35

**US3512248**

**Folder: Diary Dose 1 (1)**

**Form: Medical Attention\_Day(9)**

**Generated On: 10 Jun 2021 07:56:44**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:52:02
User entered '18 Sep 2020 12:00'	System	17 Sep 2020 00:34:02

**US3512248**

**Folder: Diary Dose 1 (1)**

**Form: Medical Attention\_Day(9)**

**Generated On: 10 Jun 2021 07:56:44**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:52:02
User entered '19 Sep 2020 11:59'	System	17 Sep 2020 00:34:02

**US3512248**

**Folder: Safety Call Day 8 (1)**

**Form: Safety Call**

**Generated On: 10 Jun 2021 07:56:44**

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:23:03
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 22:12:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Oct 2020 13:47:01
User entered 'Yes (Y)'	Taylor Johnson (b) (4) (b) (4)	18 Sep 2020 17:25:12

US3512248

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 10 Jun 2021 07:56:44

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:23:03
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 22:12:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Oct 2020 18:33:55
User closed query 'PER SOURCE CONTACT WAS MADE ON 17SEP2020. PLEASE REVIEW AND UPDATE ACCORDINGLY ' (Site from CRA).	(b) (4), (b) (6)	16 Oct 2020 18:33:51
Query 'PER SOURCE CONTACT WAS MADE ON 17SEP2020. PLEASE REVIEW AND UPDATE ACCORDINGLY ' answered with 'UPDATED' (Site from CRA).	Allison Crain (b) (4) (b) (4)	15 Oct 2020 18:50:46
User entered '17 Sep 2020' reason for change: Data Entry Error	Allison Crain (b) (4) (b) (4)	15 Oct 2020 18:50:40
User opened query 'PER SOURCE CONTACT WAS MADE ON 17SEP2020. PLEASE REVIEW AND UPDATE ACCORDINGLY ' (Site from CRA).	(b) (4), (b) (6)	07 Oct 2020 13:47:51
DataPoint Un-verified.	(b) (4), (b) (6)	07 Oct 2020 13:47:20
DataPoint Verified.	(b) (4), (b) (6)	07 Oct 2020 13:47:01
User entered '18 Sep 2020'	Taylor Johnson (b) (4) (b) (4)	18 Sep 2020 17:25:12



**US3512248**

**Folder: Safety Call Day 8 (1)**

**Form: Safety Call**

**Generated On: 10 Jun 2021 07:56:44**

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:23:03
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 22:12:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Oct 2020 13:47:01
User entered 'Contact Made (CONTACT MADE)'	Taylor Johnson (b) (4) (b) (4)	18 Sep 2020 17:25:12

US3512248

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 10 Jun 2021 07:56:44

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:23:03
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 22:12:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Oct 2020 13:47:01
User entered empty.	Taylor Johnson (b) (4) (b) (4)	18 Sep 2020 17:25:12

US3512248

Folder: Safety Call Day 8 (1)

Form: Continuing

Generated On: 10 Jun 2021 07:56:44

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:23:03
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 19:44:10
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 22:12:02
User entered 'Yes (Y)'	(b) (4) Taylor Johnson (b) (4) (b) (4)	18 Sep 2020 17:25:18

**US3512248**

**Folder: Safety Call Day 8 (1)**

**Form: Continuing**

**Generated On: 10 Jun 2021 07:56:44**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:23:03
User entered 'I'	System	18 Sep 2020 17:25:18

**US3512248**

**Folder: Safety Call Day 15 (1)**

**Form: Safety Call**

**Generated On: 10 Jun 2021 07:56:44**

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:23:03
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 22:12:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Oct 2020 13:46:51
User entered 'Yes (Y)'	Taylor Johnson (b) (4) (b) (4)	24 Sep 2020 21:06:50

**US3512248**

**Folder: Safety Call Day 15 (1)**

**Form: Safety Call**

**Generated On: 10 Jun 2021 07:56:44**

**Date of Contact or Contact Attempt (dd MMM yyyy)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:23:03
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 22:12:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Oct 2020 13:46:51
User entered '24 Sep 2020'	Taylor Johnson (b) (4) (b) (4)	24 Sep 2020 21:06:50

**US3512248**

**Folder: Safety Call Day 15 (1)**

**Form: Safety Call**

**Generated On: 10 Jun 2021 07:56:44**

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:23:03
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 22:12:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Oct 2020 13:46:51
User entered 'Contact Made (CONTACT MADE)'	Taylor Johnson (b) (4) (b) (4)	24 Sep 2020 21:06:50

US3512248

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 10 Jun 2021 07:56:44

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:23:03
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 22:12:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Oct 2020 13:46:51
User entered empty.	Taylor Johnson (b) (4) (b) (4)	24 Sep 2020 21:06:50



US3512248

Folder: Safety Call Day 15 (1)

Form: Continuing

Generated On: 10 Jun 2021 07:56:44

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:23:03
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 22:12:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Oct 2020 13:46:26
User entered 'Yes (Y)'	Taylor Johnson (b) (4) (b) (4)	24 Sep 2020 21:06:55

**US3512248**

**Folder: Safety Call Day 15 (1)**

**Form: Continuing**

**Generated On: 10 Jun 2021 07:56:44**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:23:03
User entered 'I'	System	24 Sep 2020 21:06:55

**US3512248**

**Folder: Safety Call Day 22 (1)**

**Form: Safety Call**

**Generated On: 10 Jun 2021 07:56:44**

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:23:03
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 22:12:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Nov 2020 17:14:57
User entered 'Yes (Y)'	(b) (4), (b) (6)	01 Oct 2020 16:45:46

**US3512248**

**Folder: Safety Call Day 22 (1)**

**Form: Safety Call**

**Generated On: 10 Jun 2021 07:56:44**

**Date of Contact or Contact Attempt (dd MMM yyyy)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:23:03
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 22:12:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Nov 2020 17:14:57
User entered '01 Oct 2020'	(b) (4), (b) (6)	01 Oct 2020 16:45:46

**US3512248**

**Folder: Safety Call Day 22 (1)**

**Form: Safety Call**

**Generated On: 10 Jun 2021 07:56:44**

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:23:03
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 22:12:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Nov 2020 17:14:57
User entered 'Contact Made (CONTACT MADE)'	(b) (4), (b) (6)	01 Oct 2020 16:45:46

US3512248

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 10 Jun 2021 07:56:44

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:23:03
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 22:12:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Nov 2020 17:14:57
User entered empty.	(b) (4), (b) (6)	01 Oct 2020 16:45:46

**US3512248**

**Folder: Safety Call Day 22 (1)**

**Form: Continuing**

**Generated On: 10 Jun 2021 07:56:44**

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:23:03
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 22:12:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Nov 2020 17:15:02
User entered 'Yes (Y)'	(b) (4), (b) (6)	01 Oct 2020 16:45:52

**US3512248**

**Folder: Safety Call Day 22 (1)**

**Form: Continuing**

**Generated On: 10 Jun 2021 07:56:44**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:23:03
User entered 'I'	System	01 Oct 2020 16:45:52



**US3512248**

**Folder: Visit 2 Day 29 (1)**

**Form: Visit Date**

**Generated On: 10 Jun 2021 07:56:44**

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:23:03
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 22:12:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Nov 2020 17:16:30
User entered 'Yes (Y)'	Allison Crain (b) (4) (b) (4)	08 Oct 2020 15:54:47

**US3512248**

**Folder: Visit 2 Day 29 (1)**

**Form: Visit Date**

**Generated On: 10 Jun 2021 07:56:44**

[Visit date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:23:03
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 22:12:02
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	16 Nov 2020 17:16:30
User entered '8 Oct 2020'	Allison Crain (b) (4)	08 Oct 2020 15:54:47
	(b) (4)	

US3512248

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 10 Jun 2021 07:56:44

[Was visit performed at the participant's home or at the clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:23:03
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 22:12:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Nov 2020 17:16:30
User entered 'Clinic (Clinic)'	Allison Crain (b) (4) (b) (4)	08 Oct 2020 15:54:47

**US3512248**

**Folder: Visit 2 Day 29 (1)**

**Form: Visit Date**

**Generated On: 10 Jun 2021 07:56:44**

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:23:03
User entered 'VISIT2'	System	08 Oct 2020 15:54:47

US3512248

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 07:56:44

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:23:03
User accepted default value 'Pre-Dose (PREDOSE)'	Allison Crain (b) (4) (b) (4)	08 Oct 2020 15:57:10

US3512248

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 07:56:44

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:23:03
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 22:12:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Nov 2020 17:18:45
User entered 'Yes (Y)'	Allison Crain (b) (4) (b) (4)	08 Oct 2020 15:57:10

US3512248

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 07:56:44

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:23:03
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 22:12:02
DataPoint Verified.	(b) (4)	(b) (4), (b) (6)
User entered '8 Oct 2020'	Allison Crain (b) (4)	08 Oct 2020 15:57:10
	(b) (4)	

**US3512248**

**Folder: Visit 2 Day 29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 10 Jun 2021 07:56:44**

**Time of assessment (00:00-23:59)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:23:03
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 22:12:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Nov 2020 17:18:45
User entered '11:09'	Allison Crain (b) (4) (b) (4)	08 Oct 2020 15:57:10



**US3512248**

**Folder: Visit 2 Day 29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 10 Jun 2021 07:56:44**

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:23:03
User entered '8 Oct 2020 11:09'	System	08 Oct 2020 15:57:10

US3512248

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 07:56:44

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:23:03
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 22:12:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Nov 2020 17:18:45
User entered '97.3' F	Allison Crain (b) (4) (b) (4)	08 Oct 2020 15:57:10

US3512248

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 07:56:44

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:23:03
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 22:12:02
DataPoint Verified.	(b) (4)	(b) (4), (b) (6)
	(b) (4), (b) (6)	16 Nov 2020 17:18:45
User entered 'Oral (Oral)'	Allison Crain (b) (4)	08 Oct 2020 15:57:10
	(b) (4)	

**US3512248**

**Folder: Visit 2 Day 29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 10 Jun 2021 07:56:44**

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:23:03
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 22:12:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Nov 2020 17:18:45
User entered empty.	Allison Crain (b) (4) (b) (4)	08 Oct 2020 15:57:10

**US3512248**

**Folder: Visit 2 Day 29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 10 Jun 2021 07:56:44**

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:23:03
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 22:12:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Nov 2020 17:18:45
User entered '64'	Allison Crain (b) (4) (b) (4)	08 Oct 2020 15:57:10

**US3512248**

**Folder: Visit 2 Day 29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 10 Jun 2021 07:56:44**

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:23:03
User entered 'bpm'	System	08 Oct 2020 15:57:10

US3512248

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 07:56:44

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:23:03
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 22:12:02
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	16 Nov 2020 17:18:45
User entered '20'	Allison Crain (b) (4)	08 Oct 2020 15:57:10
	(b) (4)	

US3512248

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 07:56:44

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:23:03
User entered 'breaths/min'	System	08 Oct 2020 15:57:10



US3512248

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 07:56:44

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:23:03
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 22:12:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Nov 2020 17:18:45
User entered '148'	Allison Crain (b) (4) (b) (4)	08 Oct 2020 15:57:10

US3512248

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 07:56:44

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:23:03
User entered 'mmHg'	System	08 Oct 2020 15:57:10

US3512248

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 07:56:44

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:23:03
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 22:12:02
DataPoint Verified.	(b) (4)	(b) (4), (b) (6)
User entered '77'	Allison Crain (b) (4)	08 Oct 2020 15:57:10
	(b) (4)	

US3512248

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 07:56:44

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:23:03
User entered 'mmHg'	System	08 Oct 2020 15:57:10

US3512248

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 07:56:44

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:23:03
User accepted default value 'Post-Dose (POSTDOSE)'	Brenda Anderson (b) (4) (b) (4)	08 Oct 2020 16:26:19

US3512248

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 07:56:44

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:23:03
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 22:12:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Nov 2020 17:18:45
User entered 'Yes (Y)'	Brenda Anderson (b) (4) (b) (4)	08 Oct 2020 16:26:19

US3512248

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 07:56:44

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:23:03
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 22:12:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Nov 2020 17:18:45
User entered '8 Oct 2020'	Brenda Anderson (b) (4) (b) (4)	08 Oct 2020 16:26:19

**US3512248**

**Folder: Visit 2 Day 29 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 10 Jun 2021 07:56:44**

**Time of assessment (00:00-23:59)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:23:03
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 22:12:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Nov 2020 17:18:45
User entered '12:20'	Brenda Anderson (b) (4) (b) (4)	08 Oct 2020 16:26:19



**US3512248**

**Folder: Visit 2 Day 29 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 10 Jun 2021 07:56:44**

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:23:03
User entered '8 Oct 2020 12:20'	System	08 Oct 2020 16:26:19

US3512248

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 07:56:44

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:23:03
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 22:12:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Nov 2020 17:18:45
User entered '97.8' F	Brenda Anderson (b) (4) (b) (4)	08 Oct 2020 16:26:19

US3512248

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 07:56:44

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:23:03
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 22:12:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Nov 2020 17:18:45
User entered 'Oral (Oral)'	Brenda Anderson (b) (4) (b) (4)	08 Oct 2020 16:26:19

**US3512248**

**Folder: Visit 2 Day 29 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 10 Jun 2021 07:56:44**

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:23:03
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 22:12:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Nov 2020 17:18:45
User entered empty.	Brenda Anderson (b) (4) (b) (4)	08 Oct 2020 16:26:19

US3512248

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 07:56:44

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:23:03
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 22:12:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Nov 2020 17:18:45
User entered '65'	Brenda Anderson (b) (4) (b) (4)	08 Oct 2020 16:26:19

**US3512248**

**Folder: Visit 2 Day 29 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 10 Jun 2021 07:56:44**

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:23:03
User entered 'bpm'	System	08 Oct 2020 16:26:19

US3512248

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 07:56:44

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:23:03
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 22:12:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Nov 2020 17:18:45
User entered '16'	Brenda Anderson (b) (4) (b) (4)	08 Oct 2020 16:26:19

US3512248

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 07:56:44

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:23:03
User entered 'breaths/min'	System	08 Oct 2020 16:26:19



US3512248

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 07:56:44

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:23:03
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 22:12:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Nov 2020 17:18:45
User entered '127'	Brenda Anderson (b) (4) (b) (4)	08 Oct 2020 16:26:19

US3512248

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 07:56:44

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:23:03
User entered 'mmHg'	System	08 Oct 2020 16:26:19

US3512248

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 07:56:44

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:23:03
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 22:12:02
DataPoint Verified.	(b) (4)	(b) (4), (b) (6)
User entered '70'	Brenda Anderson (b) (4)	08 Oct 2020 16:26:19
	(b) (4)	

US3512248

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 07:56:44

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:23:03
User entered 'mmHg'	System	08 Oct 2020 16:26:19

US3512248

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Generated On: 10 Jun 2021 07:56:44

Was the physical examination performed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:23:03
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 22:12:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Nov 2020 00:29:37
User closed query 'Per source a limited/partial PE was completed. Please review and update accordingly. ' (Site from CRA).	(b) (4), (b) (6)	23 Nov 2020 00:29:34
Query 'Per source a limited/partial PE was completed. Please review and update accordingly. ' answered with 'corrected' (Site from CRA).	Brenda Anderson (b) (4)	20 Nov 2020 20:38:08
User entered 'Yes (Y)' reason for change: Data Entry Error	(b) (4)	20 Nov 2020 20:37:48
User opened query 'Per source a limited/partial PE was completed. Please review and update accordingly. ' (Site from CRA).	(b) (4), (b) (6)	16 Nov 2020 17:19:34
User entered 'No (N)'	Allison Crain (b) (4)	08 Oct 2020 15:57:16

US3512248

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Generated On: 10 Jun 2021 07:56:44

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:23:03
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 22:12:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Nov 2020 00:29:37
User closed query 'The Physical Examination Date is not equal to Visit Date. Please review and reconcile.' (Site from System).	System	20 Nov 2020 20:37:58
User entered '08 Oct 2020' reason for change: Data Entry Error	Brenda Anderson (b) (4) (b) (4)	20 Nov 2020 20:37:58
User opened query 'The Physical Examination Date is not equal to Visit Date. Please review and reconcile.' (Site from System).	System	20 Nov 2020 20:37:48
User entered '08 Nov 2020' reason for change: Data Entry Error	Brenda Anderson (b) (4) (b) (4)	20 Nov 2020 20:37:48
User entered empty.	Allison Crain (b) (4) (b) (4)	08 Oct 2020 15:57:16

US3512248

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 07:56:44

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:23:03
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 22:12:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Nov 2020 17:19:50
User entered 'Yes (Y)'	Allison Crain (b) (4) (b) (4)	08 Oct 2020 16:13:55

US3512248

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 07:56:44

[If No, reason not given](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:23:03
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 22:12:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Nov 2020 17:19:50
User entered empty.	Allison Crain (b) (4) (b) (4)	08 Oct 2020 16:13:55



US3512248

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 07:56:44

If reason is Physician Decision, Withdrawal of Consent by Participant, Protocol Deviation, or Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:23:03
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 22:12:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Nov 2020 17:19:50
User entered empty.	Allison Crain (b) (4) (b) (4)	08 Oct 2020 16:13:55

US3512248

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 07:56:44

[What was the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:23:03
User entered 'MRNA-1273 OR PLACEBO'	System	08 Oct 2020 16:13:55

US3512248

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 07:56:44

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:23:03
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 22:12:02
DataPoint Verified.	(b) (4)	(b) (4), (b) (6)
User entered '8 Oct 2020'	Allison Crain (b) (4)	08 Oct 2020 16:13:55
	(b) (4)	

**US3512248**

**Folder: Visit 2 Day 29 (1)**

**Form: Exposure**

**Generated On: 10 Jun 2021 07:56:44**

[What was the treatment time? \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:23:03
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 22:12:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Nov 2020 17:19:50
User entered '11:49'	Allison Crain (b) (4) (b) (4)	08 Oct 2020 16:13:55

**US3512248**

**Folder: Visit 2 Day 29 (1)**

**Form: Exposure**

**Generated On: 10 Jun 2021 07:56:44**

[Treatment Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:23:03
User entered '8 Oct 2020 11:49'	System	08 Oct 2020 16:13:55

US3512248

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 07:56:44

[Which arm was used to give treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:23:03
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 22:12:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Nov 2020 17:19:50
User entered 'Left Arm (LEFT ARM)'	Allison Crain (b) (4) (b) (4)	08 Oct 2020 16:13:55

US3512248

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 07:56:44

[What was the frequency of the study treatment dosing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:23:03
DataPoint Verified.	(b) (4), (b) (6)	16 Nov 2020 17:19:50
User entered 'ONCE'	System	08 Oct 2020 16:13:55

US3512248

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 07:56:44

What was the route of administration for the study treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:23:03
User entered 'INTRAMUSCULAR'	System	08 Oct 2020 16:13:55



US3512248

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 07:56:44

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:23:03
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 22:12:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Nov 2020 17:20:24
User entered 'Yes (Y)'	Allison Crain (b) (4) (b) (4)	08 Oct 2020 15:57:28

US3512248

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 07:56:44

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:23:03
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 22:12:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Nov 2020 17:20:24
User closed query 'Data is required. Please provide.' (Site from System).	System	08 Oct 2020 15:57:32
User entered '8 Oct 2020' reason for change: Data Entry Error	Allison Crain (b) (4) (b) (4)	08 Oct 2020 15:57:32
User opened query 'Data is required. Please provide.' (Site from System).	System	08 Oct 2020 15:57:28
User entered empty.	Allison Crain (b) (4) (b) (4)	08 Oct 2020 15:57:28

US3512248

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 07:56:44

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:23:03
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 22:12:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Nov 2020 17:20:24
User closed query 'Data is required. Please provide.' (Site from System).	System	28 Oct 2020 12:07:54
User entered '11:25' reason for change: New Information	Brenda Anderson (b) (4) (b) (4)	28 Oct 2020 12:07:54
User opened query 'Data is required. Please provide.' (Site from System).	System	08 Oct 2020 15:57:28
User entered empty.	Allison Crain (b) (4) (b) (4)	08 Oct 2020 15:57:28

**US3512248**

**Folder: Visit 2 Day 29 (1)**

**Form: Immunogenicity Assessment**

**Generated On: 10 Jun 2021 07:56:44**

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:23:03
User entered '8 Oct 2020 11:25'	System	28 Oct 2020 12:07:54
User entered empty.	System	08 Oct 2020 15:57:28

US3512248

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 10 Jun 2021 07:56:44

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:23:03
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 22:12:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Nov 2020 17:20:31
User entered '8 Oct 2020'	Allison Crain (b) (4) (b) (4)	08 Oct 2020 15:57:47

**US3512248**

**Folder: Visit 2 Day 29 (1)**

**Form: Central Laboratory - Nasopharyngeal Swab (1)**

**Generated On: 10 Jun 2021 07:56:44**

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:23:03
User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)'	Allison Crain (b) (4) (b) (4)	08 Oct 2020 15:57:47

US3512248

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 10 Jun 2021 07:56:44

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:23:03
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 22:12:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Nov 2020 17:20:31
User entered 'Yes (Y)'	Allison Crain (b) (4) (b) (4)	08 Oct 2020 15:57:47

**US3512248**

**Folder: Visit 2 Day 29 (1)**

**Form: Central Laboratory - Nasopharyngeal Swab (1)**

**Generated On: 10 Jun 2021 07:56:44**

[Collection time \(00:00 - 23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:23:03
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 22:12:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Nov 2020 17:20:31
User entered '11:20'	Allison Crain (b) (4) (b) (4)	08 Oct 2020 15:57:47



**US3512248**

**Folder: Visit 2 Day 29 (1)**

**Form: Central Laboratory - Nasopharyngeal Swab (1)**

**Generated On: 10 Jun 2021 07:56:44**

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:23:03
User entered '8 Oct 2020 11:20'	System	08 Oct 2020 15:57:47

**US3512248**

**Folder: Visit 2 Day 29 (1)**

**Form: Central Laboratory - Nasopharyngeal Swab (2)**

**Generated On: 10 Jun 2021 07:56:44**

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:23:03
User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)'	Allison Crain (b) (4) (b) (4)	08 Oct 2020 15:57:47

**US3512248**

**Folder: Visit 2 Day 29 (1)**

**Form: Central Laboratory - Nasopharyngeal Swab (2)**

**Generated On: 10 Jun 2021 07:56:44**

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:23:03
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 22:12:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Nov 2020 17:20:31
User entered 'No (N)'	Allison Crain (b) (4) (b) (4)	08 Oct 2020 15:57:47

**US3512248**

**Folder: Visit 2 Day 29 (1)**

**Form: Central Laboratory - Nasopharyngeal Swab (2)**

**Generated On: 10 Jun 2021 07:56:44**

**Collection time (00:00 - 23:59)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:23:03
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 22:12:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Nov 2020 17:20:31
User entered empty.	Allison Crain (b) (4) (b) (4)	08 Oct 2020 15:57:47

**US3512248**

**Folder: Visit 2 Day 29 (1)**

**Form: Central Laboratory - Nasopharyngeal Swab (2)**

**Generated On: 10 Jun 2021 07:56:44**

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:23:03
User entered empty.	System	08 Oct 2020 15:57:47

US3512248

Folder: Visit 2 Day 29 (1)

Form: Continuing

Generated On: 10 Jun 2021 07:56:44

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:23:03
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 22:12:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Nov 2020 17:20:44
User entered 'Yes (Y)'	Allison Crain (b) (4) (b) (4)	08 Oct 2020 15:57:55

**US3512248**

**Folder: Visit 2 Day 29 (1)**

**Form: Continuing**

**Generated On: 10 Jun 2021 07:56:44**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:23:03
User entered 'I'	System	08 Oct 2020 15:57:55

US3512248

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/1)

Generated On: 10 Jun 2021 07:56:44

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:52:02
Data entry locked.	System	08 Oct 2020 16:13:55
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	08 Oct 2020 16:13:55



US3512248

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/1)

Generated On: 10 Jun 2021 07:56:44

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:52:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FCE43EC3-F1E0-47A1-B438-4D694934F821)', Time: '2020-10-08T12:24:41', User OID: 'PatientReportedOutcome (US3512248)', ODM File OID: 'f53bdc89-7ba1-4557-90e2-b6376f6c4f77' User entered 'Yes (Y)'	System	08 Oct 2020 16:25:12
	System	08 Oct 2020 16:25:12

US3512248

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/1)

Generated On: 10 Jun 2021 07:56:44

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:52:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FCE43EC3-F1E0-47A1-B438-4D694934F821)', Time: '2020-10-08T12:24:50', User OID: 'PatientReportedOutcome (US3512248)', ODM File OID: 'f53bdc89-7ba1-4557-90e2-b6376f6c4f77' User entered '97.8'	System	08 Oct 2020 16:25:12
	System	08 Oct 2020 16:25:12

US3512248

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/1)

Generated On: 10 Jun 2021 07:56:44

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:52:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FCE43EC3-F1E0-47A1-B438-4D694934F821)', Time: '2020-10-08T12:24:55', User OID: 'PatientReportedOutcome (US3512248)', ODM File OID: 'f53bdc89-7ba1-4557-90e2-b6376f6c4f77'	System	08 Oct 2020 16:25:12
User entered 'No (N)'	System	08 Oct 2020 16:25:12

**US3512248**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(1/1)**

**Generated On: 10 Jun 2021 07:56:44**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:52:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FCE43EC3-F1E0-47A1-B438-4D694934F821)', Time: '2020-10-08T12:25:04', User OID: 'PatientReportedOutcome (US3512248)', ODM File OID: 'f53bdc89-7ba1-4557-90e2-b6376f6c4f77' User entered '08 Oct 2020 12:25'	System	08 Oct 2020 16:25:12
	System	08 Oct 2020 16:25:12

US3512248

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/1)

Generated On: 10 Jun 2021 07:56:44

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:52:02
User entered '08 Oct 2020 12:09'	System	08 Oct 2020 16:13:55

US3512248

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/1)

Generated On: 10 Jun 2021 07:56:44

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:52:02
User entered '08 Oct 2020 14:39'	System	08 Oct 2020 16:13:55

US3512248

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/2)

Generated On: 10 Jun 2021 07:56:44

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:52:02
Data entry locked.	System	08 Oct 2020 16:13:55
User entered 'Day 1, after vaccination (at home)'	System	08 Oct 2020 16:13:55

US3512248

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/2)

Generated On: 10 Jun 2021 07:56:44

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:52:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FCE43EC3-F1E0-47A1-B438-4D694934F821)', Time: '2020-10-08T15:38:04', User OID: 'PatientReportedOutcome (US3512248)', ODM File OID: '745cb346-68ed-4fdc-bd8c-9623813e3f77' User entered 'Yes (Y)'	System	08 Oct 2020 19:38:24
	System	08 Oct 2020 19:38:24



US3512248

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/2)

Generated On: 10 Jun 2021 07:56:44

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:52:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FCE43EC3-F1E0-47A1-B438-4D694934F821)', Time: '2020-10-08T15:38:12', User OID: 'PatientReportedOutcome (US3512248)', ODM File OID: '745cb346-68ed-4fdc-bd8c-9623813e3f77' User entered '97.9'	System	08 Oct 2020 19:38:24
	System	08 Oct 2020 19:38:24

US3512248

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/2)

Generated On: 10 Jun 2021 07:56:44

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:52:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FCE43EC3-F1E0-47A1-B438-4D694934F821)', Time: '2020-10-08T15:38:16', User OID: 'PatientReportedOutcome (US3512248)', ODM File OID: '745cb346-68ed-4fdc-bd8c-9623813e3f77'	System	08 Oct 2020 19:38:24
User entered 'No (N)'	System	08 Oct 2020 19:38:24

**US3512248**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(1/2)**

**Generated On: 10 Jun 2021 07:56:44**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:52:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FCE43EC3-F1E0-47A1-B438-4D694934F821)', Time: '2020-10-08T15:38:20', User OID: 'PatientReportedOutcome (US3512248)', ODM File OID: '745cb346-68ed-4fdc-bd8c-9623813e3f77' User entered '08 Oct 2020 15:38'	System	08 Oct 2020 19:38:24
	System	08 Oct 2020 19:38:24

US3512248

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/2)

Generated On: 10 Jun 2021 07:56:44

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:52:02
User entered '08 Oct 2020 15:34'	System	08 Oct 2020 16:13:55

US3512248

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/2)

Generated On: 10 Jun 2021 07:56:44

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:52:02
User entered '09 Oct 2020 11:59'	System	08 Oct 2020 16:13:55

US3512248

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(2)

Generated On: 10 Jun 2021 07:56:44

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:52:02
Data entry locked.	System	08 Oct 2020 16:13:55
User entered 'Day 2'	System	08 Oct 2020 16:13:55

US3512248

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(2)

Generated On: 10 Jun 2021 07:56:44

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:52:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FCE43EC3-F1E0-47A1-B438-4D694934F821)', Time: '2020-10-09T22:00:33', User OID: 'PatientReportedOutcome (US3512248)', ODM File OID: '754947c4-945a-4ced-af9a-6af7ba22bc40' User entered 'Yes (Y)'	System	10 Oct 2020 02:00:52
	System	10 Oct 2020 02:00:52

US3512248

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(2)

Generated On: 10 Jun 2021 07:56:44

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:52:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FCE43EC3-F1E0-47A1-B438-4D694934F821)', Time: '2020-10-09T22:00:41', User OID: 'PatientReportedOutcome (US3512248)', ODM File OID: '754947c4-945a-4ced-af9a-6af7ba22bc40' User entered '97.0'	System	10 Oct 2020 02:00:52
	System	10 Oct 2020 02:00:52



US3512248

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(2)

Generated On: 10 Jun 2021 07:56:44

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:52:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FCE43EC3-F1E0-47A1-B438-4D694934F821)', Time: '2020-10-09T22:00:44', User OID: 'PatientReportedOutcome (US3512248)', ODM File OID: '754947c4-945a-4ced-af9a-6af7ba22bc40' User entered 'No (N)'	System	10 Oct 2020 02:00:52
	System	10 Oct 2020 02:00:52

**US3512248**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(2)**

**Generated On: 10 Jun 2021 07:56:44**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:52:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FCE43EC3-F1E0-47A1-B438-4D694934F821)', Time: '2020-10-09T22:00:48', User OID: 'PatientReportedOutcome (US3512248)', ODM File OID: '754947c4-945a-4ced-af9a-6af7ba22bc40' User entered '09 Oct 2020 22:00'	System	10 Oct 2020 02:00:52
	System	10 Oct 2020 02:00:52

US3512248

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(2)

Generated On: 10 Jun 2021 07:56:44

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:52:02
User entered '09 Oct 2020 12:00'	System	08 Oct 2020 16:13:55

US3512248

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(2)

Generated On: 10 Jun 2021 07:56:44

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:52:02
User entered '10 Oct 2020 11:59'	System	08 Oct 2020 16:13:55

US3512248

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(3)

Generated On: 10 Jun 2021 07:56:44

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:52:02
Data entry locked.	System	08 Oct 2020 16:13:55
User entered 'Day 3'	System	08 Oct 2020 16:13:55

US3512248

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(3)

Generated On: 10 Jun 2021 07:56:44

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:52:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FCE43EC3-F1E0-47A1-B438-4D694934F821)', Time: '2020-10-10T20:48:00', User OID: 'PatientReportedOutcome (US3512248)', ODM File OID: '8c48cb4f-bc85-4de7-b4ff-eb33ee1471b6' User entered 'Yes (Y)'	System	11 Oct 2020 00:48:20
	System	11 Oct 2020 00:48:20

US3512248

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(3)

Generated On: 10 Jun 2021 07:56:44

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:52:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FCE43EC3-F1E0-47A1-B438-4D694934F821)', Time: '2020-10-10T20:48:06', User OID: 'PatientReportedOutcome (US3512248)', ODM File OID: '8c48cb4f-bc85-4de7-b4ff-eb33ee1471b6' User entered '97.9'	System	11 Oct 2020 00:48:20
	System	11 Oct 2020 00:48:20

US3512248

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(3)

Generated On: 10 Jun 2021 07:56:44

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:52:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FCE43EC3-F1E0-47A1-B438-4D694934F821)', Time: '2020-10-10T20:48:10', User OID: 'PatientReportedOutcome (US3512248)', ODM File OID: '8c48cb4f-bc85-4de7-b4ff-eb33ee1471b6'	System	11 Oct 2020 00:48:20
User entered 'No (N)'	System	11 Oct 2020 00:48:20



**US3512248**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(3)**

**Generated On: 10 Jun 2021 07:56:44**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:52:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FCE43EC3-F1E0-47A1-B438-4D694934F821)', Time: '2020-10-10T20:48:16', User OID: 'PatientReportedOutcome (US3512248)', ODM File OID: '8c48cb4f-bc85-4de7-b4ff-eb33ee1471b6' User entered '10 Oct 2020 20:48'	System	11 Oct 2020 00:48:20
	System	11 Oct 2020 00:48:20

**US3512248**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(3)**

**Generated On: 10 Jun 2021 07:56:44**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:52:02
User entered '10 Oct 2020 12:00'	System	08 Oct 2020 16:13:55

US3512248

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(3)

Generated On: 10 Jun 2021 07:56:44

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:52:02
User entered '11 Oct 2020 11:59'	System	08 Oct 2020 16:13:55

US3512248

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(4)

Generated On: 10 Jun 2021 07:56:44

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:52:02
Data entry locked.	System	08 Oct 2020 16:13:55
User entered 'Day 4'	System	08 Oct 2020 16:13:55

US3512248

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(4)

Generated On: 10 Jun 2021 07:56:44

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:52:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FCE43EC3-F1E0-47A1-B438-4D694934F821)', Time: '2020-10-11T15:36:11', User OID: 'PatientReportedOutcome (US3512248)', ODM File OID: 'e3589c87-5564-4ff6-a687-fba0ae64de16' User entered 'Yes (Y)'	System	11 Oct 2020 19:36:28
	System	11 Oct 2020 19:36:28

US3512248

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(4)

Generated On: 10 Jun 2021 07:56:44

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:52:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FCE43EC3-F1E0-47A1-B438-4D694934F821)', Time: '2020-10-11T15:36:17', User OID: 'PatientReportedOutcome (US3512248)', ODM File OID: 'e3589c87-5564-4ff6-a687-fba0ae64de16' User entered '97.9'	System	11 Oct 2020 19:36:28
	System	11 Oct 2020 19:36:28

US3512248

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(4)

Generated On: 10 Jun 2021 07:56:44

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:52:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FCE43EC3-F1E0-47A1-B438-4D694934F821)', Time: '2020-10-11T15:36:21', User OID: 'PatientReportedOutcome (US3512248)', ODM File OID: 'e3589c87-5564-4ff6-a687-fba0ae64de16' User entered 'No (N)'	System	11 Oct 2020 19:36:28
	System	11 Oct 2020 19:36:28

**US3512248**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(4)**

**Generated On: 10 Jun 2021 07:56:44**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:52:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FCE43EC3-F1E0-47A1-B438-4D694934F821)', Time: '2020-10-11T15:36:25', User OID: 'PatientReportedOutcome (US3512248)', ODM File OID: 'e3589c87-5564-4ff6-a687-fba0ae64de16' User entered '11 Oct 2020 15:36'	System	11 Oct 2020 19:36:28
	System	11 Oct 2020 19:36:28



US3512248

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(4)

Generated On: 10 Jun 2021 07:56:44

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:52:02
User entered '11 Oct 2020 12:00'	System	08 Oct 2020 16:13:55

**US3512248**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(4)**

**Generated On: 10 Jun 2021 07:56:44**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:52:02
User entered '12 Oct 2020 11:59'	System	08 Oct 2020 16:13:55

**US3512248**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(5)**

**Generated On: 10 Jun 2021 07:56:44**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:52:02
Data entry locked.	System	08 Oct 2020 16:13:55
User entered 'Day 5'	System	08 Oct 2020 16:13:55

US3512248

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(5)

Generated On: 10 Jun 2021 07:56:44

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:52:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FCE43EC3-F1E0-47A1-B438-4D694934F821)', Time: '2020-10-12T13:53:17', User OID: 'PatientReportedOutcome (US3512248)', ODM File OID: '074a922d-658d-4a09-a8de-61151ee54831' User entered 'Yes (Y)'	System	12 Oct 2020 17:53:35
	System	12 Oct 2020 17:53:35

US3512248

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(5)

Generated On: 10 Jun 2021 07:56:44

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:52:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FCE43EC3-F1E0-47A1-B438-4D694934F821)', Time: '2020-10-12T13:53:22', User OID: 'PatientReportedOutcome (US3512248)', ODM File OID: '074a922d-658d-4a09-a8de-61151ee54831' User entered '98.1'	System	12 Oct 2020 17:53:35
	System	12 Oct 2020 17:53:35

US3512248

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(5)

Generated On: 10 Jun 2021 07:56:44

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:52:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FCE43EC3-F1E0-47A1-B438-4D694934F821)', Time: '2020-10-12T13:53:27', User OID: 'PatientReportedOutcome (US3512248)', ODM File OID: '074a922d-658d-4a09-a8de-61151ee54831' User entered 'No (N)'	System	12 Oct 2020 17:53:35
	System	12 Oct 2020 17:53:35

**US3512248**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(5)**

**Generated On: 10 Jun 2021 07:56:44**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:52:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FCE43EC3-F1E0-47A1-B438-4D694934F821)', Time: '2020-10-12T13:53:33', User OID: 'PatientReportedOutcome (US3512248)', ODM File OID: '074a922d-658d-4a09-a8de-61151ee54831' User entered '12 Oct 2020 13:53'	System	12 Oct 2020 17:53:35
	System	12 Oct 2020 17:53:35

**US3512248**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(5)**

**Generated On: 10 Jun 2021 07:56:44**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:52:02
User entered '12 Oct 2020 12:00'	System	08 Oct 2020 16:13:55



**US3512248**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(5)**

**Generated On: 10 Jun 2021 07:56:44**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:52:02
User entered '13 Oct 2020 11:59'	System	08 Oct 2020 16:13:55

US3512248

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(6)

Generated On: 10 Jun 2021 07:56:44

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:52:02
Data entry locked.	System	08 Oct 2020 16:13:55
User entered 'Day 6'	System	08 Oct 2020 16:13:55

US3512248

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(6)

Generated On: 10 Jun 2021 07:56:44

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:52:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FCE43EC3-F1E0-47A1-B438-4D694934F821)', Time: '2020-10-13T14:52:19', User OID: 'PatientReportedOutcome (US3512248)', ODM File OID: '84e71195-7030-4f4e-b547-e52d37062661' User entered 'Yes (Y)'	System	13 Oct 2020 18:52:44
	System	13 Oct 2020 18:52:44

US3512248

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(6)

Generated On: 10 Jun 2021 07:56:44

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:52:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FCE43EC3-F1E0-47A1-B438-4D694934F821)', Time: '2020-10-13T14:52:30', User OID: 'PatientReportedOutcome (US3512248)', ODM File OID: '84e71195-7030-4f4e-b547-e52d37062661' User entered '97.6'	System	13 Oct 2020 18:52:44
	System	13 Oct 2020 18:52:44

US3512248

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(6)

Generated On: 10 Jun 2021 07:56:44

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:52:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FCE43EC3-F1E0-47A1-B438-4D694934F821)', Time: '2020-10-13T14:52:36', User OID: 'PatientReportedOutcome (US3512248)', ODM File OID: '84e71195-7030-4f4e-b547-e52d37062661' User entered 'No (N)'	System	13 Oct 2020 18:52:44
	System	13 Oct 2020 18:52:44

**US3512248**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(6)**

**Generated On: 10 Jun 2021 07:56:44**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:52:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FCE43EC3-F1E0-47A1-B438-4D694934F821)', Time: '2020-10-13T14:52:41', User OID: 'PatientReportedOutcome (US3512248)', ODM File OID: '84e71195-7030-4f4e-b547-e52d37062661' User entered '13 Oct 2020 14:52'	System	13 Oct 2020 18:52:44
	System	13 Oct 2020 18:52:44

**US3512248**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(6)**

**Generated On: 10 Jun 2021 07:56:44**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:52:02
User entered '13 Oct 2020 12:00'	System	08 Oct 2020 16:13:55

**US3512248**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(6)**

**Generated On: 10 Jun 2021 07:56:44**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:52:02
User entered '14 Oct 2020 11:59'	System	08 Oct 2020 16:13:55



US3512248

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(7)

Generated On: 10 Jun 2021 07:56:44

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:52:02
Data entry locked.	System	08 Oct 2020 16:13:55
User entered 'Day 7'	System	08 Oct 2020 16:13:55

US3512248

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(7)

Generated On: 10 Jun 2021 07:56:44

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:52:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FCE43EC3-F1E0-47A1-B438-4D694934F821)', Time: '2020-10-14T15:53:30', User OID: 'PatientReportedOutcome (US3512248)', ODM File OID: '20ffab5c-3336-4658-b864-535353ed44fb' User entered 'Yes (Y)'	System	14 Oct 2020 19:53:52
	System	14 Oct 2020 19:53:52

US3512248

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(7)

Generated On: 10 Jun 2021 07:56:44

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:52:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FCE43EC3-F1E0-47A1-B438-4D694934F821)', Time: '2020-10-14T15:53:37', User OID: 'PatientReportedOutcome (US3512248)', ODM File OID: '20ffab5c-3336-4658-b864-535353ed44fb' User entered '98.1'	System	14 Oct 2020 19:53:52
	System	14 Oct 2020 19:53:52

US3512248

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(7)

Generated On: 10 Jun 2021 07:56:44

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:52:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FCE43EC3-F1E0-47A1-B438-4D694934F821)', Time: '2020-10-14T15:53:41', User OID: 'PatientReportedOutcome (US3512248)', ODM File OID: '20ffab5c-3336-4658-b864-535353ed44fb' User entered 'No (N)'	System	14 Oct 2020 19:53:52
	System	14 Oct 2020 19:53:52

**US3512248**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(7)**

**Generated On: 10 Jun 2021 07:56:44**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:52:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FCE43EC3-F1E0-47A1-B438-4D694934F821)', Time: '2020-10-14T15:53:49', User OID: 'PatientReportedOutcome (US3512248)', ODM File OID: '20ffab5c-3336-4658-b864-535353ed44fb' User entered '14 Oct 2020 15:53'	System	14 Oct 2020 19:53:52
	System	14 Oct 2020 19:53:52

**US3512248**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(7)**

**Generated On: 10 Jun 2021 07:56:44**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:52:02
User entered '14 Oct 2020 12:00'	System	08 Oct 2020 16:13:55

US3512248

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(7)

Generated On: 10 Jun 2021 07:56:44

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:52:02
User entered '15 Oct 2020 11:59'	System	08 Oct 2020 16:13:55

US3512248

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/1)

Generated On: 10 Jun 2021 07:56:44

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:52:02
Data entry locked.	System	08 Oct 2020 16:13:55
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	08 Oct 2020 16:13:55



US3512248

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/1)

Generated On: 10 Jun 2021 07:56:44

Please record - **PAIN AT INJECTION SITE.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:52:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FCE43EC3-F1E0-47A1-B438-4D694934F821)', Time: '2020-10-08T12:25:15', User OID: 'PatientReportedOutcome (US3512248)', ODM File OID: 'cf31622b-a0f3-49fe-b795-49e94243b345'	System	08 Oct 2020 16:25:34
User entered 'None (1)'	System	08 Oct 2020 16:25:34

US3512248

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/1)

Generated On: 10 Jun 2021 07:56:44

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:52:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FCE43EC3-F1E0-47A1-B438-4D694934F821)', Time: '2020-10-08T12:25:19', User OID: 'PatientReportedOutcome (US3512248)', ODM File OID: 'cf31622b-a0f3-49fe-b795-49e94243b345' User entered 'No (N)'	System	08 Oct 2020 16:25:34
	System	08 Oct 2020 16:25:34

US3512248

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/1)

Generated On: 10 Jun 2021 07:56:44

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:52:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FCE43EC3-F1E0-47A1-B438-4D694934F821)', Time: '2020-10-08T12:25:22', User OID: 'PatientReportedOutcome (US3512248)', ODM File OID: 'cf31622b-a0f3-49fe-b795-49e94243b345' User entered 'No (N)'	System	08 Oct 2020 16:25:34
	System	08 Oct 2020 16:25:34

US3512248

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/1)

Generated On: 10 Jun 2021 07:56:44

Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:52:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FCE43EC3-F1E0-47A1-B438-4D694934F821)', Time: '2020-10-08T12:25:27', User OID: 'PatientReportedOutcome (US3512248)', ODM File OID: 'cf31622b-a0f3-49fe-b795-49e94243b345'	System	08 Oct 2020 16:25:34
User entered 'None (1)'	System	08 Oct 2020 16:25:34

**US3512248**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(1/1)**

**Generated On: 10 Jun 2021 07:56:44**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:52:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FCE43EC3-F1E0-47A1-B438-4D694934F821)', Time: '2020-10-08T12:25:31', User OID: 'PatientReportedOutcome (US3512248)', ODM File OID: 'cf31622b-a0f3-49fe-b795-49e94243b345' User entered '08 Oct 2020 12:25'	System	08 Oct 2020 16:25:34
	System	08 Oct 2020 16:25:34

US3512248

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/1)

Generated On: 10 Jun 2021 07:56:44

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:52:02
User entered '08 Oct 2020 12:09'	System	08 Oct 2020 16:13:55

**US3512248**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(1/1)**

**Generated On: 10 Jun 2021 07:56:44**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:52:02
User entered '08 Oct 2020 14:39'	System	08 Oct 2020 16:13:55

US3512248

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/2)

Generated On: 10 Jun 2021 07:56:44

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:52:02
Data entry locked.	System	08 Oct 2020 16:13:55
User entered 'Day 1, after vaccination (at home)'	System	08 Oct 2020 16:13:55



US3512248

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/2)

Generated On: 10 Jun 2021 07:56:44

Please record - **PAIN AT INJECTION SITE.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:52:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FCE43EC3-F1E0-47A1-B438-4D694934F821)', Time: '2020-10-08T15:37:09', User OID: 'PatientReportedOutcome (US3512248)', ODM File OID: '9f7a078b-7029-44bb-a0ea-966d6b5432c7' User entered 'None (1)'	System	08 Oct 2020 19:37:57
	System	08 Oct 2020 19:37:57

US3512248

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/2)

Generated On: 10 Jun 2021 07:56:44

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:52:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FCE43EC3-F1E0-47A1-B438-4D694934F821)', Time: '2020-10-08T15:37:13', User OID: 'PatientReportedOutcome (US3512248)', ODM File OID: '9f7a078b-7029-44bb-a0ea-966d6b5432c7' User entered 'No (N)'	System	08 Oct 2020 19:37:57
	System	08 Oct 2020 19:37:57

US3512248

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/2)

Generated On: 10 Jun 2021 07:56:44

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:52:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FCE43EC3-F1E0-47A1-B438-4D694934F821)', Time: '2020-10-08T15:37:18', User OID: 'PatientReportedOutcome (US3512248)', ODM File OID: '9f7a078b-7029-44bb-a0ea-966d6b5432c7' User entered 'No (N)'	System	08 Oct 2020 19:37:57
	System	08 Oct 2020 19:37:57

US3512248

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/2)

Generated On: 10 Jun 2021 07:56:44

Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:52:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FCE43EC3-F1E0-47A1-B438-4D694934F821)', Time: '2020-10-08T15:37:26', User OID: 'PatientReportedOutcome (US3512248)', ODM File OID: '9f7a078b-7029-44bb-a0ea-966d6b5432c7' User entered 'None (1)'	System	08 Oct 2020 19:37:57
	System	08 Oct 2020 19:37:57

**US3512248**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(1/2)**

**Generated On: 10 Jun 2021 07:56:44**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:52:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FCE43EC3-F1E0-47A1-B438-4D694934F821)', Time: '2020-10-08T15:37:54', User OID: 'PatientReportedOutcome (US3512248)', ODM File OID: '9f7a078b-7029-44bb-a0ea-966d6b5432c7' User entered '08 Oct 2020 15:37'	System	08 Oct 2020 19:37:57
	System	08 Oct 2020 19:37:57

US3512248

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/2)

Generated On: 10 Jun 2021 07:56:44

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:52:02
User entered '08 Oct 2020 15:34'	System	08 Oct 2020 16:13:55

US3512248

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/2)

Generated On: 10 Jun 2021 07:56:44

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:52:02
User entered '09 Oct 2020 11:59'	System	08 Oct 2020 16:13:55

US3512248

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(2)

Generated On: 10 Jun 2021 07:56:44

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:52:02
Data entry locked.	System	08 Oct 2020 16:13:55
User entered 'Day 2'	System	08 Oct 2020 16:13:55



US3512248

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(2)

Generated On: 10 Jun 2021 07:56:44

Please record - **PAIN AT INJECTION SITE.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:52:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FCE43EC3-F1E0-47A1-B438-4D694934F821)', Time: '2020-10-09T22:00:53', User OID: 'PatientReportedOutcome (US3512248)', ODM File OID: '91bb384f-b8d2-496d-b74f-626ed876482d' User entered 'None (1)'	System	10 Oct 2020 02:01:17
	System	10 Oct 2020 02:01:17

US3512248

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(2)

Generated On: 10 Jun 2021 07:56:44

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:52:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FCE43EC3-F1E0-47A1-B438-4D694934F821)', Time: '2020-10-09T22:00:59', User OID: 'PatientReportedOutcome (US3512248)', ODM File OID: '91bb384f-b8d2-496d-b74f-626ed876482d' User entered 'No (N)'	System	10 Oct 2020 02:01:17
	System	10 Oct 2020 02:01:17

US3512248

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(2)

Generated On: 10 Jun 2021 07:56:44

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:52:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FCE43EC3-F1E0-47A1-B438-4D694934F821)', Time: '2020-10-09T22:01:03', User OID: 'PatientReportedOutcome (US3512248)', ODM File OID: '91bb384f-b8d2-496d-b74f-626ed876482d' User entered 'No (N)'	System	10 Oct 2020 02:01:17
	System	10 Oct 2020 02:01:17

US3512248

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(2)

Generated On: 10 Jun 2021 07:56:44

Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:52:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FCE43EC3-F1E0-47A1-B438-4D694934F821)', Time: '2020-10-09T22:01:08', User OID: 'PatientReportedOutcome (US3512248)', ODM File OID: '91bb384f-b8d2-496d-b74f-626ed876482d' User entered 'None (1)'	System	10 Oct 2020 02:01:17
	System	10 Oct 2020 02:01:17

**US3512248**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(2)**

**Generated On: 10 Jun 2021 07:56:44**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:52:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FCE43EC3-F1E0-47A1-B438-4D694934F821)', Time: '2020-10-09T22:01:14', User OID: 'PatientReportedOutcome (US3512248)', ODM File OID: '91bb384f-b8d2-496d-b74f-626ed876482d' User entered '09 Oct 2020 22:01'	System	10 Oct 2020 02:01:17
	System	10 Oct 2020 02:01:17

US3512248

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(2)

Generated On: 10 Jun 2021 07:56:44

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:52:02
User entered '09 Oct 2020 12:00'	System	08 Oct 2020 16:13:55

**US3512248**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(2)**

**Generated On: 10 Jun 2021 07:56:44**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:52:02
User entered '10 Oct 2020 11:59'	System	08 Oct 2020 16:13:55

US3512248

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(3)

Generated On: 10 Jun 2021 07:56:44

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:52:02
Data entry locked.	System	08 Oct 2020 16:13:55
User entered 'Day 3'	System	08 Oct 2020 16:13:55



US3512248

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(3)

Generated On: 10 Jun 2021 07:56:44

Please record - **PAIN AT INJECTION SITE.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:52:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FCE43EC3-F1E0-47A1-B438-4D694934F821)', Time: '2020-10-10T20:48:23', User OID: 'PatientReportedOutcome (US3512248)', ODM File OID: 'f51daa68-5a32-419e-945e-3f7091477446'	System	11 Oct 2020 00:48:40
User entered 'None (1)'	System	11 Oct 2020 00:48:40

US3512248

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(3)

Generated On: 10 Jun 2021 07:56:44

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:52:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FCE43EC3-F1E0-47A1-B438-4D694934F821)', Time: '2020-10-10T20:48:27', User OID: 'PatientReportedOutcome (US3512248)', ODM File OID: 'f51daa68-5a32-419e-945e-3f7091477446' User entered 'No (N)'	System	11 Oct 2020 00:48:40
	System	11 Oct 2020 00:48:40

US3512248

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(3)

Generated On: 10 Jun 2021 07:56:44

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:52:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FCE43EC3-F1E0-47A1-B438-4D694934F821)', Time: '2020-10-10T20:48:30', User OID: 'PatientReportedOutcome (US3512248)', ODM File OID: 'f51daa68-5a32-419e-945e-3f7091477446' User entered 'No (N)'	System	11 Oct 2020 00:48:40
	System	11 Oct 2020 00:48:40

US3512248

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(3)

Generated On: 10 Jun 2021 07:56:44

Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:52:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FCE43EC3-F1E0-47A1-B438-4D694934F821)', Time: '2020-10-10T20:48:34', User OID: 'PatientReportedOutcome (US3512248)', ODM File OID: 'f51daa68-5a32-419e-945e-3f7091477446'	System	11 Oct 2020 00:48:40
User entered 'None (1)'	System	11 Oct 2020 00:48:40

**US3512248**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(3)**

**Generated On: 10 Jun 2021 07:56:44**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:52:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FCE43EC3-F1E0-47A1-B438-4D694934F821)', Time: '2020-10-10T20:48:37', User OID: 'PatientReportedOutcome (US3512248)', ODM File OID: 'f51daa68-5a32-419e-945e-3f7091477446' User entered '10 Oct 2020 20:48'	System	11 Oct 2020 00:48:40
	System	11 Oct 2020 00:48:40

**US3512248**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(3)**

**Generated On: 10 Jun 2021 07:56:44**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:52:02
User entered '10 Oct 2020 12:00'	System	08 Oct 2020 16:13:55

US3512248

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(3)

Generated On: 10 Jun 2021 07:56:44

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:52:02
User entered '11 Oct 2020 11:59'	System	08 Oct 2020 16:13:55

US3512248

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(4)

Generated On: 10 Jun 2021 07:56:44

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:52:02
Data entry locked.	System	08 Oct 2020 16:13:55
User entered 'Day 4'	System	08 Oct 2020 16:13:55



US3512248

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(4)

Generated On: 10 Jun 2021 07:56:44

Please record - **PAIN AT INJECTION SITE.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:52:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FCE43EC3-F1E0-47A1-B438-4D694934F821)', Time: '2020-10-11T15:36:32', User OID: 'PatientReportedOutcome (US3512248)', ODM File OID: 'b312abef-ab3c-457e-81f3-664cb013021a' User entered 'None (1)'	System	11 Oct 2020 19:36:54
	System	11 Oct 2020 19:36:54

US3512248

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(4)

Generated On: 10 Jun 2021 07:56:44

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:52:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FCE43EC3-F1E0-47A1-B438-4D694934F821)', Time: '2020-10-11T15:36:36', User OID: 'PatientReportedOutcome (US3512248)', ODM File OID: 'b312abef-ab3c-457e-81f3-664cb013021a' User entered 'No (N)'	System	11 Oct 2020 19:36:54
	System	11 Oct 2020 19:36:54

US3512248

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(4)

Generated On: 10 Jun 2021 07:56:44

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:52:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FCE43EC3-F1E0-47A1-B438-4D694934F821)', Time: '2020-10-11T15:36:39', User OID: 'PatientReportedOutcome (US3512248)', ODM File OID: 'b312abef-ab3c-457e-81f3-664cb013021a' User entered 'No (N)'	System	11 Oct 2020 19:36:54
	System	11 Oct 2020 19:36:54

US3512248

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(4)

Generated On: 10 Jun 2021 07:56:44

Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:52:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FCE43EC3-F1E0-47A1-B438-4D694934F821)', Time: '2020-10-11T15:36:43', User OID: 'PatientReportedOutcome (US3512248)', ODM File OID: 'b312abef-ab3c-457e-81f3-664cb013021a' User entered 'None (1)'	System	11 Oct 2020 19:36:54
	System	11 Oct 2020 19:36:54

**US3512248**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(4)**

**Generated On: 10 Jun 2021 07:56:44**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:52:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FCE43EC3-F1E0-47A1-B438-4D694934F821)', Time: '2020-10-11T15:36:52', User OID: 'PatientReportedOutcome (US3512248)', ODM File OID: 'b312abef-ab3c-457e-81f3-664cb013021a' User entered '11 Oct 2020 15:36'	System	11 Oct 2020 19:36:54
	System	11 Oct 2020 19:36:54

US3512248

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(4)

Generated On: 10 Jun 2021 07:56:44

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:52:02
User entered '11 Oct 2020 12:00'	System	08 Oct 2020 16:13:55

US3512248

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(4)

Generated On: 10 Jun 2021 07:56:44

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:52:02
User entered '12 Oct 2020 11:59'	System	08 Oct 2020 16:13:55

US3512248

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(5)

Generated On: 10 Jun 2021 07:56:44

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:52:02
Data entry locked.	System	08 Oct 2020 16:13:55
User entered 'Day 5'	System	08 Oct 2020 16:13:55



US3512248

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(5)

Generated On: 10 Jun 2021 07:56:44

Please record - **PAIN AT INJECTION SITE.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:52:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FCE43EC3-F1E0-47A1-B438-4D694934F821)', Time: '2020-10-12T13:53:43', User OID: 'PatientReportedOutcome (US3512248)', ODM File OID: 'd211a9e6-82c4-4fad-ac97-5e653e717c1a' User entered 'None (1)'	System	12 Oct 2020 17:54:03
	System	12 Oct 2020 17:54:03

US3512248

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(5)

Generated On: 10 Jun 2021 07:56:44

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:52:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FCE43EC3-F1E0-47A1-B438-4D694934F821)', Time: '2020-10-12T13:53:48', User OID: 'PatientReportedOutcome (US3512248)', ODM File OID: 'd211a9e6-82c4-4fad-ac97-5e653e717c1a' User entered 'No (N)'	System	12 Oct 2020 17:54:03
	System	12 Oct 2020 17:54:03

US3512248

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(5)

Generated On: 10 Jun 2021 07:56:44

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:52:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FCE43EC3-F1E0-47A1-B438-4D694934F821)', Time: '2020-10-12T13:53:50', User OID: 'PatientReportedOutcome (US3512248)', ODM File OID: 'd211a9e6-82c4-4fad-ac97-5e653e717c1a' User entered 'No (N)'	System	12 Oct 2020 17:54:03
	System	12 Oct 2020 17:54:03

US3512248

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(5)

Generated On: 10 Jun 2021 07:56:44

Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:52:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FCE43EC3-F1E0-47A1-B438-4D694934F821)', Time: '2020-10-12T13:53:55', User OID: 'PatientReportedOutcome (US3512248)', ODM File OID: 'd211a9e6-82c4-4fad-ac97-5e653e717c1a' User entered 'None (1)'	System	12 Oct 2020 17:54:03
	System	12 Oct 2020 17:54:03

**US3512248**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(5)**

**Generated On: 10 Jun 2021 07:56:44**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:52:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FCE43EC3-F1E0-47A1-B438-4D694934F821)', Time: '2020-10-12T13:53:58', User OID: 'PatientReportedOutcome (US3512248)', ODM File OID: 'd211a9e6-82c4-4fad-ac97-5e653e717c1a' User entered '12 Oct 2020 13:53'	System	12 Oct 2020 17:54:03
	System	12 Oct 2020 17:54:03

**US3512248**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(5)**

**Generated On: 10 Jun 2021 07:56:44**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:52:02
User entered '12 Oct 2020 12:00'	System	08 Oct 2020 16:13:55

**US3512248**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(5)**

**Generated On: 10 Jun 2021 07:56:44**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:52:02
User entered '13 Oct 2020 11:59'	System	08 Oct 2020 16:13:55

US3512248

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(6)

Generated On: 10 Jun 2021 07:56:44

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:52:02
Data entry locked.	System	08 Oct 2020 16:13:55
User entered 'Day 6'	System	08 Oct 2020 16:13:55



US3512248

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(6)

Generated On: 10 Jun 2021 07:56:44

Please record - **PAIN AT INJECTION SITE.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:52:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FCE43EC3-F1E0-47A1-B438-4D694934F821)', Time: '2020-10-13T14:52:47', User OID: 'PatientReportedOutcome (US3512248)', ODM File OID: 'df99ac60-3818-4dc4-9bed-17da9192cced' User entered 'None (1)'	System	13 Oct 2020 18:53:09
	System	13 Oct 2020 18:53:09

US3512248

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(6)

Generated On: 10 Jun 2021 07:56:44

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:52:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FCE43EC3-F1E0-47A1-B438-4D694934F821)', Time: '2020-10-13T14:52:51', User OID: 'PatientReportedOutcome (US3512248)', ODM File OID: 'df99ac60-3818-4dc4-9bed-17da9192cced' User entered 'No (N)'	System	13 Oct 2020 18:53:09
	System	13 Oct 2020 18:53:09

US3512248

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(6)

Generated On: 10 Jun 2021 07:56:44

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:52:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FCE43EC3-F1E0-47A1-B438-4D694934F821)', Time: '2020-10-13T14:52:54', User OID: 'PatientReportedOutcome (US3512248)', ODM File OID: 'df99ac60-3818-4dc4-9bed-17da9192cced' User entered 'No (N)'	System	13 Oct 2020 18:53:09
	System	13 Oct 2020 18:53:09

US3512248

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(6)

Generated On: 10 Jun 2021 07:56:44

Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:52:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FCE43EC3-F1E0-47A1-B438-4D694934F821)', Time: '2020-10-13T14:52:58', User OID: 'PatientReportedOutcome (US3512248)', ODM File OID: 'df99ac60-3818-4dc4-9bed-17da9192cced' User entered 'None (1)'	System	13 Oct 2020 18:53:09
	System	13 Oct 2020 18:53:09

**US3512248**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(6)**

**Generated On: 10 Jun 2021 07:56:44**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:52:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FCE43EC3-F1E0-47A1-B438-4D694934F821)', Time: '2020-10-13T14:53:06', User OID: 'PatientReportedOutcome (US3512248)', ODM File OID: 'df99ac60-3818-4dc4-9bed-17da9192cced' User entered '13 Oct 2020 14:53'	System	13 Oct 2020 18:53:09
	System	13 Oct 2020 18:53:09

**US3512248**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(6)**

**Generated On: 10 Jun 2021 07:56:44**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:52:02
User entered '13 Oct 2020 12:00'	System	08 Oct 2020 16:13:55

**US3512248**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(6)**

**Generated On: 10 Jun 2021 07:56:44**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:52:02
User entered '14 Oct 2020 11:59'	System	08 Oct 2020 16:13:55

US3512248

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(7)

Generated On: 10 Jun 2021 07:56:44

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:52:02
Data entry locked.	System	08 Oct 2020 16:13:55
User entered 'Day 7'	System	08 Oct 2020 16:13:55



US3512248

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(7)

Generated On: 10 Jun 2021 07:56:44

Please record - **PAIN AT INJECTION SITE.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:52:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FCE43EC3-F1E0-47A1-B438-4D694934F821)', Time: '2020-10-14T15:53:59', User OID: 'PatientReportedOutcome (US3512248)', ODM File OID: '0d77c989-eaff-4558-9b42-14f9161d754a' User entered 'None (1)'	System	14 Oct 2020 19:54:24
	System	14 Oct 2020 19:54:24

US3512248

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(7)

Generated On: 10 Jun 2021 07:56:44

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:52:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FCE43EC3-F1E0-47A1-B438-4D694934F821)', Time: '2020-10-14T15:54:04', User OID: 'PatientReportedOutcome (US3512248)', ODM File OID: '0d77c989-eaff-4558-9b42-14f9161d754a' User entered 'No (N)'	System	14 Oct 2020 19:54:24
	System	14 Oct 2020 19:54:24

US3512248

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(7)

Generated On: 10 Jun 2021 07:56:44

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:52:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FCE43EC3-F1E0-47A1-B438-4D694934F821)', Time: '2020-10-14T15:54:07', User OID: 'PatientReportedOutcome (US3512248)', ODM File OID: '0d77c989-eaff-4558-9b42-14f9161d754a' User entered 'No (N)'	System	14 Oct 2020 19:54:24
	System	14 Oct 2020 19:54:24

US3512248

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(7)

Generated On: 10 Jun 2021 07:56:44

Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:52:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FCE43EC3-F1E0-47A1-B438-4D694934F821)', Time: '2020-10-14T15:54:12', User OID: 'PatientReportedOutcome (US3512248)', ODM File OID: '0d77c989-eaff-4558-9b42-14f9161d754a' User entered 'None (1)'	System	14 Oct 2020 19:54:24
	System	14 Oct 2020 19:54:24

**US3512248**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(7)**

**Generated On: 10 Jun 2021 07:56:44**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:52:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FCE43EC3-F1E0-47A1-B438-4D694934F821)', Time: '2020-10-14T15:54:22', User OID: 'PatientReportedOutcome (US3512248)', ODM File OID: '0d77c989-eaff-4558-9b42-14f9161d754a' User entered '14 Oct 2020 15:54'	System	14 Oct 2020 19:54:24
	System	14 Oct 2020 19:54:24

US3512248

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(7)

Generated On: 10 Jun 2021 07:56:44

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:52:02
User entered '14 Oct 2020 12:00'	System	08 Oct 2020 16:13:55

**US3512248**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(7)**

**Generated On: 10 Jun 2021 07:56:44**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:52:02
User entered '15 Oct 2020 11:59'	System	08 Oct 2020 16:13:55

US3512248

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 10 Jun 2021 07:56:44

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:52:02
Data entry locked.	System	08 Oct 2020 16:13:55
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	08 Oct 2020 16:13:55



**US3512248**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(1/1)**

**Generated On: 10 Jun 2021 07:56:44**

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:52:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FCE43EC3-F1E0-47A1-B438-4D694934F821)', Time: '2020-10-08T12:25:40', User OID: 'PatientReportedOutcome (US3512248)', ODM File OID: 'ff9617af-0e7c-4293-ac83-38798df07c58' User entered 'None (0)'	System	08 Oct 2020 16:26:19
	System	08 Oct 2020 16:26:19

**US3512248**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(1/1)**

**Generated On: 10 Jun 2021 07:56:44**

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:52:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FCE43EC3-F1E0-47A1-B438-4D694934F821)', Time: '2020-10-08T12:25:45', User OID: 'PatientReportedOutcome (US3512248)', ODM File OID: 'ff9617af-0e7c-4293-ac83-38798df07c58' User entered 'None (0)'	System	08 Oct 2020 16:26:19
	System	08 Oct 2020 16:26:19

US3512248

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 10 Jun 2021 07:56:44

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:52:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FCE43EC3-F1E0-47A1-B438-4D694934F821)', Time: '2020-10-08T12:25:50', User OID: 'PatientReportedOutcome (US3512248)', ODM File OID: 'ff9617af-0e7c-4293-ac83-38798df07c58' User entered 'None (0)'	System	08 Oct 2020 16:26:19
	System	08 Oct 2020 16:26:19

US3512248

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 10 Jun 2021 07:56:44

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:52:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FCE43EC3-F1E0-47A1-B438-4D694934F821)', Time: '2020-10-08T12:25:56', User OID: 'PatientReportedOutcome (US3512248)', ODM File OID: 'ff9617af-0e7c-4293-ac83-38798df07c58' User entered 'None (0)'	System	08 Oct 2020 16:26:19
	System	08 Oct 2020 16:26:19

US3512248

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 10 Jun 2021 07:56:44

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:52:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FCE43EC3-F1E0-47A1-B438-4D694934F821)', Time: '2020-10-08T12:26:01', User OID: 'PatientReportedOutcome (US3512248)', ODM File OID: 'ff9617af-0e7c-4293-ac83-38798df07c58' User entered 'None (0)'	System	08 Oct 2020 16:26:19
	System	08 Oct 2020 16:26:19

US3512248

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 10 Jun 2021 07:56:44

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:52:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FCE43EC3-F1E0-47A1-B438-4D694934F821)', Time: '2020-10-08T12:26:06', User OID: 'PatientReportedOutcome (US3512248)', ODM File OID: 'ff9617af-0e7c-4293-ac83-38798df07c58' User entered 'None (0)'	System	08 Oct 2020 16:26:19
	System	08 Oct 2020 16:26:19

US3512248

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 10 Jun 2021 07:56:44

Did you receive any **MEDICAL ATTENTION** (doctor visit, other) for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:52:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FCE43EC3-F1E0-47A1-B438-4D694934F821)', Time: '2020-10-08T12:26:11', User OID: 'PatientReportedOutcome (US3512248)', ODM File OID: 'ff9617af-0e7c-4293-ac83-38798df07c58' User entered 'No (N)'	System	08 Oct 2020 16:26:19
	System	08 Oct 2020 16:26:19

US3512248

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 10 Jun 2021 07:56:44

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:52:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FCE43EC3-F1E0-47A1-B438-4D694934F821)', Time: '2020-10-08T12:26:15', User OID: 'PatientReportedOutcome (US3512248)', ODM File OID: 'ff9617af-0e7c-4293-ac83-38798df07c58' User entered '08 Oct 2020 12:26'	System	08 Oct 2020 16:26:19
	System	08 Oct 2020 16:26:19



**US3512248**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(1/1)**

**Generated On: 10 Jun 2021 07:56:44**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:52:02
User entered '08 Oct 2020 12:09'	System	08 Oct 2020 16:13:55

**US3512248**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(1/1)**

**Generated On: 10 Jun 2021 07:56:44**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:52:02
User entered '08 Oct 2020 14:39'	System	08 Oct 2020 16:13:55

US3512248

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 10 Jun 2021 07:56:44

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:52:02
Data entry locked.	System	08 Oct 2020 16:13:55
User entered 'Day 1, after vaccination (at home)'	System	08 Oct 2020 16:13:55

US3512248

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 10 Jun 2021 07:56:44

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:52:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FCE43EC3-F1E0-47A1-B438-4D694934F821)', Time: '2020-10-08T15:38:26', User OID: 'PatientReportedOutcome (US3512248)', ODM File OID: 'b3fd00c5-4621-4a94-82a4-ae8ef6b9cb46'	System	08 Oct 2020 19:39:07
User entered 'None (0)'	System	08 Oct 2020 19:39:07

US3512248

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 10 Jun 2021 07:56:44

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:52:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FCE43EC3-F1E0-47A1-B438-4D694934F821)', Time: '2020-10-08T15:38:30', User OID: 'PatientReportedOutcome (US3512248)', ODM File OID: 'b3fd00c5-4621-4a94-82a4-ae8ef6b9cb46' User entered 'None (0)'	System	08 Oct 2020 19:39:07
	System	08 Oct 2020 19:39:07

US3512248

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 10 Jun 2021 07:56:44

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:52:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FCE43EC3-F1E0-47A1-B438-4D694934F821)', Time: '2020-10-08T15:38:33', User OID: 'PatientReportedOutcome (US3512248)', ODM File OID: 'b3fd00c5-4621-4a94-82a4-ae8ef6b9cb46' User entered 'None (0)'	System	08 Oct 2020 19:39:07
	System	08 Oct 2020 19:39:07

US3512248

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 10 Jun 2021 07:56:44

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:52:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FCE43EC3-F1E0-47A1-B438-4D694934F821)', Time: '2020-10-08T15:38:38', User OID: 'PatientReportedOutcome (US3512248)', ODM File OID: 'b3fd00c5-4621-4a94-82a4-ae8ef6b9cb46' User entered 'None (0)'	System	08 Oct 2020 19:39:07
	System	08 Oct 2020 19:39:07

US3512248

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 10 Jun 2021 07:56:44

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:52:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FCE43EC3-F1E0-47A1-B438-4D694934F821)', Time: '2020-10-08T15:38:41', User OID: 'PatientReportedOutcome (US3512248)', ODM File OID: 'b3fd00c5-4621-4a94-82a4-ae8ef6b9cb46' User entered 'None (0)'	System	08 Oct 2020 19:39:07
	System	08 Oct 2020 19:39:07



US3512248

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 10 Jun 2021 07:56:44

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:52:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FCE43EC3-F1E0-47A1-B438-4D694934F821)', Time: '2020-10-08T15:38:45', User OID: 'PatientReportedOutcome (US3512248)', ODM File OID: 'b3fd00c5-4621-4a94-82a4-ae8ef6b9cb46' User entered 'None (0)'	System	08 Oct 2020 19:39:07
	System	08 Oct 2020 19:39:07

US3512248

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 10 Jun 2021 07:56:44

Did you receive any **MEDICAL ATTENTION** (doctor visit, other) for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:52:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FCE43EC3-F1E0-47A1-B438-4D694934F821)', Time: '2020-10-08T15:38:51', User OID: 'PatientReportedOutcome (US3512248)', ODM File OID: 'b3fd00c5-4621-4a94-82a4-ae8ef6b9cb46' User entered 'No (N)'	System	08 Oct 2020 19:39:07
	System	08 Oct 2020 19:39:07

**US3512248**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(1/2)**

**Generated On: 10 Jun 2021 07:56:44**

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:52:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FCE43EC3-F1E0-47A1-B438-4D694934F821)', Time: '2020-10-08T15:39:04', User OID: 'PatientReportedOutcome (US3512248)', ODM File OID: 'b3fd00c5-4621-4a94-82a4-ae8ef6b9cb46' User entered '08 Oct 2020 15:39'	System	08 Oct 2020 19:39:07
	System	08 Oct 2020 19:39:07

**US3512248**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(1/2)**

**Generated On: 10 Jun 2021 07:56:44**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:52:02
User entered '08 Oct 2020 15:34'	System	08 Oct 2020 16:13:55

**US3512248**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(1/2)**

**Generated On: 10 Jun 2021 07:56:44**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:52:02
User entered '09 Oct 2020 11:59'	System	08 Oct 2020 16:13:55

**US3512248**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(2)**

**Generated On: 10 Jun 2021 07:56:44**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:52:02
Data entry locked.	System	08 Oct 2020 16:13:55
User entered 'Day 2'	System	08 Oct 2020 16:13:55

**US3512248**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(2)**

**Generated On: 10 Jun 2021 07:56:44**

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:52:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FCE43EC3-F1E0-47A1-B438-4D694934F821)', Time: '2020-10-09T22:01:22', User OID: 'PatientReportedOutcome (US3512248)', ODM File OID: '0a9f0e70-b20f-4c9d-a3d1-d24f4e22bf83' User entered 'None (0)'	System	10 Oct 2020 02:01:53
	System	10 Oct 2020 02:01:53

US3512248

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 10 Jun 2021 07:56:44

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:52:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FCE43EC3-F1E0-47A1-B438-4D694934F821)', Time: '2020-10-09T22:01:25', User OID: 'PatientReportedOutcome (US3512248)', ODM File OID: '0a9f0e70-b20f-4c9d-a3d1-d24f4e22bf83' User entered 'None (0)'	System	10 Oct 2020 02:01:53
	System	10 Oct 2020 02:01:53



US3512248

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 10 Jun 2021 07:56:44

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:52:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FCE43EC3-F1E0-47A1-B438-4D694934F821)', Time: '2020-10-09T22:01:28', User OID: 'PatientReportedOutcome (US3512248)', ODM File OID: '0a9f0e70-b20f-4c9d-a3d1-d24f4e22bf83' User entered 'None (0)'	System	10 Oct 2020 02:01:53
	System	10 Oct 2020 02:01:53

US3512248

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 10 Jun 2021 07:56:44

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:52:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FCE43EC3-F1E0-47A1-B438-4D694934F821)', Time: '2020-10-09T22:01:32', User OID: 'PatientReportedOutcome (US3512248)', ODM File OID: '0a9f0e70-b20f-4c9d-a3d1-d24f4e22bf83' User entered 'None (0)'	System	10 Oct 2020 02:01:53
	System	10 Oct 2020 02:01:53

US3512248

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 10 Jun 2021 07:56:44

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:52:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FCE43EC3-F1E0-47A1-B438-4D694934F821)', Time: '2020-10-09T22:01:35', User OID: 'PatientReportedOutcome (US3512248)', ODM File OID: '0a9f0e70-b20f-4c9d-a3d1-d24f4e22bf83' User entered 'None (0)'	System	10 Oct 2020 02:01:53
	System	10 Oct 2020 02:01:53

US3512248

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 10 Jun 2021 07:56:44

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:52:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FCE43EC3-F1E0-47A1-B438-4D694934F821)', Time: '2020-10-09T22:01:39', User OID: 'PatientReportedOutcome (US3512248)', ODM File OID: '0a9f0e70-b20f-4c9d-a3d1-d24f4e22bf83' User entered 'None (0)'	System	10 Oct 2020 02:01:53
	System	10 Oct 2020 02:01:53

US3512248

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 10 Jun 2021 07:56:44

Did you receive any **MEDICAL ATTENTION** (doctor visit, other) for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:52:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FCE43EC3-F1E0-47A1-B438-4D694934F821)', Time: '2020-10-09T22:01:43', User OID: 'PatientReportedOutcome (US3512248)', ODM File OID: '0a9f0e70-b20f-4c9d-a3d1-d24f4e22bf83' User entered 'No (N)'	System	10 Oct 2020 02:01:53
	System	10 Oct 2020 02:01:53

**US3512248**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(2)**

**Generated On: 10 Jun 2021 07:56:44**

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:52:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FCE43EC3-F1E0-47A1-B438-4D694934F821)', Time: '2020-10-09T22:01:50', User OID: 'PatientReportedOutcome (US3512248)', ODM File OID: '0a9f0e70-b20f-4c9d-a3d1-d24f4e22bf83' User entered '09 Oct 2020 22:01'	System	10 Oct 2020 02:01:53
	System	10 Oct 2020 02:01:53

**US3512248**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(2)**

**Generated On: 10 Jun 2021 07:56:44**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:52:02
User entered '09 Oct 2020 12:00'	System	08 Oct 2020 16:13:55

**US3512248**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(2)**

**Generated On: 10 Jun 2021 07:56:44**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:52:02
User entered '10 Oct 2020 11:59'	System	08 Oct 2020 16:13:55



**US3512248**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(3)**

**Generated On: 10 Jun 2021 07:56:44**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:52:02
Data entry locked.	System	08 Oct 2020 16:13:55
User entered 'Day 3'	System	08 Oct 2020 16:13:55

US3512248

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 10 Jun 2021 07:56:44

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:52:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FCE43EC3-F1E0-47A1-B438-4D694934F821)', Time: '2020-10-10T20:48:45', User OID: 'PatientReportedOutcome (US3512248)', ODM File OID: '90274b54-8e1f-4a50-9be7-1c6ed5b5809e' User entered 'None (0)'	System	11 Oct 2020 00:49:20
	System	11 Oct 2020 00:49:20

US3512248

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 10 Jun 2021 07:56:44

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:52:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FCE43EC3-F1E0-47A1-B438-4D694934F821)', Time: '2020-10-10T20:48:49', User OID: 'PatientReportedOutcome (US3512248)', ODM File OID: '90274b54-8e1f-4a50-9be7-1c6ed5b5809e' User entered 'None (0)'	System	11 Oct 2020 00:49:20
	System	11 Oct 2020 00:49:20

US3512248

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 10 Jun 2021 07:56:44

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:52:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FCE43EC3-F1E0-47A1-B438-4D694934F821)', Time: '2020-10-10T20:48:53', User OID: 'PatientReportedOutcome (US3512248)', ODM File OID: '90274b54-8e1f-4a50-9be7-1c6ed5b5809e' User entered 'None (0)'	System	11 Oct 2020 00:49:20
	System	11 Oct 2020 00:49:20

US3512248

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 10 Jun 2021 07:56:44

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:52:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FCE43EC3-F1E0-47A1-B438-4D694934F821)', Time: '2020-10-10T20:48:58', User OID: 'PatientReportedOutcome (US3512248)', ODM File OID: '90274b54-8e1f-4a50-9be7-1c6ed5b5809e' User entered 'None (0)'	System	11 Oct 2020 00:49:20
	System	11 Oct 2020 00:49:20

**US3512248**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(3)**

**Generated On: 10 Jun 2021 07:56:44**

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:52:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FCE43EC3-F1E0-47A1-B438-4D694934F821)', Time: '2020-10-10T20:49:01', User OID: 'PatientReportedOutcome (US3512248)', ODM File OID: '90274b54-8e1f-4a50-9be7-1c6ed5b5809e' User entered 'None (0)'	System	11 Oct 2020 00:49:20
	System	11 Oct 2020 00:49:20

US3512248

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 10 Jun 2021 07:56:44

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:52:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FCE43EC3-F1E0-47A1-B438-4D694934F821)', Time: '2020-10-10T20:49:05', User OID: 'PatientReportedOutcome (US3512248)', ODM File OID: '90274b54-8e1f-4a50-9be7-1c6ed5b5809e' User entered 'None (0)'	System	11 Oct 2020 00:49:20
	System	11 Oct 2020 00:49:20

US3512248

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 10 Jun 2021 07:56:44

Did you receive any **MEDICAL ATTENTION** (doctor visit, other) for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:52:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FCE43EC3-F1E0-47A1-B438-4D694934F821)', Time: '2020-10-10T20:49:16', User OID: 'PatientReportedOutcome (US3512248)', ODM File OID: '90274b54-8e1f-4a50-9be7-1c6ed5b5809e' User entered 'No (N)'	System	11 Oct 2020 00:49:20
	System	11 Oct 2020 00:49:20



US3512248

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 10 Jun 2021 07:56:44

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:52:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FCE43EC3-F1E0-47A1-B438-4D694934F821)', Time: '2020-10-10T20:49:19', User OID: 'PatientReportedOutcome (US3512248)', ODM File OID: '90274b54-8e1f-4a50-9be7-1c6ed5b5809e' User entered '10 Oct 2020 20:49'	System	11 Oct 2020 00:49:20
	System	11 Oct 2020 00:49:20

**US3512248**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(3)**

**Generated On: 10 Jun 2021 07:56:44**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:52:02
User entered '10 Oct 2020 12:00'	System	08 Oct 2020 16:13:55

**US3512248**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(3)**

**Generated On: 10 Jun 2021 07:56:44**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:52:02
User entered '11 Oct 2020 11:59'	System	08 Oct 2020 16:13:55

US3512248

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 10 Jun 2021 07:56:44

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:52:02
Data entry locked.	System	08 Oct 2020 16:13:55
User entered 'Day 4'	System	08 Oct 2020 16:13:55

US3512248

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 10 Jun 2021 07:56:44

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:52:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FCE43EC3-F1E0-47A1-B438-4D694934F821)', Time: '2020-10-11T15:36:58', User OID: 'PatientReportedOutcome (US3512248)', ODM File OID: '0504e680-54ce-4479-b9b7-ebcbb5b5b66d' User entered 'None (0)'	System	11 Oct 2020 19:37:33
	System	11 Oct 2020 19:37:33

US3512248

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 10 Jun 2021 07:56:44

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:52:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FCE43EC3-F1E0-47A1-B438-4D694934F821)', Time: '2020-10-11T15:37:03', User OID: 'PatientReportedOutcome (US3512248)', ODM File OID: '0504e680-54ce-4479-b9b7-ebcbb5b5b66d' User entered 'None (0)'	System	11 Oct 2020 19:37:33
	System	11 Oct 2020 19:37:33

US3512248

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 10 Jun 2021 07:56:44

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:52:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FCE43EC3-F1E0-47A1-B438-4D694934F821)', Time: '2020-10-11T15:37:06', User OID: 'PatientReportedOutcome (US3512248)', ODM File OID: '0504e680-54ce-4479-b9b7-ebcbb5b5b66d' User entered 'None (0)'	System	11 Oct 2020 19:37:33
	System	11 Oct 2020 19:37:33

US3512248

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 10 Jun 2021 07:56:44

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:52:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FCE43EC3-F1E0-47A1-B438-4D694934F821)', Time: '2020-10-11T15:37:10', User OID: 'PatientReportedOutcome (US3512248)', ODM File OID: '0504e680-54ce-4479-b9b7-ebcbb5b5b66d' User entered 'None (0)'	System	11 Oct 2020 19:37:33
	System	11 Oct 2020 19:37:33



US3512248

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 10 Jun 2021 07:56:44

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:52:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FCE43EC3-F1E0-47A1-B438-4D694934F821)', Time: '2020-10-11T15:37:14', User OID: 'PatientReportedOutcome (US3512248)', ODM File OID: '0504e680-54ce-4479-b9b7-ebcbb5b5b66d' User entered 'None (0)'	System	11 Oct 2020 19:37:33
	System	11 Oct 2020 19:37:33

**US3512248**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(4)**

**Generated On: 10 Jun 2021 07:56:44**

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:52:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FCE43EC3-F1E0-47A1-B438-4D694934F821)', Time: '2020-10-11T15:37:19', User OID: 'PatientReportedOutcome (US3512248)', ODM File OID: '0504e680-54ce-4479-b9b7-ebcbb5b5b66d' User entered 'None (0)'	System	11 Oct 2020 19:37:33
	System	11 Oct 2020 19:37:33

US3512248

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 10 Jun 2021 07:56:44

Did you receive any **MEDICAL ATTENTION** (doctor visit, other) for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:52:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FCE43EC3-F1E0-47A1-B438-4D694934F821)', Time: '2020-10-11T15:37:25', User OID: 'PatientReportedOutcome (US3512248)', ODM File OID: '0504e680-54ce-4479-b9b7-ebcbb5b5b66d' User entered 'No (N)'	System	11 Oct 2020 19:37:33
	System	11 Oct 2020 19:37:33

**US3512248**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(4)**

**Generated On: 10 Jun 2021 07:56:44**

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:52:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FCE43EC3-F1E0-47A1-B438-4D694934F821)', Time: '2020-10-11T15:37:28', User OID: 'PatientReportedOutcome (US3512248)', ODM File OID: '0504e680-54ce-4479-b9b7-ebcbb5b5b66d' User entered '11 Oct 2020 15:37'	System	11 Oct 2020 19:37:33
	System	11 Oct 2020 19:37:33

**US3512248**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(4)**

**Generated On: 10 Jun 2021 07:56:44**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:52:02
User entered '11 Oct 2020 12:00'	System	08 Oct 2020 16:13:55

**US3512248**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(4)**

**Generated On: 10 Jun 2021 07:56:44**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:52:02
User entered '12 Oct 2020 11:59'	System	08 Oct 2020 16:13:55

US3512248

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 10 Jun 2021 07:56:44

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:52:02
Data entry locked.	System	08 Oct 2020 16:13:55
User entered 'Day 5'	System	08 Oct 2020 16:13:55

US3512248

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 10 Jun 2021 07:56:44

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:52:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FCE43EC3-F1E0-47A1-B438-4D694934F821)', Time: '2020-10-12T13:54:05', User OID: 'PatientReportedOutcome (US3512248)', ODM File OID: '78c6a180-f8b6-4a41-9625-46ad904f587f' User entered 'None (0)'	System	12 Oct 2020 17:54:46
	System	12 Oct 2020 17:54:46



US3512248

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 10 Jun 2021 07:56:44

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:52:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FCE43EC3-F1E0-47A1-B438-4D694934F821)', Time: '2020-10-12T13:54:10', User OID: 'PatientReportedOutcome (US3512248)', ODM File OID: '78c6a180-f8b6-4a41-9625-46ad904f587f' User entered 'None (0)'	System	12 Oct 2020 17:54:46
	System	12 Oct 2020 17:54:46

US3512248

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 10 Jun 2021 07:56:44

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:52:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FCE43EC3-F1E0-47A1-B438-4D694934F821)', Time: '2020-10-12T13:54:15', User OID: 'PatientReportedOutcome (US3512248)', ODM File OID: '78c6a180-f8b6-4a41-9625-46ad904f587f' User entered 'None (0)'	System	12 Oct 2020 17:54:46
	System	12 Oct 2020 17:54:46

US3512248

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 10 Jun 2021 07:56:44

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:52:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FCE43EC3-F1E0-47A1-B438-4D694934F821)', Time: '2020-10-12T13:54:22', User OID: 'PatientReportedOutcome (US3512248)', ODM File OID: '78c6a180-f8b6-4a41-9625-46ad904f587f' User entered 'None (0)'	System	12 Oct 2020 17:54:46
	System	12 Oct 2020 17:54:46

US3512248

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 10 Jun 2021 07:56:44

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:52:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FCE43EC3-F1E0-47A1-B438-4D694934F821)', Time: '2020-10-12T13:54:28', User OID: 'PatientReportedOutcome (US3512248)', ODM File OID: '78c6a180-f8b6-4a41-9625-46ad904f587f' User entered 'None (0)'	System	12 Oct 2020 17:54:46
	System	12 Oct 2020 17:54:46

US3512248

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 10 Jun 2021 07:56:44

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:52:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FCE43EC3-F1E0-47A1-B438-4D694934F821)', Time: '2020-10-12T13:54:35', User OID: 'PatientReportedOutcome (US3512248)', ODM File OID: '78c6a180-f8b6-4a41-9625-46ad904f587f' User entered 'None (0)'	System	12 Oct 2020 17:54:46
	System	12 Oct 2020 17:54:46

US3512248

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 10 Jun 2021 07:56:44

Did you receive any **MEDICAL ATTENTION** (doctor visit, other) for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:52:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FCE43EC3-F1E0-47A1-B438-4D694934F821)', Time: '2020-10-12T13:54:39', User OID: 'PatientReportedOutcome (US3512248)', ODM File OID: '78c6a180-f8b6-4a41-9625-46ad904f587f' User entered 'No (N)'	System	12 Oct 2020 17:54:46
	System	12 Oct 2020 17:54:46

**US3512248**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(5)**

**Generated On: 10 Jun 2021 07:56:44**

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:52:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FCE43EC3-F1E0-47A1-B438-4D694934F821)', Time: '2020-10-12T13:54:42', User OID: 'PatientReportedOutcome (US3512248)', ODM File OID: '78c6a180-f8b6-4a41-9625-46ad904f587f' User entered '12 Oct 2020 13:54'	System	12 Oct 2020 17:54:46
	System	12 Oct 2020 17:54:46

**US3512248**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(5)**

**Generated On: 10 Jun 2021 07:56:44**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:52:02
User entered '12 Oct 2020 12:00'	System	08 Oct 2020 16:13:55



**US3512248**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(5)**

**Generated On: 10 Jun 2021 07:56:44**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:52:02
User entered '13 Oct 2020 11:59'	System	08 Oct 2020 16:13:55

US3512248

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 10 Jun 2021 07:56:44

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:52:02
Data entry locked.	System	08 Oct 2020 16:13:55
User entered 'Day 6'	System	08 Oct 2020 16:13:55

**US3512248**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(6)**

**Generated On: 10 Jun 2021 07:56:44**

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:52:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FCE43EC3-F1E0-47A1-B438-4D694934F821)', Time: '2020-10-13T14:53:12', User OID: 'PatientReportedOutcome (US3512248)', ODM File OID: '2126f449-f124-415a-af68-b81b0e52b772' User entered 'None (0)'	System	13 Oct 2020 18:53:48
	System	13 Oct 2020 18:53:48

US3512248

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 10 Jun 2021 07:56:44

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:52:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FCE43EC3-F1E0-47A1-B438-4D694934F821)', Time: '2020-10-13T14:53:17', User OID: 'PatientReportedOutcome (US3512248)', ODM File OID: '2126f449-f124-415a-af68-b81b0e52b772' User entered 'None (0)'	System	13 Oct 2020 18:53:48
	System	13 Oct 2020 18:53:48

US3512248

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 10 Jun 2021 07:56:44

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:52:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FCE43EC3-F1E0-47A1-B438-4D694934F821)', Time: '2020-10-13T14:53:21', User OID: 'PatientReportedOutcome (US3512248)', ODM File OID: '2126f449-f124-415a-af68-b81b0e52b772' User entered 'None (0)'	System	13 Oct 2020 18:53:48
	System	13 Oct 2020 18:53:48

US3512248

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 10 Jun 2021 07:56:44

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:52:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FCE43EC3-F1E0-47A1-B438-4D694934F821)', Time: '2020-10-13T14:53:25', User OID: 'PatientReportedOutcome (US3512248)', ODM File OID: '2126f449-f124-415a-af68-b81b0e52b772' User entered 'None (0)'	System	13 Oct 2020 18:53:48
	System	13 Oct 2020 18:53:48

**US3512248**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(6)**

**Generated On: 10 Jun 2021 07:56:44**

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:52:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FCE43EC3-F1E0-47A1-B438-4D694934F821)', Time: '2020-10-13T14:53:29', User OID: 'PatientReportedOutcome (US3512248)', ODM File OID: '2126f449-f124-415a-af68-b81b0e52b772' User entered 'None (0)'	System	13 Oct 2020 18:53:48
	System	13 Oct 2020 18:53:48

US3512248

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 10 Jun 2021 07:56:44

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:52:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FCE43EC3-F1E0-47A1-B438-4D694934F821)', Time: '2020-10-13T14:53:34', User OID: 'PatientReportedOutcome (US3512248)', ODM File OID: '2126f449-f124-415a-af68-b81b0e52b772' User entered 'None (0)'	System	13 Oct 2020 18:53:48
	System	13 Oct 2020 18:53:48



US3512248

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 10 Jun 2021 07:56:44

Did you receive any **MEDICAL ATTENTION** (doctor visit, other) for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:52:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FCE43EC3-F1E0-47A1-B438-4D694934F821)', Time: '2020-10-13T14:53:37', User OID: 'PatientReportedOutcome (US3512248)', ODM File OID: '2126f449-f124-415a-af68-b81b0e52b772' User entered 'No (N)'	System	13 Oct 2020 18:53:48
	System	13 Oct 2020 18:53:48

**US3512248**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(6)**

**Generated On: 10 Jun 2021 07:56:44**

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:52:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FCE43EC3-F1E0-47A1-B438-4D694934F821)', Time: '2020-10-13T14:53:45', User OID: 'PatientReportedOutcome (US3512248)', ODM File OID: '2126f449-f124-415a-af68-b81b0e52b772' User entered '13 Oct 2020 14:53'	System	13 Oct 2020 18:53:48
	System	13 Oct 2020 18:53:48

**US3512248**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(6)**

**Generated On: 10 Jun 2021 07:56:44**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:52:02
User entered '13 Oct 2020 12:00'	System	08 Oct 2020 16:13:55

**US3512248**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(6)**

**Generated On: 10 Jun 2021 07:56:44**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:52:02
User entered '14 Oct 2020 11:59'	System	08 Oct 2020 16:13:55

**US3512248**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(7)**

**Generated On: 10 Jun 2021 07:56:44**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:52:02
Data entry locked.	System	08 Oct 2020 16:13:55
User entered 'Day 7'	System	08 Oct 2020 16:13:55

US3512248

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 10 Jun 2021 07:56:44

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:52:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FCE43EC3-F1E0-47A1-B438-4D694934F821)', Time: '2020-10-14T15:54:30', User OID: 'PatientReportedOutcome (US3512248)', ODM File OID: '4b0e8532-00f6-403d-bc28-2af1e51b4718' User entered 'None (0)'	System	14 Oct 2020 19:55:23
	System	14 Oct 2020 19:55:23

US3512248

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 10 Jun 2021 07:56:44

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:52:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FCE43EC3-F1E0-47A1-B438-4D694934F821)', Time: '2020-10-14T15:54:36', User OID: 'PatientReportedOutcome (US3512248)', ODM File OID: '4b0e8532-00f6-403d-bc28-2af1e51b4718' User entered 'None (0)'	System	14 Oct 2020 19:55:23
	System	14 Oct 2020 19:55:23

US3512248

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 10 Jun 2021 07:56:44

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:52:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FCE43EC3-F1E0-47A1-B438-4D694934F821)', Time: '2020-10-14T15:54:46', User OID: 'PatientReportedOutcome (US3512248)', ODM File OID: '4b0e8532-00f6-403d-bc28-2af1e51b4718' User entered 'None (0)'	System	14 Oct 2020 19:55:23
	System	14 Oct 2020 19:55:23



US3512248

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 10 Jun 2021 07:56:44

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:52:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FCE43EC3-F1E0-47A1-B438-4D694934F821)', Time: '2020-10-14T15:54:52', User OID: 'PatientReportedOutcome (US3512248)', ODM File OID: '4b0e8532-00f6-403d-bc28-2af1e51b4718' User entered 'None (0)'	System	14 Oct 2020 19:55:23
	System	14 Oct 2020 19:55:23

**US3512248**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(7)**

**Generated On: 10 Jun 2021 07:56:44**

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:52:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FCE43EC3-F1E0-47A1-B438-4D694934F821)', Time: '2020-10-14T15:54:56', User OID: 'PatientReportedOutcome (US3512248)', ODM File OID: '4b0e8532-00f6-403d-bc28-2af1e51b4718' User entered 'None (0)'	System	14 Oct 2020 19:55:23
	System	14 Oct 2020 19:55:23

**US3512248**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(7)**

**Generated On: 10 Jun 2021 07:56:44**

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:52:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FCE43EC3-F1E0-47A1-B438-4D694934F821)', Time: '2020-10-14T15:55:02', User OID: 'PatientReportedOutcome (US3512248)', ODM File OID: '4b0e8532-00f6-403d-bc28-2af1e51b4718' User entered 'None (0)'	System	14 Oct 2020 19:55:23
	System	14 Oct 2020 19:55:23

US3512248

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 10 Jun 2021 07:56:44

Did you receive any **MEDICAL ATTENTION** (doctor visit, other) for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:52:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FCE43EC3-F1E0-47A1-B438-4D694934F821)', Time: '2020-10-14T15:55:11', User OID: 'PatientReportedOutcome (US3512248)', ODM File OID: '4b0e8532-00f6-403d-bc28-2af1e51b4718' User entered 'No (N)'	System	14 Oct 2020 19:55:23
	System	14 Oct 2020 19:55:23

**US3512248**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(7)**

**Generated On: 10 Jun 2021 07:56:44**

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:52:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FCE43EC3-F1E0-47A1-B438-4D694934F821)', Time: '2020-10-14T15:55:20', User OID: 'PatientReportedOutcome (US3512248)', ODM File OID: '4b0e8532-00f6-403d-bc28-2af1e51b4718' User entered '14 Oct 2020 15:55'	System	14 Oct 2020 19:55:23
	System	14 Oct 2020 19:55:23

**US3512248**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(7)**

**Generated On: 10 Jun 2021 07:56:44**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:52:02
User entered '14 Oct 2020 12:00'	System	08 Oct 2020 16:13:55

**US3512248**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(7)**

**Generated On: 10 Jun 2021 07:56:44**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:52:02
User entered '15 Oct 2020 11:59'	System	08 Oct 2020 16:13:55

**US3512248**

**Folder: Safety Call Day 36 (1)**

**Form: Safety Call**

**Generated On: 10 Jun 2021 07:56:44**

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:23:03
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 22:12:02
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	17 Nov 2020 19:28:27
User entered 'Yes (Y)'	Sheldon Warren (b) (4)	16 Oct 2020 00:36:31
	(b) (4)	



**US3512248**

**Folder: Safety Call Day 36 (1)**

**Form: Safety Call**

**Generated On: 10 Jun 2021 07:56:44**

[Date of Contact or Contact Attempt \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:23:03
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 22:12:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 19:28:27
User entered '15 Oct 2020'	Sheldon Warren (b) (4) (b) (4)	16 Oct 2020 00:36:31

US3512248

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 10 Jun 2021 07:56:44

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:23:03
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 22:12:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 19:28:27
User entered 'Contact Made (CONTACT MADE)'	Sheldon Warren (b) (4) (b) (4)	16 Oct 2020 00:36:31

US3512248

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 10 Jun 2021 07:56:44

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:23:03
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 22:12:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 19:28:27
User entered empty.	Sheldon Warren (b) (4) (b) (4)	16 Oct 2020 00:36:31

US3512248

Folder: Safety Call Day 36 (1)

Form: Continuing

Generated On: 10 Jun 2021 07:56:44

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:23:03
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 22:12:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 19:28:35
User entered 'Yes (Y)'	Sheldon Warren (b) (4) (b) (4)	16 Oct 2020 00:36:37

**US3512248**

**Folder: Safety Call Day 36 (1)**

**Form: Continuing**

**Generated On: 10 Jun 2021 07:56:44**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:23:03
User entered 'I'	System	16 Oct 2020 00:36:37

**US3512248**

**Folder: Safety Call Day 43 (1)**

**Form: Safety Call**

**Generated On: 10 Jun 2021 07:56:44**

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:23:03
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 22:12:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 19:28:48
User entered 'Yes (Y)'	Sheldon Warren (b) (4) (b) (4)	22 Oct 2020 20:41:26

**US3512248**

**Folder: Safety Call Day 43 (1)**

**Form: Safety Call**

**Generated On: 10 Jun 2021 07:56:44**

[Date of Contact or Contact Attempt \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:23:03
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 22:12:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 19:28:48
User entered '22 Oct 2020'	Sheldon Warren (b) (4) (b) (4)	22 Oct 2020 20:41:26

**US3512248**

**Folder: Safety Call Day 43 (1)**

**Form: Safety Call**

**Generated On: 10 Jun 2021 07:56:44**

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:23:03
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 22:12:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 19:28:48
User entered 'Contact Made (CONTACT MADE)'	Sheldon Warren (b) (4) (b) (4)	22 Oct 2020 20:41:26



US3512248

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 10 Jun 2021 07:56:44

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:23:03
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 22:12:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 19:28:48
User entered empty.	Sheldon Warren (b) (4) (b) (4)	22 Oct 2020 20:41:26

**US3512248**

**Folder: Safety Call Day 43 (1)**

**Form: Continuing**

**Generated On: 10 Jun 2021 07:56:44**

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:23:03
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 22:12:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 19:28:52
User entered 'Yes (Y)'	Sheldon Warren (b) (4) (b) (4)	22 Oct 2020 20:41:30

**US3512248**

**Folder: Safety Call Day 43 (1)**

**Form: Continuing**

**Generated On: 10 Jun 2021 07:56:44**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:23:03
User entered 'I'	System	22 Oct 2020 20:41:30

**US3512248**

**Folder: Safety Call Day 50 (1)**

**Form: Safety Call**

**Generated On: 10 Jun 2021 07:56:44**

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:23:03
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 22:12:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 19:30:03
User entered 'Yes (Y)'	Sheldon Warren (b) (4) (b) (4)	29 Oct 2020 21:35:06

**US3512248**

**Folder: Safety Call Day 50 (1)**

**Form: Safety Call**

**Generated On: 10 Jun 2021 07:56:44**

[Date of Contact or Contact Attempt \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:23:03
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 22:12:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 19:30:03
User entered '29 Oct 2020'	Sheldon Warren (b) (4) (b) (4)	29 Oct 2020 21:35:06

US3512248

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 10 Jun 2021 07:56:44

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:23:03
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 22:12:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 19:30:03
User entered 'Contact Made (CONTACT MADE)'	Sheldon Warren (b) (4) (b) (4)	29 Oct 2020 21:35:06

US3512248

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 10 Jun 2021 07:56:44

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:23:03
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 22:12:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 19:30:03
User entered empty.	Sheldon Warren (b) (4) (b) (4)	29 Oct 2020 21:35:06

**US3512248**

**Folder: Safety Call Day 50 (1)**

**Form: Continuing**

**Generated On: 10 Jun 2021 07:56:44**

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:23:03
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 22:12:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 19:30:12
User entered 'Yes (Y)'	Sheldon Warren (b) (4) (b) (4)	29 Oct 2020 21:35:10



**US3512248**

**Folder: Safety Call Day 50 (1)**

**Form: Continuing**

**Generated On: 10 Jun 2021 07:56:44**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:23:03
User entered 'I'	System	29 Oct 2020 21:35:10

**US3512248**

**Folder: Visit 3 Day 57 (1)**

**Form: Visit Date**

**Generated On: 10 Jun 2021 07:56:44**

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:23:03
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 22:12:02
DataPoint Verified.	(b) (4)	(b) (4), (b) (6)
DataPoint Verified.	(b) (4), (b) (6)	14 Dec 2020 16:38:54
DataPoint Un-verified.	(b) (4), (b) (6)	17 Nov 2020 19:30:51
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 19:30:19
User entered 'Yes (Y)'	Brenda Anderson (b) (4)	12 Nov 2020 13:22:43
	(b) (4)	

**US3512248**

**Folder: Visit 3 Day 57 (1)**

**Form: Visit Date**

**Generated On: 10 Jun 2021 07:56:44**

[Visit date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:23:03
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 22:12:02
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	14 Dec 2020 16:38:54
DataPoint Un-verified.	(b) (4), (b) (6)	17 Nov 2020 19:30:52
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 19:30:19
User entered '5 Nov 2020'	Brenda Anderson (b) (4)	12 Nov 2020 13:22:43
	(b) (4)	

US3512248

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 10 Jun 2021 07:56:44

[Was visit performed at the participant's home or at the clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:23:03
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 22:12:02
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	14 Dec 2020 16:38:54
DataPoint Un-verified.	(b) (4), (b) (6)	17 Nov 2020 19:30:54
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 19:30:19
User entered 'Clinic (Clinic)'	Brenda Anderson (b) (4)	12 Nov 2020 13:22:43
	(b) (4)	

**US3512248**

**Folder: Visit 3 Day 57 (1)**

**Form: Visit Date**

**Generated On: 10 Jun 2021 07:56:44**

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:23:03
User entered 'VISIT3'	System	12 Nov 2020 13:22:43

US3512248

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 07:56:44

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:23:03
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 22:12:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Dec 2020 16:39:09
User entered 'Yes (Y)'	Brenda Anderson (b) (4) (b) (4)	12 Nov 2020 13:23:22

US3512248

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 07:56:44

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:23:03
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 22:12:02
DataPoint Verified.	(b) (4)	(b) (4), (b) (6)
User entered '5 Nov 2020'	Brenda Anderson (b) (4)	12 Nov 2020 13:23:22
	(b) (4)	

**US3512248**

**Folder: Visit 3 Day 57 (1)**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 07:56:44**

[Time of assessment \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:23:03
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 22:12:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Dec 2020 16:39:09
User entered '11:10'	Brenda Anderson (b) (4) (b) (4)	12 Nov 2020 13:23:22



**US3512248**

**Folder: Visit 3 Day 57 (1)**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 07:56:44**

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:23:03
User entered '5 Nov 2020 11:10'	System	12 Nov 2020 13:23:22

US3512248

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 07:56:44

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:23:03
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 22:12:02
DataPoint Verified.	(b) (4)	(b) (4), (b) (6)
User entered '97.3' F	Brenda Anderson (b) (4)	12 Nov 2020 13:23:22
	(b) (4)	

US3512248

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 07:56:44

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:23:03
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 22:12:02
DataPoint Verified.	(b) (4)	(b) (4), (b) (6)
User entered 'Oral (Oral)'	Brenda Anderson (b) (4)	12 Nov 2020 13:23:22
	(b) (4)	

**US3512248**

**Folder: Visit 3 Day 57 (1)**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 07:56:44**

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:23:03
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 22:12:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Dec 2020 16:39:09
User entered empty.	Brenda Anderson (b) (4) (b) (4)	12 Nov 2020 13:23:22

**US3512248**

**Folder: Visit 3 Day 57 (1)**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 07:56:44**

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:23:03
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 22:12:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Dec 2020 16:39:09
User entered '66'	Brenda Anderson (b) (4) (b) (4)	12 Nov 2020 13:23:22

**US3512248**

**Folder: Visit 3 Day 57 (1)**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 07:56:44**

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:23:03
User entered 'bpm'	System	12 Nov 2020 13:23:22

US3512248

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 07:56:44

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:23:03
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 22:12:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Dec 2020 16:39:09
User entered '18'	Brenda Anderson (b) (4) (b) (4)	12 Nov 2020 13:23:22

US3512248

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 07:56:44

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:23:03
User entered 'breaths/min'	System	12 Nov 2020 13:23:22



US3512248

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 07:56:44

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:23:03
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 22:12:02
DataPoint Verified.	(b) (4)	(b) (4), (b) (6)
User entered '145'	Brenda Anderson (b) (4)	12 Nov 2020 13:23:22
	(b) (4)	

**US3512248**

**Folder: Visit 3 Day 57 (1)**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 07:56:44**

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:23:03
User entered 'mmHg'	System	12 Nov 2020 13:23:22

**US3512248**

**Folder: Visit 3 Day 57 (1)**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 07:56:44**

[Diastolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:23:03
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 22:12:02
DataPoint Verified.	(b) (4)	(b) (4), (b) (6)
User entered '88'	Brenda Anderson (b) (4)	12 Nov 2020 13:23:22
	(b) (4)	

**US3512248**

**Folder: Visit 3 Day 57 (1)**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 07:56:44**

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:23:03
User entered 'mmHg'	System	12 Nov 2020 13:23:22

US3512248

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 07:56:44

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) [REDACTED]	24 Apr 2021 14:23:03

**US3512248**

**Folder: Visit 3 Day 57 (1)**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 07:56:44**

[Weight \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) [REDACTED]	24 Apr 2021 14:23:03

US3512248

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Generated On: 10 Jun 2021 07:56:44

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:23:03
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 22:12:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Dec 2020 16:39:14
User entered 'No (N)'	Brenda Anderson (b) (4) (b) (4)	12 Nov 2020 13:23:28

US3512248

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Generated On: 10 Jun 2021 07:56:44

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:23:03
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 22:12:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Dec 2020 16:39:14
User entered empty.	Brenda Anderson (b) (4) (b) (4)	12 Nov 2020 13:23:28



**US3512248**

**Folder: Visit 3 Day 57 (1)**

**Form: Immunogenicity Assessment**

**Generated On: 10 Jun 2021 07:56:44**

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:23:03
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 22:12:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Dec 2020 16:39:18
User entered 'Yes (Y)'	Brenda Anderson (b) (4) (b) (4)	12 Nov 2020 13:23:49

US3512248

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 07:56:44

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:23:03
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 22:12:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Dec 2020 16:39:18
User entered '5 Nov 2020'	Brenda Anderson (b) (4) (b) (4)	12 Nov 2020 13:23:49

**US3512248**

**Folder: Visit 3 Day 57 (1)**

**Form: Immunogenicity Assessment**

**Generated On: 10 Jun 2021 07:56:44**

[Collection time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:23:03
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 22:12:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Dec 2020 16:39:18
User entered '11:16'	Brenda Anderson (b) (4) (b) (4)	12 Nov 2020 13:23:49

**US3512248**

**Folder: Visit 3 Day 57 (1)**

**Form: Immunogenicity Assessment**

**Generated On: 10 Jun 2021 07:56:44**

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:23:03
User entered '5 Nov 2020 11:16'	System	12 Nov 2020 13:23:49

US3512248

Folder: Visit 3 Day 57 (1)

Form: Continuing

Generated On: 10 Jun 2021 07:56:44

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:23:03
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 22:12:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Dec 2020 16:39:22
User entered 'Yes (Y)'	Brenda Anderson (b) (4) (b) (4)	12 Nov 2020 13:23:55

**US3512248**

**Folder: Visit 3 Day 57 (1)**

**Form: Continuing**

**Generated On: 10 Jun 2021 07:56:44**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:23:03
User entered 'I'	System	12 Nov 2020 13:23:55

**US3512248**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:56:44**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:52:02
Data entry locked.	System	10 Sep 2020 17:24:28
User entered 'Day 64'	System	10 Sep 2020 17:24:28

**US3512248**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:56:44**

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:52:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FCE43EC3-F1E0-47A1-B438-4D694934F821)', Time: '2020-11-13T16:01:06', User OID: 'PatientReportedOutcome (US3512248)', ODM File OID: '1b829c12-e781-415e-9945-eb87b5382a11'	System	13 Nov 2020 21:01:43
User entered 'No (N)'	System	13 Nov 2020 21:01:43



US3512248

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:56:44

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:52:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FCE43EC3-F1E0-47A1-B438-4D694934F821)', Time: '2020-11-13T16:01:21', User OID: 'PatientReportedOutcome (US3512248)', ODM File OID: '1b829c12-e781-415e-9945-eb87b5382a11'	System	13 Nov 2020 21:01:43
User entered 'No (N)'	System	13 Nov 2020 21:01:43

**US3512248**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:56:44**

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:52:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FCE43EC3-F1E0-47A1-B438-4D694934F821)', Time: '2020-11-13T16:01:32', User OID: 'PatientReportedOutcome (US3512248)', ODM File OID: '1b829c12-e781-415e-9945-eb87b5382a11' User entered '13 Nov 2020 16:01:32'	System	13 Nov 2020 21:01:43
	System	13 Nov 2020 21:01:43

**US3512248**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:56:44**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:52:02
Data entry locked.	System	10 Sep 2020 17:24:28
User entered '10 Nov 2020 00:01'	System	10 Sep 2020 17:24:28

**US3512248**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:56:44**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:52:02
Data entry locked.	System	10 Sep 2020 17:24:28
User entered '14 Nov 2020 23:59'	System	10 Sep 2020 17:24:28

**US3512248**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:56:44**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:44:55
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 07:06:03
Data entry locked.	System	10 Sep 2020 17:24:28
User entered 'Day 71'	System	10 Sep 2020 17:24:28

US3512248

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:56:44

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:44:55
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 07:06:03

US3512248

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:56:44

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:44:55
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 07:06:03

**US3512248**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:56:44**

[Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:44:55
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 07:06:03



US3512248

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:56:44

[Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:44:55
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 07:06:03

**US3512248**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:56:44**

**Fever (Temperature  $\geq$  100.4°F/38°C)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:44:55
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 07:06:03

**US3512248**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:56:44**

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:44:55
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 07:06:03

**US3512248**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:56:44**

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:44:55
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 07:06:03

**US3512248**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:56:44**

[Shortness of breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:44:55
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 07:06:03

**US3512248**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:56:44**

[Difficulty breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:44:55
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 07:06:03

**US3512248**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:56:44**

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:44:55
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 07:06:03

**US3512248**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:56:44**

[Muscle aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:44:55
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 07:06:03



**US3512248**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:56:44**

[Body aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:44:55
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 07:06:03

**US3512248**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:56:44**

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:44:55
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 07:06:03

**US3512248**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:56:44**

[New loss of taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:44:55
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 07:06:03

**US3512248**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:56:44**

[New loss of smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:44:55
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 07:06:03

**US3512248**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:56:44**

[Sore throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:44:55
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 07:06:03

**US3512248**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:56:44**

[Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:44:55
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 07:06:03

**US3512248**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:56:44**

[Runny nose](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:44:55
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 07:06:03

**US3512248**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:56:44**

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:44:55
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 07:06:03



**US3512248**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:56:44**

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:44:55
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 07:06:03

**US3512248**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:56:44**

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:44:55
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 07:06:03

**US3512248**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:56:44**

[Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:44:55
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 07:06:03

US3512248

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:56:44

[Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:44:55
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 07:06:03

**US3512248**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:56:44**

[Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:44:55
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 07:06:03

**US3512248**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:56:44**

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:44:55
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 07:06:03

**US3512248**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:56:44**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:44:55
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 07:06:03
Data entry locked.	System	10 Sep 2020 17:24:28
User entered '17 Nov 2020 00:01'	System	10 Sep 2020 17:24:28

**US3512248**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:56:44**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:44:55
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 07:06:03
Data entry locked.	System	10 Sep 2020 17:24:28
User entered '21 Nov 2020 23:59'	System	10 Sep 2020 17:24:28



**US3512248**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:56:44**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:06:03
Amendment Manager: User entered 'Day 75'	System	20 Nov 2020 07:06:03

**US3512248**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:56:44**

[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 (FCE43EC3-F1E0-47A1-B438-4D694934F821)', Time: '2020-11-24T07:11:08', User OID: 'PatientReportedOutcome (US3512248)', ODM File OID: 'cc64359d-d3e6-425f-bde4-79c9104057b5'	System	24 Nov 2020 12:11:43
User entered 'No (N)'	System	24 Nov 2020 12:11:43

**US3512248**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:56:44**

[Have you been exposed to someone with 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 (FCE43EC3-F1E0-47A1-B438-4D694934F821)', Time: '2020-11-24T07:11:20', User OID: 'PatientReportedOutcome (US3512248)', ODM File OID: 'cc64359d-d3e6-425f-bde4-79c9104057b5' User entered 'No (N)'	System	24 Nov 2020 12:11:43

**US3512248**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:56:44**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FCE43EC3-F1E0-47A1-B438-4D694934F821)', Time: '2020-11-24T07:11:37', User OID: 'PatientReportedOutcome (US3512248)', ODM File OID: 'cc64359d-d3e6-425f-bde4-79c9104057b5' User entered '24 Nov 2020 07:11:37'	System	24 Nov 2020 12:11:43
	System	24 Nov 2020 12:11:43

**US3512248**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:56:44**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:06:03
Amendment Manager: User entered '21 Nov 2020 00:01'	System	20 Nov 2020 07:06:03

**US3512248**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:56:44**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:06:03
Amendment Manager: User entered '25 Nov 2020 23:59'	System	20 Nov 2020 07:06:03

**US3512248**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:56:44**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:06:03
Amendment Manager: User entered 'Day 82'	System	20 Nov 2020 07:06:03

**US3512248**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:56:44**

[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 (FCE43EC3-F1E0-47A1-B438-4D694934F821)', Time: '2020-11-30T23:08:27', User OID: 'PatientReportedOutcome (US3512248)', ODM File OID: '2f5c575a-09b4-4995-ae0b-e571e22c30d7' User entered 'No (N)'	System	01 Dec 2020 04:08:44
	System	01 Dec 2020 04:08:44



**US3512248**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:56:44**

Have you been exposed to someone with 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 (FCE43EC3-F1E0-47A1-B438-4D694934F821)', Time: '2020-11-30T23:08:34', User OID: 'PatientReportedOutcome (US3512248)', ODM File OID: '2f5c575a-09b4-4995-ae0b-e571e22c30d7' User entered 'No (N)'	System	01 Dec 2020 04:08:44
	System	01 Dec 2020 04:08:44

**US3512248**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:56:44**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FCE43EC3-F1E0-47A1-B438-4D694934F821)', Time: '2020-11-30T23:08:40', User OID: 'PatientReportedOutcome (US3512248)', ODM File OID: '2f5c575a-09b4-4995-ae0b-e571e22c30d7'	System	01 Dec 2020 04:08:44
User entered '30 Nov 2020 23:08:40'	System	01 Dec 2020 04:08:44

**US3512248**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:56:44**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:06:03
Amendment Manager: User entered '28 Nov 2020 00:01'	System	20 Nov 2020 07:06:03

**US3512248**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:56:44**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:06:03
Amendment Manager: User entered '02 Dec 2020 23:59'	System	20 Nov 2020 07:06:03

**US3512248**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:56:44**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:06:03
Amendment Manager: User entered 'Day 89'	System	20 Nov 2020 07:06:03

**US3512248**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:56:44**

[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 (FCE43EC3-F1E0-47A1-B438-4D694934F821)', Time: '2020-12-05T07:08:03', User OID: 'PatientReportedOutcome (US3512248)', ODM File OID: 'd9313ca1-b7e9-419a-9062-66a459451cad' User entered 'No (N)'	System	05 Dec 2020 12:08:25
	System	05 Dec 2020 12:08:25

**US3512248**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:56:44**

[Have you been exposed to someone with 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 (FCE43EC3-F1E0-47A1-B438-4D694934F821)', Time: '2020-12-05T07:08:11', User OID: 'PatientReportedOutcome (US3512248)', ODM File OID: 'd9313ca1-b7e9-419a-9062-66a459451cad' User entered 'No (N)'	System	05 Dec 2020 12:08:25
	System	05 Dec 2020 12:08:25

**US3512248**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:56:44**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FCE43EC3-F1E0-47A1-B438-4D694934F821)', Time: '2020-12-05T07:08:22', User OID: 'PatientReportedOutcome (US3512248)', ODM File OID: 'd9313ca1-b7e9-419a-9062-66a459451cad' User entered '05 Dec 2020 07:08:22'	System	05 Dec 2020 12:08:25
	System	05 Dec 2020 12:08:25



**US3512248**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:56:44**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:06:03
Amendment Manager: User entered '05 Dec 2020 00:01'	System	20 Nov 2020 07:06:03

**US3512248**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:56:44**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:06:03
Amendment Manager: User entered '09 Dec 2020 23:59'	System	20 Nov 2020 07:06:03

**US3512248**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:56:44**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:06:03
Amendment Manager: User entered 'Day 96'	System	20 Nov 2020 07:06:03

**US3512248**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:56:44**

[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 (FCE43EC3-F1E0-47A1-B438-4D694934F821)', Time: '2020-12-12T08:47:49', User OID: 'PatientReportedOutcome (US3512248)', ODM File OID: '18d4ebf5-137b-4464-83f8-c25e2bde5f43'	System	12 Dec 2020 13:48:20
User entered 'No (N)'	System	12 Dec 2020 13:48:20

**US3512248**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:56:44**

Have you been exposed to someone with 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 (FCE43EC3-F1E0-47A1-B438-4D694934F821)', Time: '2020-12-12T08:48:05', User OID: 'PatientReportedOutcome (US3512248)', ODM File OID: '18d4ebf5-137b-4464-83f8-c25e2bde5f43'	System	12 Dec 2020 13:48:20
User entered 'No (N)'	System	12 Dec 2020 13:48:20

**US3512248**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:56:44**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FCE43EC3-F1E0-47A1-B438-4D694934F821)', Time: '2020-12-12T08:48:18', User OID: 'PatientReportedOutcome (US3512248)', ODM File OID: '18d4ebf5-137b-4464-83f8-c25e2bde5f43' User entered '12 Dec 2020 08:48:18'	System	12 Dec 2020 13:48:20
	System	12 Dec 2020 13:48:20

**US3512248**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:56:44**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:06:03
Amendment Manager: User entered '12 Dec 2020 00:01'	System	20 Nov 2020 07:06:03

**US3512248**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:56:44**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:06:03
Amendment Manager: User entered '16 Dec 2020 23:59'	System	20 Nov 2020 07:06:03



**US3512248**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:56:44**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:06:03
Amendment Manager: User entered 'Day 103'	System	20 Nov 2020 07:06:03

**US3512248**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:56:44**

[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 (FCE43EC3-F1E0-47A1-B438-4D694934F821)', Time: '2020-12-19T07:40:10', User OID: 'PatientReportedOutcome (US3512248)', ODM File OID: '22e95c4c-a8d8-4d0d-b8b4-1bc3b1d217bf' User entered 'No (N)'	System	19 Dec 2020 12:40:33
	System	19 Dec 2020 12:40:33

**US3512248**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:56:44**

Have you been exposed to someone with 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 (FCE43EC3-F1E0-47A1-B438-4D694934F821)', Time: '2020-12-19T07:40:20', User OID: 'PatientReportedOutcome (US3512248)', ODM File OID: '22e95c4c-a8d8-4d0d-b8b4-1bc3b1d217bf' User entered 'No (N)'	System	19 Dec 2020 12:40:33
	System	19 Dec 2020 12:40:33

**US3512248**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:56:44**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FCE43EC3-F1E0-47A1-B438-4D694934F821)', Time: '2020-12-19T07:40:30', User OID: 'PatientReportedOutcome (US3512248)', ODM File OID: '22e95c4c-a8d8-4d0d-b8b4-1bc3b1d217bf' User entered '19 Dec 2020 07:40:30'	System	19 Dec 2020 12:40:33
	System	19 Dec 2020 12:40:33

**US3512248**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:56:44**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:06:03
Amendment Manager: User entered '19 Dec 2020 00:01'	System	20 Nov 2020 07:06:03

**US3512248**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:56:44**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:06:03
Amendment Manager: User entered '23 Dec 2020 23:59'	System	20 Nov 2020 07:06:03

**US3512248**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:56:44**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:06:03
Amendment Manager: User entered 'Day 110'	System	20 Nov 2020 07:06:03

**US3512248**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:56:44**

[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 (FCE43EC3-F1E0-47A1-B438-4D694934F821)', Time: '2020-12-28T19:16:24', User OID: 'PatientReportedOutcome (US3512248)', ODM File OID: 'd6dfb62e-9c2b-43bc-924b-7231969240a0' User entered 'No (N)'	System	29 Dec 2020 00:16:41
	System	29 Dec 2020 00:16:41



**US3512248**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:56:44**

Have you been exposed to someone with 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 (FCE43EC3-F1E0-47A1-B438-4D694934F821)', Time: '2020-12-28T19:16:31', User OID: 'PatientReportedOutcome (US3512248)', ODM File OID: 'd6dfb62e-9c2b-43bc-924b-7231969240a0' User entered 'No (N)'	System	29 Dec 2020 00:16:41
	System	29 Dec 2020 00:16:41

**US3512248**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:56:44**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FCE43EC3-F1E0-47A1-B438-4D694934F821)', Time: '2020-12-28T19:16:39', User OID: 'PatientReportedOutcome (US3512248)', ODM File OID: 'd6dfb62e-9c2b-43bc-924b-7231969240a0' User entered '28 Dec 2020 19:16:39'	System	29 Dec 2020 00:16:41
	System	29 Dec 2020 00:16:41

**US3512248**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:56:44**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:06:03
Amendment Manager: User entered '26 Dec 2020 00:01'	System	20 Nov 2020 07:06:03

**US3512248**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:56:44**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:06:03
Amendment Manager: User entered '30 Dec 2020 23:59'	System	20 Nov 2020 07:06:03

**US3512248**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:56:44**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:06:03
Amendment Manager: User entered 'Day 117'	System	20 Nov 2020 07:06:03

**US3512248**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:56:44**

[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 (FCE43EC3-F1E0-47A1-B438-4D694934F821)', Time: '2021-01-02T19:20:53', User OID: 'PatientReportedOutcome (US3512248)', ODM File OID: '17b37f71-3a31-4698-938f-7668a618d41a' User entered 'No (N)'	System	03 Jan 2021 00:21:07
	System	03 Jan 2021 00:21:07

**US3512248**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:56:44**

Have you been exposed to someone with 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 (FCE43EC3-F1E0-47A1-B438-4D694934F821)', Time: '2021-01-02T19:20:56', User OID: 'PatientReportedOutcome (US3512248)', ODM File OID: '17b37f71-3a31-4698-938f-7668a618d41a'	System	03 Jan 2021 00:21:07
User entered 'No (N)'	System	03 Jan 2021 00:21:07

**US3512248**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:56:44**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FCE43EC3-F1E0-47A1-B438-4D694934F821)', Time: '2021-01-02T19:21:04', User OID: 'PatientReportedOutcome (US3512248)', ODM File OID: '17b37f71-3a31-4698-938f-7668a618d41a' User entered '02 Jan 2021 19:21:04'	System	03 Jan 2021 00:21:07
	System	03 Jan 2021 00:21:07



**US3512248**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:56:44**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:06:03
Amendment Manager: User entered '02 Jan 2021 00:01'	System	20 Nov 2020 07:06:03

**US3512248**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:56:44**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:06:03
Amendment Manager: User entered '06 Jan 2021 23:59'	System	20 Nov 2020 07:06:03

**US3512248**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:56:44**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:06:03
Amendment Manager: User entered 'Day 124'	System	20 Nov 2020 07:06:03

**US3512248**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:56:44**

[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 (FCE43EC3-F1E0-47A1-B438-4D694934F821)', Time: '2021-01-09T09:49:11', User OID: 'PatientReportedOutcome (US3512248)', ODM File OID: '7df8ddea-f5a6-451c-8457-4e51de8ef879'	System	09 Jan 2021 14:49:37
User entered 'No (N)'	System	09 Jan 2021 14:49:37

**US3512248**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:56:44**

Have you been exposed to someone with 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 (FCE43EC3-F1E0-47A1-B438-4D694934F821)', Time: '2021-01-09T09:49:21', User OID: 'PatientReportedOutcome (US3512248)', ODM File OID: '7df8ddea-f5a6-451c-8457-4e51de8ef879'	System	09 Jan 2021 14:49:37
User entered 'No (N)'	System	09 Jan 2021 14:49:37

**US3512248**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:56:44**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FCE43EC3-F1E0-47A1-B438-4D694934F821)', Time: '2021-01-09T09:49:33', User OID: 'PatientReportedOutcome (US3512248)', ODM File OID: '7df8ddea-f5a6-451c-8457-4e51de8ef879' User entered '09 Jan 2021 09:49:33'	System	09 Jan 2021 14:49:37
	System	09 Jan 2021 14:49:37

**US3512248**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:56:44**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:06:03
Amendment Manager: User entered '09 Jan 2021 00:01'	System	20 Nov 2020 07:06:03

**US3512248**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:56:44**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:06:03
Amendment Manager: User entered '13 Jan 2021 23:59'	System	20 Nov 2020 07:06:03



**US3512248**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:56:44**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:06:03
Amendment Manager: User entered 'Day 131'	System	20 Nov 2020 07:06:03

**US3512248**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:56:44**

[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 (FCE43EC3-F1E0-47A1-B438-4D694934F821)', Time: '2021-01-16T20:16:27', User OID: 'PatientReportedOutcome (US3512248)', ODM File OID: '7af2b6e3-732c-4c66-ba30-17a16877d79f' User entered 'No (N)'	System	17 Jan 2021 01:16:46
	System	17 Jan 2021 01:16:46

**US3512248**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:56:44**

Have you been exposed to someone with 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 (FCE43EC3-F1E0-47A1-B438-4D694934F821)', Time: '2021-01-16T20:16:34', User OID: 'PatientReportedOutcome (US3512248)', ODM File OID: '7af2b6e3-732c-4c66-ba30-17a16877d79f' User entered 'No (N)'	System	17 Jan 2021 01:16:46

**US3512248**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:56:44**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FCE43EC3-F1E0-47A1-B438-4D694934F821)', Time: '2021-01-16T20:16:44', User OID: 'PatientReportedOutcome (US3512248)', ODM File OID: '7af2b6e3-732c-4c66-ba30-17a16877d79f' User entered '16 Jan 2021 20:16:44'	System	17 Jan 2021 01:16:46
	System	17 Jan 2021 01:16:46

**US3512248**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:56:44**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:06:03
Amendment Manager: User entered '16 Jan 2021 00:01'	System	20 Nov 2020 07:06:03

**US3512248**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:56:44**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:06:03
Amendment Manager: User entered '20 Jan 2021 23:59'	System	20 Nov 2020 07:06:03

**US3512248**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:56:44**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:06:03
Amendment Manager: User entered 'Day 138'	System	20 Nov 2020 07:06:03

**US3512248**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:56:44**

[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 (FCE43EC3-F1E0-47A1-B438-4D694934F821)', Time: '2021-01-23T00:01:39', User OID: 'PatientReportedOutcome (US3512248)', ODM File OID: '9503739e-3b68-4cfa-88eb-cb923e8aa365' User entered 'No (N)'	System	23 Jan 2021 05:02:29
	System	23 Jan 2021 05:02:29



**US3512248**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:56:44**

Have you been exposed to someone with 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 (FCE43EC3-F1E0-47A1-B438-4D694934F821)', Time: '2021-01-23T00:01:45', User OID: 'PatientReportedOutcome (US3512248)', ODM File OID: '9503739e-3b68-4cfa-88eb-cb923e8aa365'	System	23 Jan 2021 05:02:29
User entered 'No (N)'	System	23 Jan 2021 05:02:29

**US3512248**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:56:44**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FCE43EC3-F1E0-47A1-B438-4D694934F821)', Time: '2021-01-23T00:01:54', User OID: 'PatientReportedOutcome (US3512248)', ODM File OID: '9503739e-3b68-4cfa-88eb-cb923e8aa365' User entered '23 Jan 2021 00:01:54'	System	23 Jan 2021 05:02:29
	System	23 Jan 2021 05:02:29

**US3512248**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:56:44**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:06:03
Amendment Manager: User entered '23 Jan 2021 00:01'	System	20 Nov 2020 07:06:03

**US3512248**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:56:44**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:06:03
Amendment Manager: User entered '27 Jan 2021 23:59'	System	20 Nov 2020 07:06:03

**US3512248**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:56:44**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:06:03
Amendment Manager: User entered 'Day 145'	System	20 Nov 2020 07:06:03

**US3512248**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:56:44**

[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 (FCE43EC3-F1E0-47A1-B438-4D694934F821)', Time: '2021-01-30T08:18:24', User OID: 'PatientReportedOutcome (US3512248)', ODM File OID: '4fd17553-0833-495a-9b25-d17791bfe421' User entered 'No (N)'	System	30 Jan 2021 13:19:56
	System	30 Jan 2021 13:19:56

**US3512248**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:56:44**

Have you been exposed to someone with 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 (FCE43EC3-F1E0-47A1-B438-4D694934F821)', Time: '2021-01-30T08:18:31', User OID: 'PatientReportedOutcome (US3512248)', ODM File OID: '4fd17553-0833-495a-9b25-d17791bfe421' User entered 'No (N)'	System	30 Jan 2021 13:19:56
	System	30 Jan 2021 13:19:56

**US3512248**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:56:44**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FCE43EC3-F1E0-47A1-B438-4D694934F821)', Time: '2021-01-30T08:18:48', User OID: 'PatientReportedOutcome (US3512248)', ODM File OID: '4fd17553-0833-495a-9b25-d17791bfe421' User entered '30 Jan 2021 08:18:48'	System	30 Jan 2021 13:19:56
	System	30 Jan 2021 13:19:56



**US3512248**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:56:44**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:06:03
Amendment Manager: User entered '30 Jan 2021 00:01'	System	20 Nov 2020 07:06:03

**US3512248**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:56:44**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:06:03
Amendment Manager: User entered '03 Feb 2021 23:59'	System	20 Nov 2020 07:06:03

**US3512248**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:56:44**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:06:03
Amendment Manager: User entered 'Day 152'	System	20 Nov 2020 07:06:03

**US3512248**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:56:44**

[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 (FCE43EC3-F1E0-47A1-B438-4D694934F821)', Time: '2021-02-06T12:54:30', User OID: 'PatientReportedOutcome (US3512248)', ODM File OID: 'f3014190-6a35-4d87-9c16-b7e3d95526b2' User entered 'No (N)'	System	06 Feb 2021 17:54:43

**US3512248**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:56:44**

Have you been exposed to someone with 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 (FCE43EC3-F1E0-47A1-B438-4D694934F821)', Time: '2021-02-06T12:54:35', User OID: 'PatientReportedOutcome (US3512248)', ODM File OID: 'f3014190-6a35-4d87-9c16-b7e3d95526b2' User entered 'No (N)'	System	06 Feb 2021 17:54:43

**US3512248**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:56:44**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FCE43EC3-F1E0-47A1-B438-4D694934F821)', Time: '2021-02-06T12:54:41', User OID: 'PatientReportedOutcome (US3512248)', ODM File OID: 'f3014190-6a35-4d87-9c16-b7e3d95526b2' User entered '06 Feb 2021 12:54:41'	System	06 Feb 2021 17:54:43
	System	06 Feb 2021 17:54:43

**US3512248**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:56:44**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:06:03
Amendment Manager: User entered '06 Feb 2021 00:01'	System	20 Nov 2020 07:06:03

**US3512248**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:56:44**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:06:03
Amendment Manager: User entered '10 Feb 2021 23:59'	System	20 Nov 2020 07:06:03



**US3512248**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:56:44**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:06:03
Amendment Manager: User entered 'Day 159'	System	20 Nov 2020 07:06:03

**US3512248**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:56:44**

[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 (FCE43EC3-F1E0-47A1-B438-4D694934F821)', Time: '2021-02-15T12:18:44', User OID: 'PatientReportedOutcome (US3512248)', ODM File OID: 'ccfc109d-ae51-424e-adeb-18786219641a' User entered 'No (N)'	System	15 Feb 2021 18:19:05
	System	15 Feb 2021 18:19:05

**US3512248**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:56:44**

Have you been exposed to someone with 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 (FCE43EC3-F1E0-47A1-B438-4D694934F821)', Time: '2021-02-15T12:18:48', User OID: 'PatientReportedOutcome (US3512248)', ODM File OID: 'ccfc109d-ae51-424e-adeb-18786219641a' User entered 'No (N)'	System	15 Feb 2021 18:19:05

**US3512248**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:56:44**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FCE43EC3-F1E0-47A1-B438-4D694934F821)', Time: '2021-02-15T12:18:59', User OID: 'PatientReportedOutcome (US3512248)', ODM File OID: 'ccfc109d-ae51-424e-adeb-18786219641a' User entered '15 Feb 2021 12:18:59'	System	15 Feb 2021 18:19:05
	System	15 Feb 2021 18:19:05

**US3512248**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:56:44**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:06:03
Amendment Manager: User entered '13 Feb 2021 00:01'	System	20 Nov 2020 07:06:03

**US3512248**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:56:44**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:06:03
Amendment Manager: User entered '17 Feb 2021 23:59'	System	20 Nov 2020 07:06:03

**US3512248**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:56:44**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:06:03
Amendment Manager: User entered 'Day 166'	System	20 Nov 2020 07:06:03

**US3512248**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:56:44**

[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 (FCE43EC3-F1E0-47A1-B438-4D694934F821)', Time: '2021-02-20T00:25:28', User OID: 'PatientReportedOutcome (US3512248)', ODM File OID: '2547b943-012a-46f5-8178-95784c61b1be' User entered 'Yes (Y)'	System	20 Feb 2021 05:26:12
	System	20 Feb 2021 05:26:12



**US3512248**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:56:44**

Have you been exposed to someone with 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 (FCE43EC3-F1E0-47A1-B438-4D694934F821)', Time: '2021-02-20T00:25:34', User OID: 'PatientReportedOutcome (US3512248)', ODM File OID: '2547b943-012a-46f5-8178-95784c61b1be' User entered 'No (N)'	System	20 Feb 2021 05:26:12
	System	20 Feb 2021 05:26:12

**US3512248**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:56:44**

[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 (FCE43EC3-F1E0-47A1-B438-4D694934F821)', Time: '2021-02-20T00:25:41', User OID: 'PatientReportedOutcome (US3512248)', ODM File OID: '2547b943-012a-46f5-8178-95784c61b1be' User entered 'No (N)'	System	20 Feb 2021 05:26:12
	System	20 Feb 2021 05:26:12

**US3512248**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:56:44**

[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 (FCE43EC3-F1E0-47A1-B438-4D694934F821)', Time: '2021-02-20T00:25:47', User OID: 'PatientReportedOutcome (US3512248)', ODM File OID: '2547b943-012a-46f5-8178-95784c61b1be' User entered 'No (N)'	System	20 Feb 2021 05:26:12
	System	20 Feb 2021 05:26:12

**US3512248**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:56:44**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FCE43EC3-F1E0-47A1-B438-4D694934F821)', Time: '2021-02-20T00:26:08', User OID: 'PatientReportedOutcome (US3512248)', ODM File OID: '2547b943-012a-46f5-8178-95784c61b1be' User entered '20 Feb 2021 00:26:08'	System	20 Feb 2021 05:26:12
	System	20 Feb 2021 05:26:12

**US3512248**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:56:44**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:06:03
Amendment Manager: User entered '20 Feb 2021 00:01'	System	20 Nov 2020 07:06:03

**US3512248**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:56:44**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:06:03
Amendment Manager: User entered '24 Feb 2021 23:59'	System	20 Nov 2020 07:06:03

**US3512248**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:56:44**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:06:03
Amendment Manager: User entered 'Day 173'	System	20 Nov 2020 07:06:03

**US3512248**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:56:44**

[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 (FCE43EC3-F1E0-47A1-B438-4D694934F821)', Time: '2021-03-02T17:59:51-05:00', User OID: 'PatientReportedOutcome (US3512248)', ODM File OID: '8e7a2a10-500b-4c55-8d78-d47ce1b2963f' User entered 'No (N)'	System	02 Mar 2021 23:00:20
	System	02 Mar 2021 23:00:20



**US3512248**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:56:44**

Have you been exposed to someone with 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 (FCE43EC3-F1E0-47A1-B438-4D694934F821)', Time: '2021-03-02T17:59:54-05:00', User OID: 'PatientReportedOutcome (US3512248)', ODM File OID: '8e7a2a10-500b-4c55-8d78-d47ce1b2963f'	System	02 Mar 2021 23:00:20
User entered 'No (N)'	System	02 Mar 2021 23:00:20

**US3512248**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:56:44**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FCE43EC3-F1E0-47A1-B438-4D694934F821)', Time: '2021-03-02T18:00:15-05:00', User OID: 'PatientReportedOutcome (US3512248)', ODM File OID: '8e7a2a10-500b-4c55-8d78-d47ce1b2963f'	System	02 Mar 2021 23:00:20
User entered '02 Mar 2021 18:00:15'	System	02 Mar 2021 23:00:20

**US3512248**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:56:44**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:06:03
Amendment Manager: User entered '27 Feb 2021 00:01'	System	20 Nov 2020 07:06:03

**US3512248**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:56:44**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:06:03
Amendment Manager: User entered '03 Mar 2021 23:59'	System	20 Nov 2020 07:06:03

**US3512248**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:56:44**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:06:03
Amendment Manager: User entered 'Day 180'	System	20 Nov 2020 07:06:03

**US3512248**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:56:44**

[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 (FCE43EC3-F1E0-47A1-B438-4D694934F821)', Time: '2021-03-08T12:20:11-05:00', User OID: 'PatientReportedOutcome (US3512248)', ODM File OID: 'd79ce928-6b78-47b5-8773-fab882ddb968'	System	08 Mar 2021 17:25:42
User entered 'No (N)'	System	08 Mar 2021 17:25:42

**US3512248**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:56:44**

Have you been exposed to someone with 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 (FCE43EC3-F1E0-47A1-B438-4D694934F821)', Time: '2021-03-08T12:20:20-05:00', User OID: 'PatientReportedOutcome (US3512248)', ODM File OID: 'd79ce928-6b78-47b5-8773-fab882ddb968'	System	08 Mar 2021 17:25:42
User entered 'No (N)'	System	08 Mar 2021 17:25:42

**US3512248**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:56:44**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FCE43EC3-F1E0-47A1-B438-4D694934F821)', Time: '2021-03-08T12:20:31-05:00', User OID: 'PatientReportedOutcome (US3512248)', ODM File OID: 'd79ce928-6b78-47b5-8773-fab882ddb968'	System	08 Mar 2021 17:25:42
User entered '08 Mar 2021 12:20:31'	System	08 Mar 2021 17:25:42



**US3512248**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:56:44**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:06:03
Amendment Manager: User entered '06 Mar 2021 00:01'	System	20 Nov 2020 07:06:03

**US3512248**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:56:44**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:06:03
Amendment Manager: User entered '10 Mar 2021 23:59'	System	20 Nov 2020 07:06:03

**US3512248**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:56:44**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:06:03
Amendment Manager: User entered 'Day 187'	System	20 Nov 2020 07:06:03

**US3512248**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:56:44**

[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 (FCE43EC3-F1E0-47A1-B438-4D694934F821)', Time: '2021-03-15T16:38:32-04:00', User OID: 'PatientReportedOutcome (US3512248)', ODM File OID: '5180584e-c7d7-4952-a467-201350d76bb4'	System	15 Mar 2021 20:38:47
User entered 'No (N)'	System	15 Mar 2021 20:38:47

**US3512248**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:56:44**

Have you been exposed to someone with 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 (FCE43EC3-F1E0-47A1-B438-4D694934F821)', Time: '2021-03-15T16:38:37-04:00', User OID: 'PatientReportedOutcome (US3512248)', ODM File OID: '5180584e-c7d7-4952-a467-201350d76bb4'	System	15 Mar 2021 20:38:47
User entered 'No (N)'	System	15 Mar 2021 20:38:47

**US3512248**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:56:44**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FCE43EC3-F1E0-47A1-B438-4D694934F821)', Time: '2021-03-15T16:38:44-04:00', User OID: 'PatientReportedOutcome (US3512248)', ODM File OID: '5180584e-c7d7-4952-a467-201350d76bb4' User entered '15 Mar 2021 16:38:44'	System	15 Mar 2021 20:38:47
	System	15 Mar 2021 20:38:47

**US3512248**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:56:44**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:06:03
Amendment Manager: User entered '13 Mar 2021 00:01'	System	20 Nov 2020 07:06:03

**US3512248**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:56:44**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:06:03
Amendment Manager: User entered '17 Mar 2021 23:59'	System	20 Nov 2020 07:06:03



**US3512248**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:56:44**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:06:03
Amendment Manager: User entered 'Day 194'	System	20 Nov 2020 07:06:03

**US3512248**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:56:44**

[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 (FCE43EC3-F1E0-47A1-B438-4D694934F821)', Time: '2021-03-22T12:13:44-04:00', User OID: 'PatientReportedOutcome (US3512248)', ODM File OID: 'a5691aa7-73f6-476f-95f8-9af48e54ff16'	System	22 Mar 2021 16:28:54
User entered 'No (N)'	System	22 Mar 2021 16:28:54

**US3512248**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:56:44**

Have you been exposed to someone with 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 (FCE43EC3-F1E0-47A1-B438-4D694934F821)', Time: '2021-03-22T12:13:51-04:00', User OID: 'PatientReportedOutcome (US3512248)', ODM File OID: 'a5691aa7-73f6-476f-95f8-9af48e54ff16'	System	22 Mar 2021 16:28:54
User entered 'No (N)'	System	22 Mar 2021 16:28:54

**US3512248**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:56:44**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FCE43EC3-F1E0-47A1-B438-4D694934F821)', Time: '2021-03-22T12:14:00-04:00', User OID: 'PatientReportedOutcome (US3512248)', ODM File OID: 'a5691aa7-73f6-476f-95f8-9af48e54ff16'	System	22 Mar 2021 16:28:54
User entered '22 Mar 2021 12:14:00'	System	22 Mar 2021 16:28:54

**US3512248**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:56:44**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:06:03
Amendment Manager: User entered '20 Mar 2021 00:01'	System	20 Nov 2020 07:06:03

**US3512248**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:56:44**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:06:03
Amendment Manager: User entered '24 Mar 2021 23:59'	System	20 Nov 2020 07:06:03

**US3512248**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:56:44**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:06:03
Amendment Manager: User entered 'Day 201'	System	20 Nov 2020 07:06:03

**US3512248**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:56:44**

[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 (FCE43EC3-F1E0-47A1-B438-4D694934F821)', Time: '2021-03-29T15:49:05-04:00', User OID: 'PatientReportedOutcome (US3512248)', ODM File OID: '9844c9e3-2b4f-46bf-b978-db3f230e7b9b'	System	29 Mar 2021 19:49:33
User entered 'No (N)'	System	29 Mar 2021 19:49:33



**US3512248**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:56:44**

[Have you been exposed to someone with 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 (FCE43EC3-F1E0-47A1-B438-4D694934F821)', Time: '2021-03-29T15:49:19-04:00', User OID: 'PatientReportedOutcome (US3512248)', ODM File OID: '9844c9e3-2b4f-46bf-b978-db3f230e7b9b'	System	29 Mar 2021 19:49:33
User entered 'No (N)'	System	29 Mar 2021 19:49:33

**US3512248**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:56:44**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FCE43EC3-F1E0-47A1-B438-4D694934F821)', Time: '2021-03-29T15:49:29-04:00', User OID: 'PatientReportedOutcome (US3512248)', ODM File OID: '9844c9e3-2b4f-46bf-b978-db3f230e7b9b'	System	29 Mar 2021 19:49:33
User entered '29 Mar 2021 15:49:29'	System	29 Mar 2021 19:49:33

**US3512248**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:56:44**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:06:03
Amendment Manager: User entered '27 Mar 2021 00:01'	System	20 Nov 2020 07:06:03

**US3512248**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:56:44**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:06:03
Amendment Manager: User entered '31 Mar 2021 23:59'	System	20 Nov 2020 07:06:03

**US3512248**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:56:44**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:06:03
Amendment Manager: User entered 'Day 208'	System	20 Nov 2020 07:06:03

**US3512248**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:56:44**

[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 (FCE43EC3-F1E0-47A1-B438-4D694934F821)', Time: '2021-04-07T15:20:48-04:00', User OID: 'PatientReportedOutcome (US3512248)', ODM File OID: '40132da7-1af3-4484-a92b-1bb25bae12e9'	System	07 Apr 2021 19:21:14
User entered 'No (N)'	System	07 Apr 2021 19:21:14

**US3512248**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:56:44**

Have you been exposed to someone with 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 (FCE43EC3-F1E0-47A1-B438-4D694934F821)', Time: '2021-04-07T15:20:53-04:00', User OID: 'PatientReportedOutcome (US3512248)', ODM File OID: '40132da7-1af3-4484-a92b-1bb25bae12e9'	System	07 Apr 2021 19:21:14
User entered 'No (N)'	System	07 Apr 2021 19:21:14

**US3512248**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:56:44**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FCE43EC3-F1E0-47A1-B438-4D694934F821)', Time: '2021-04-07T15:21:03-04:00', User OID: 'PatientReportedOutcome (US3512248)', ODM File OID: '40132da7-1af3-4484-a92b-1bb25bae12e9' User entered '07 Apr 2021 15:21:03'	System	07 Apr 2021 19:21:14
	System	07 Apr 2021 19:21:14



**US3512248**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:56:44**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:06:03
Amendment Manager: User entered '03 Apr 2021 00:01'	System	20 Nov 2020 07:06:03

**US3512248**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:56:44**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:06:03
Amendment Manager: User entered '07 Apr 2021 23:59'	System	20 Nov 2020 07:06:03

**US3512248**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:56:44**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:06:03
Amendment Manager: User entered 'Day 215'	System	20 Nov 2020 07:06:03

**US3512248**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:56:44**

[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 (FCE43EC3-F1E0-47A1-B438-4D694934F821)', Time: '2021-04-10T11:16:01-04:00', User OID: 'PatientReportedOutcome (US3512248)', ODM File OID: 'ca8418ea-2fbd-43fb-aea3-da8124c55237'	System	10 Apr 2021 15:16:16
User entered 'No (N)'	System	10 Apr 2021 15:16:16

**US3512248**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:56:44**

Have you been exposed to someone with 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 (FCE43EC3-F1E0-47A1-B438-4D694934F821)', Time: '2021-04-10T11:16:07-04:00', User OID: 'PatientReportedOutcome (US3512248)', ODM File OID: 'ca8418ea-2fbd-43fb-aea3-da8124c55237'	System	10 Apr 2021 15:16:16
User entered 'No (N)'	System	10 Apr 2021 15:16:16

**US3512248**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:56:44**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FCE43EC3-F1E0-47A1-B438-4D694934F821)', Time: '2021-04-10T11:16:13-04:00', User OID: 'PatientReportedOutcome (US3512248)', ODM File OID: 'ca8418ea-2fbd-43fb-aea3-da8124c55237'	System	10 Apr 2021 15:16:16
User entered '10 Apr 2021 11:16:13'	System	10 Apr 2021 15:16:16

**US3512248**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:56:44**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:06:03
Amendment Manager: User entered '10 Apr 2021 00:01'	System	20 Nov 2020 07:06:03

**US3512248**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:56:44**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:06:03
Amendment Manager: User entered '14 Apr 2021 23:59'	System	20 Nov 2020 07:06:03



**US3512248**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:56:44**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:06:03
Amendment Manager: User entered 'Day 222'	System	20 Nov 2020 07:06:03

**US3512248**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:56:44**

[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 (FCE43EC3-F1E0-47A1-B438-4D694934F821)', Time: '2021-04-17T10:29:39-04:00', User OID: 'PatientReportedOutcome (US3512248)', ODM File OID: '90e4b7ec-ca58-4f03-832c-7b2b32dfdebb'	System	17 Apr 2021 14:39:21
User entered 'Yes (Y)'	System	17 Apr 2021 14:39:21

**US3512248**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:56:44**

Have you been exposed to someone with 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 (FCE43EC3-F1E0-47A1-B438-4D694934F821)', Time: '2021-04-17T10:29:48-04:00', User OID: 'PatientReportedOutcome (US3512248)', ODM File OID: '90e4b7ec-ca58-4f03-832c-7b2b32dfdebb'	System	17 Apr 2021 14:39:21
User entered 'No (N)'	System	17 Apr 2021 14:39:21

**US3512248**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:56:44**

[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 (FCE43EC3-F1E0-47A1-B438-4D694934F821)', Time: '2021-04-17T10:30:04-04:00', User OID: 'PatientReportedOutcome (US3512248)', ODM File OID: '90e4b7ec-ca58-4f03-832c-7b2b32dfdebb'	System	17 Apr 2021 14:39:21
User entered 'Yes (Y)'	System	17 Apr 2021 14:39:21

**US3512248**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:56:44**

**Fever (Temperature  $\geq$  100.4°F/38°C)**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FCE43EC3-F1E0-47A1-B438-4D694934F821)', Time: '2021-04-17T10:38:42-04:00', User OID: 'PatientReportedOutcome (US3512248)', ODM File OID: '90e4b7ec-ca58-4f03-832c-7b2b32dfdebb' User entered '0'	System	17 Apr 2021 14:39:21
	System	17 Apr 2021 14:39:21

**US3512248**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:56:44**

[Chills](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FCE43EC3-F1E0-47A1-B438-4D694934F821)', Time: '2021-04-17T10:38:42-04:00', User OID: 'PatientReportedOutcome (US3512248)', ODM File OID: '90e4b7ec-ca58-4f03-832c-7b2b32dfdebb' User entered '0'	System	17 Apr 2021 14:39:21

**US3512248**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:56:44**

[Cough](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FCE43EC3-F1E0-47A1-B438-4D694934F821)', Time: '2021-04-17T10:38:42-04:00', User OID: 'PatientReportedOutcome (US3512248)', ODM File OID: '90e4b7ec-ca58-4f03-832c-7b2b32dfdebb'	System	17 Apr 2021 14:39:21
User entered '1'	System	17 Apr 2021 14:39:21

**US3512248**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:56:44**

[Shortness of breath](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FCE43EC3-F1E0-47A1-B438-4D694934F821)', Time: '2021-04-17T10:38:42-04:00', User OID: 'PatientReportedOutcome (US3512248)', ODM File OID: '90e4b7ec-ca58-4f03-832c-7b2b32dfdebb' User entered '0'	System	17 Apr 2021 14:39:21



**US3512248**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:56:44**

[Difficulty breathing](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FCE43EC3-F1E0-47A1-B438-4D694934F821)', Time: '2021-04-17T10:38:42-04:00', User OID: 'PatientReportedOutcome (US3512248)', ODM File OID: '90e4b7ec-ca58-4f03-832c-7b2b32dfdebb'	System	17 Apr 2021 14:39:21
User entered '0'	System	17 Apr 2021 14:39:21

**US3512248**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:56:44**

[Fatigue](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FCE43EC3-F1E0-47A1-B438-4D694934F821)', Time: '2021-04-17T10:38:42-04:00', User OID: 'PatientReportedOutcome (US3512248)', ODM File OID: '90e4b7ec-ca58-4f03-832c-7b2b32dfdebb' User entered '0'	System	17 Apr 2021 14:39:21
	System	17 Apr 2021 14:39:21

**US3512248**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:56:44**

[Muscle aches](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FCE43EC3-F1E0-47A1-B438-4D694934F821)', Time: '2021-04-17T10:38:42-04:00', User OID: 'PatientReportedOutcome (US3512248)', ODM File OID: '90e4b7ec-ca58-4f03-832c-7b2b32dfdebb' User entered '0'	System	17 Apr 2021 14:39:21

**US3512248**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:56:44**

[Body aches](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FCE43EC3-F1E0-47A1-B438-4D694934F821)', Time: '2021-04-17T10:38:42-04:00', User OID: 'PatientReportedOutcome (US3512248)', ODM File OID: '90e4b7ec-ca58-4f03-832c-7b2b32dfdebb'	System	17 Apr 2021 14:39:21
User entered '0'	System	17 Apr 2021 14:39:21

**US3512248**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:56:44**

[Headache](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FCE43EC3-F1E0-47A1-B438-4D694934F821)', Time: '2021-04-17T10:38:42-04:00', User OID: 'PatientReportedOutcome (US3512248)', ODM File OID: '90e4b7ec-ca58-4f03-832c-7b2b32dfdebb'	System	17 Apr 2021 14:39:21
User entered '0'	System	17 Apr 2021 14:39:21

**US3512248**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:56:44**

[New loss of taste](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FCE43EC3-F1E0-47A1-B438-4D694934F821)', Time: '2021-04-17T10:38:42-04:00', User OID: 'PatientReportedOutcome (US3512248)', ODM File OID: '90e4b7ec-ca58-4f03-832c-7b2b32dfdebb' User entered '0'	System	17 Apr 2021 14:39:21

**US3512248**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:56:44**

[New loss of smell](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FCE43EC3-F1E0-47A1-B438-4D694934F821)', Time: '2021-04-17T10:38:42-04:00', User OID: 'PatientReportedOutcome (US3512248)', ODM File OID: '90e4b7ec-ca58-4f03-832c-7b2b32dfdebb'	System	17 Apr 2021 14:39:21
User entered '0'	System	17 Apr 2021 14:39:21

**US3512248**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:56:44**

[Sore throat](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FCE43EC3-F1E0-47A1-B438-4D694934F821)', Time: '2021-04-17T10:38:42-04:00', User OID: 'PatientReportedOutcome (US3512248)', ODM File OID: '90e4b7ec-ca58-4f03-832c-7b2b32dfdebb' User entered '0'	System	17 Apr 2021 14:39:21



**US3512248**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:56:44**

[Congestion](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FCE43EC3-F1E0-47A1-B438-4D694934F821)', Time: '2021-04-17T10:38:42-04:00', User OID: 'PatientReportedOutcome (US3512248)', ODM File OID: '90e4b7ec-ca58-4f03-832c-7b2b32dfdebb' User entered '0'	System	17 Apr 2021 14:39:21

**US3512248**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:56:44**

[Runny nose](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FCE43EC3-F1E0-47A1-B438-4D694934F821)', Time: '2021-04-17T10:38:42-04:00', User OID: 'PatientReportedOutcome (US3512248)', ODM File OID: '90e4b7ec-ca58-4f03-832c-7b2b32dfdebb' User entered '1'	System	17 Apr 2021 14:39:21

**US3512248**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:56:44**

[Nausea](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FCE43EC3-F1E0-47A1-B438-4D694934F821)', Time: '2021-04-17T10:38:42-04:00', User OID: 'PatientReportedOutcome (US3512248)', ODM File OID: '90e4b7ec-ca58-4f03-832c-7b2b32dfdebb' User entered '0'	System	17 Apr 2021 14:39:21

**US3512248**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:56:44**

[Vomiting](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FCE43EC3-F1E0-47A1-B438-4D694934F821)', Time: '2021-04-17T10:38:42-04:00', User OID: 'PatientReportedOutcome (US3512248)', ODM File OID: '90e4b7ec-ca58-4f03-832c-7b2b32dfdebb' User entered '0'	System	17 Apr 2021 14:39:21

**US3512248**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:56:44**

[Diarrhea](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FCE43EC3-F1E0-47A1-B438-4D694934F821)', Time: '2021-04-17T10:38:42-04:00', User OID: 'PatientReportedOutcome (US3512248)', ODM File OID: '90e4b7ec-ca58-4f03-832c-7b2b32dfdebb'	System	17 Apr 2021 14:39:21
User entered '0'	System	17 Apr 2021 14:39:21

**US3512248**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:56:44**

[Please 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 (FCE43EC3-F1E0-47A1-B438-4D694934F821)', Time: '2021-04-17T10:37:41-04:00', User OID: 'PatientReportedOutcome (US3512248)', ODM File OID: '90e4b7ec-ca58-4f03-832c-7b2b32dfdebb'	System	17 Apr 2021 14:39:21
User entered 'I confirm I have read this message and will call the study clinic immediately (9)'	System	17 Apr 2021 14:39:21

**US3512248**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:56:44**

[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 (FCE43EC3-F1E0-47A1-B438-4D694934F821)', Time: '2021-04-17T10:37:50-04:00', User OID: 'PatientReportedOutcome (US3512248)', ODM File OID: '90e4b7ec-ca58-4f03-832c-7b2b32dfdebb'	System	17 Apr 2021 14:39:21
User entered 'No (N)'	System	17 Apr 2021 14:39:21

**US3512248**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:56:44**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FCE43EC3-F1E0-47A1-B438-4D694934F821)', Time: '2021-04-17T10:39:12-04:00', User OID: 'PatientReportedOutcome (US3512248)', ODM File OID: '90e4b7ec-ca58-4f03-832c-7b2b32dfdebb'	System	17 Apr 2021 14:39:21
User entered '17 Apr 2021 10:39:12'	System	17 Apr 2021 14:39:21



**US3512248**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:56:44**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:06:03
Amendment Manager: User entered '17 Apr 2021 00:01'	System	20 Nov 2020 07:06:03

**US3512248**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:56:44**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:06:03
Amendment Manager: User entered '21 Apr 2021 23:59'	System	20 Nov 2020 07:06:03

**US3512248**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:56:44**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:06:03
Amendment Manager: User entered 'Day 229'	System	20 Nov 2020 07:06:03

**US3512248**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:56:44**

[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 (FCE43EC3-F1E0-47A1-B438-4D694934F821)', Time: '2021-04-27T21:50:13-04:00', User OID: 'PatientReportedOutcome (US3512248)', ODM File OID: 'aae008ff-8df3-4b22-8e1b-939a0f2bfdd8'	System	29 Apr 2021 02:43:13
User entered 'No (N)'	System	29 Apr 2021 02:43:13

**US3512248**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:56:44**

[Have you been exposed to someone with 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 (FCE43EC3-F1E0-47A1-B438-4D694934F821)', Time: '2021-04-27T21:50:19-04:00', User OID: 'PatientReportedOutcome (US3512248)', ODM File OID: 'aae008ff-8df3-4b22-8e1b-939a0f2bfdd8'	System	29 Apr 2021 02:43:13
User entered 'No (N)'	System	29 Apr 2021 02:43:13

**US3512248**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:56:44**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FCE43EC3-F1E0-47A1-B438-4D694934F821)', Time: '2021-04-27T21:50:32-04:00', User OID: 'PatientReportedOutcome (US3512248)', ODM File OID: 'aae008ff-8df3-4b22-8e1b-939a0f2bfdd8'	System	29 Apr 2021 02:43:13
User entered '27 Apr 2021 21:50:32'	System	29 Apr 2021 02:43:13

**US3512248**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:56:44**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:06:03
Amendment Manager: User entered '24 Apr 2021 00:01'	System	20 Nov 2020 07:06:03

**US3512248**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:56:44**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:06:03
Amendment Manager: User entered '28 Apr 2021 23:59'	System	20 Nov 2020 07:06:03



**US3512248**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:56:44**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:06:03
Amendment Manager: User entered 'Day 236'	System	20 Nov 2020 07:06:03

**US3512248**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:56:44**

[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 (FCE43EC3-F1E0-47A1-B438-4D694934F821)', Time: '2021-05-01T08:25:26-04:00', User OID: 'PatientReportedOutcome (US3512248)', ODM File OID: '9fab294d-cf26-4978-8967-549621923269' User entered 'No (N)'	System	01 May 2021 12:25:44
	System	01 May 2021 12:25:44

**US3512248**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:56:44**

Have you been exposed to someone with 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 (FCE43EC3-F1E0-47A1-B438-4D694934F821)', Time: '2021-05-01T08:25:32-04:00', User OID: 'PatientReportedOutcome (US3512248)', ODM File OID: '9fab294d-cf26-4978-8967-549621923269' User entered 'No (N)'	System	01 May 2021 12:25:44
	System	01 May 2021 12:25:44

**US3512248**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:56:44**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FCE43EC3-F1E0-47A1-B438-4D694934F821)', Time: '2021-05-01T08:25:41-04:00', User OID: 'PatientReportedOutcome (US3512248)', ODM File OID: '9fab294d-cf26-4978-8967-549621923269'	System	01 May 2021 12:25:44
User entered '01 May 2021 08:25:41'	System	01 May 2021 12:25:44

**US3512248**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:56:44**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:06:03
Amendment Manager: User entered '01 May 2021 00:01'	System	20 Nov 2020 07:06:03

**US3512248**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:56:44**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:06:03
Amendment Manager: User entered '05 May 2021 23:59'	System	20 Nov 2020 07:06:03

**US3512248**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:56:44**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:06:03
Amendment Manager: User entered 'Day 243'	System	20 Nov 2020 07:06:03

**US3512248**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:56:44**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:06:03
Amendment Manager: User entered '08 May 2021 00:01'	System	20 Nov 2020 07:06:03



**US3512248**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:56:44**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:06:03
Amendment Manager: User entered '12 May 2021 23:59'	System	20 Nov 2020 07:06:03

**US3512248**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:56:44**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:06:03
Amendment Manager: User entered 'Day 250'	System	20 Nov 2020 07:06:03

**US3512248**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:56:44**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:06:03
Amendment Manager: User entered '15 May 2021 00:01'	System	20 Nov 2020 07:06:03

**US3512248**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:56:44**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:06:03
Amendment Manager: User entered '19 May 2021 23:59'	System	20 Nov 2020 07:06:03

**US3512248**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:56:44**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:06:03
Amendment Manager: User entered 'Day 257'	System	20 Nov 2020 07:06:03

**US3512248**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:56:44**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:06:03
Amendment Manager: User entered '22 May 2021 00:01'	System	20 Nov 2020 07:06:03

**US3512248**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:56:44**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:06:03
Amendment Manager: User entered '26 May 2021 23:59'	System	20 Nov 2020 07:06:03

**US3512248**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:56:44**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:06:03
Amendment Manager: User entered 'Day 264'	System	20 Nov 2020 07:06:03



**US3512248**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:56:44**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:06:03
Amendment Manager: User entered '29 May 2021 00:01'	System	20 Nov 2020 07:06:03

**US3512248**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:56:44**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:06:03
Amendment Manager: User entered '02 Jun 2021 23:59'	System	20 Nov 2020 07:06:03

**US3512248**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:56:44**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:06:03
Amendment Manager: User entered 'Day 271'	System	20 Nov 2020 07:06:03

**US3512248**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:56:44**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:06:03
Amendment Manager: User entered '05 Jun 2021 00:01'	System	20 Nov 2020 07:06:03

**US3512248**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:56:44**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:06:03
Amendment Manager: User entered '09 Jun 2021 23:59'	System	20 Nov 2020 07:06:03

**US3512248**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:56:44**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:06:03
Amendment Manager: User entered 'Day 278'	System	20 Nov 2020 07:06:03

**US3512248**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:56:44**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:06:03
Amendment Manager: User entered '12 Jun 2021 00:01'	System	20 Nov 2020 07:06:03

**US3512248**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:56:44**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:06:03
Amendment Manager: User entered '16 Jun 2021 23:59'	System	20 Nov 2020 07:06:03



**US3512248**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:56:44**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:06:03
Amendment Manager: User entered 'Day 285'	System	20 Nov 2020 07:06:03

**US3512248**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:56:44**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:06:03
Amendment Manager: User entered '19 Jun 2021 00:01'	System	20 Nov 2020 07:06:03

**US3512248**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:56:44**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:06:03
Amendment Manager: User entered '23 Jun 2021 23:59'	System	20 Nov 2020 07:06:03

**US3512248**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:56:44**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:06:03
Amendment Manager: User entered 'Day 292'	System	20 Nov 2020 07:06:03

**US3512248**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:56:44**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:06:03
Amendment Manager: User entered '26 Jun 2021 00:01'	System	20 Nov 2020 07:06:03

**US3512248**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:56:44**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:06:03
Amendment Manager: User entered '30 Jun 2021 23:59'	System	20 Nov 2020 07:06:03

**US3512248**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:56:44**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:06:03
Amendment Manager: User entered 'Day 299'	System	20 Nov 2020 07:06:03

**US3512248**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:56:44**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:06:03
Amendment Manager: User entered '03 Jul 2021 00:01'	System	20 Nov 2020 07:06:03



**US3512248**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:56:44**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:06:03
Amendment Manager: User entered '07 Jul 2021 23:59'	System	20 Nov 2020 07:06:03

**US3512248**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:56:44**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:06:03
Amendment Manager: User entered 'Day 306'	System	20 Nov 2020 07:06:03

**US3512248**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:56:44**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:06:03
Amendment Manager: User entered '10 Jul 2021 00:01'	System	20 Nov 2020 07:06:03

**US3512248**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:56:44**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:06:03
Amendment Manager: User entered '14 Jul 2021 23:59'	System	20 Nov 2020 07:06:03

**US3512248**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:56:44**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:06:03
Amendment Manager: User entered 'Day 313'	System	20 Nov 2020 07:06:03

**US3512248**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:56:44**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:06:03
Amendment Manager: User entered '17 Jul 2021 00:01'	System	20 Nov 2020 07:06:03

**US3512248**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:56:44**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:06:03
Amendment Manager: User entered '21 Jul 2021 23:59'	System	20 Nov 2020 07:06:03

**US3512248**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:56:44**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:06:03
Amendment Manager: User entered 'Day 320'	System	20 Nov 2020 07:06:03



**US3512248**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:56:44**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:06:03
Amendment Manager: User entered '24 Jul 2021 00:01'	System	20 Nov 2020 07:06:03

**US3512248**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:56:44**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:06:03
Amendment Manager: User entered '28 Jul 2021 23:59'	System	20 Nov 2020 07:06:03

**US3512248**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:56:44**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:06:03
Amendment Manager: User entered 'Day 327'	System	20 Nov 2020 07:06:03

**US3512248**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:56:44**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:06:03
Amendment Manager: User entered '31 Jul 2021 00:01'	System	20 Nov 2020 07:06:03

**US3512248**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:56:44**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:06:03
Amendment Manager: User entered '04 Aug 2021 23:59'	System	20 Nov 2020 07:06:03

**US3512248**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:56:44**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:06:03
Amendment Manager: User entered 'Day 334'	System	20 Nov 2020 07:06:03

**US3512248**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:56:44**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:06:03
Amendment Manager: User entered '07 Aug 2021 00:01'	System	20 Nov 2020 07:06:03

**US3512248**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:56:44**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:06:03
Amendment Manager: User entered '11 Aug 2021 23:59'	System	20 Nov 2020 07:06:03



**US3512248**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:56:44**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:06:03
Amendment Manager: User entered 'Day 341'	System	20 Nov 2020 07:06:03

**US3512248**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:56:44**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:06:03
Amendment Manager: User entered '14 Aug 2021 00:01'	System	20 Nov 2020 07:06:03

**US3512248**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:56:44**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:06:03
Amendment Manager: User entered '18 Aug 2021 23:59'	System	20 Nov 2020 07:06:03

**US3512248**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:56:44**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:06:03
Amendment Manager: User entered 'Day 348'	System	20 Nov 2020 07:06:03

**US3512248**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:56:44**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:06:03
Amendment Manager: User entered '21 Aug 2021 00:01'	System	20 Nov 2020 07:06:03

**US3512248**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:56:44**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:06:03
Amendment Manager: User entered '25 Aug 2021 23:59'	System	20 Nov 2020 07:06:03

**US3512248**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:56:44**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:06:03
Amendment Manager: User entered 'Day 355'	System	20 Nov 2020 07:06:03

**US3512248**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:56:44**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:06:03
Amendment Manager: User entered '28 Aug 2021 00:01'	System	20 Nov 2020 07:06:03



**US3512248**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:56:44**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:06:03
Amendment Manager: User entered '01 Sep 2021 23:59'	System	20 Nov 2020 07:06:03

**US3512248**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:56:44**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:06:03
Amendment Manager: User entered 'Day 362'	System	20 Nov 2020 07:06:03

**US3512248**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:56:44**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:06:03
Amendment Manager: User entered '04 Sep 2021 00:01'	System	20 Nov 2020 07:06:03

**US3512248**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:56:44**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:06:03
Amendment Manager: User entered '08 Sep 2021 23:59'	System	20 Nov 2020 07:06:03

**US3512248**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:56:44**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:06:03
Amendment Manager: User entered 'Day 369'	System	20 Nov 2020 07:06:03

**US3512248**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:56:44**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:06:03
Amendment Manager: User entered '11 Sep 2021 00:01'	System	20 Nov 2020 07:06:03

**US3512248**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:56:44**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:06:03
Amendment Manager: User entered '15 Sep 2021 23:59'	System	20 Nov 2020 07:06:03

**US3512248**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:56:44**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:06:03
Amendment Manager: User entered 'Day 376'	System	20 Nov 2020 07:06:03



**US3512248**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:56:44**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:06:03
Amendment Manager: User entered '18 Sep 2021 00:01'	System	20 Nov 2020 07:06:03

**US3512248**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:56:44**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:06:03
Amendment Manager: User entered '22 Sep 2021 23:59'	System	20 Nov 2020 07:06:03

**US3512248**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:56:44**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:06:03
Amendment Manager: User entered 'Day 383'	System	20 Nov 2020 07:06:03

**US3512248**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:56:44**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:06:03
Amendment Manager: User entered '25 Sep 2021 00:01'	System	20 Nov 2020 07:06:03

**US3512248**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:56:44**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:06:03
Amendment Manager: User entered '29 Sep 2021 23:59'	System	20 Nov 2020 07:06:03

**US3512248**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:56:44**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:06:03
Amendment Manager: User entered 'Day 390'	System	20 Nov 2020 07:06:03

**US3512248**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:56:44**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:06:03
Amendment Manager: User entered '02 Oct 2021 00:01'	System	20 Nov 2020 07:06:03

**US3512248**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:56:44**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:06:03
Amendment Manager: User entered '06 Oct 2021 23:59'	System	20 Nov 2020 07:06:03



**US3512248**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:56:44**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:06:03
Amendment Manager: User entered 'Day 397'	System	20 Nov 2020 07:06:03

**US3512248**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:56:44**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:06:03
Amendment Manager: User entered '09 Oct 2021 00:01'	System	20 Nov 2020 07:06:03

**US3512248**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:56:44**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:06:03
Amendment Manager: User entered '13 Oct 2021 23:59'	System	20 Nov 2020 07:06:03

**US3512248**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:56:44**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:06:03
Amendment Manager: User entered 'Day 404'	System	20 Nov 2020 07:06:03

**US3512248**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:56:44**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:06:03
Amendment Manager: User entered '16 Oct 2021 00:01'	System	20 Nov 2020 07:06:03

**US3512248**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:56:44**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:06:03
Amendment Manager: User entered '20 Oct 2021 23:59'	System	20 Nov 2020 07:06:03

**US3512248**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:56:44**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:06:03
Amendment Manager: User entered 'Day 411'	System	20 Nov 2020 07:06:03

**US3512248**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:56:44**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:06:03
Amendment Manager: User entered '23 Oct 2021 00:01'	System	20 Nov 2020 07:06:03



**US3512248**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:56:44**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:06:03
Amendment Manager: User entered '27 Oct 2021 23:59'	System	20 Nov 2020 07:06:03

**US3512248**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:56:44**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:06:03
Amendment Manager: User entered 'Day 418'	System	20 Nov 2020 07:06:03

**US3512248**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:56:44**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:06:03
Amendment Manager: User entered '30 Oct 2021 00:01'	System	20 Nov 2020 07:06:03

**US3512248**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:56:44**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:06:03
Amendment Manager: User entered '03 Nov 2021 23:59'	System	20 Nov 2020 07:06:03

**US3512248**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:56:44**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:06:03
Amendment Manager: User entered 'Day 425'	System	20 Nov 2020 07:06:03

**US3512248**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:56:44**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:06:03
Amendment Manager: User entered '06 Nov 2021 00:01'	System	20 Nov 2020 07:06:03

**US3512248**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:56:44**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:06:03
Amendment Manager: User entered '10 Nov 2021 23:59'	System	20 Nov 2020 07:06:03

**US3512248**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:56:44**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:06:03
Amendment Manager: User entered 'Day 432'	System	20 Nov 2020 07:06:03



**US3512248**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:56:44**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:06:03
Amendment Manager: User entered '13 Nov 2021 00:01'	System	20 Nov 2020 07:06:03

**US3512248**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:56:44**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:06:03
Amendment Manager: User entered '17 Nov 2021 23:59'	System	20 Nov 2020 07:06:03

**US3512248**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:56:44**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:06:03
Amendment Manager: User entered 'Day 439'	System	20 Nov 2020 07:06:03

**US3512248**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:56:44**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:06:03
Amendment Manager: User entered '20 Nov 2021 00:01'	System	20 Nov 2020 07:06:03

**US3512248**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:56:44**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:06:03
Amendment Manager: User entered '24 Nov 2021 23:59'	System	20 Nov 2020 07:06:03

**US3512248**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:56:44**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:06:03
Amendment Manager: User entered 'Day 446'	System	20 Nov 2020 07:06:03

**US3512248**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:56:44**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:06:03
Amendment Manager: User entered '27 Nov 2021 00:01'	System	20 Nov 2020 07:06:03

**US3512248**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:56:44**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:06:03
Amendment Manager: User entered '01 Dec 2021 23:59'	System	20 Nov 2020 07:06:03



**US3512248**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:56:44**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:06:03
Amendment Manager: User entered 'Day 453'	System	20 Nov 2020 07:06:03

**US3512248**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:56:44**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:06:03
Amendment Manager: User entered '04 Dec 2021 00:01'	System	20 Nov 2020 07:06:03

**US3512248**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:56:44**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:06:03
Amendment Manager: User entered '08 Dec 2021 23:59'	System	20 Nov 2020 07:06:03

**US3512248**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:56:44**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:06:03
Amendment Manager: User entered 'Day 460'	System	20 Nov 2020 07:06:03

**US3512248**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:56:44**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:06:03
Amendment Manager: User entered '11 Dec 2021 00:01'	System	20 Nov 2020 07:06:03

**US3512248**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:56:44**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:06:03
Amendment Manager: User entered '15 Dec 2021 23:59'	System	20 Nov 2020 07:06:03

**US3512248**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:56:44**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:06:03
Amendment Manager: User entered 'Day 467'	System	20 Nov 2020 07:06:03

**US3512248**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:56:44**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:06:03
Amendment Manager: User entered '18 Dec 2021 00:01'	System	20 Nov 2020 07:06:03



**US3512248**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:56:44**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:06:03
Amendment Manager: User entered '22 Dec 2021 23:59'	System	20 Nov 2020 07:06:03

**US3512248**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:56:44**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:06:03
Amendment Manager: User entered 'Day 474'	System	20 Nov 2020 07:06:03

**US3512248**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:56:44**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:06:03
Amendment Manager: User entered '25 Dec 2021 00:01'	System	20 Nov 2020 07:06:03

**US3512248**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:56:44**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:06:03
Amendment Manager: User entered '29 Dec 2021 23:59'	System	20 Nov 2020 07:06:03

**US3512248**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:56:44**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:06:03
Amendment Manager: User entered 'Day 481'	System	20 Nov 2020 07:06:03

**US3512248**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:56:44**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:06:03
Amendment Manager: User entered '01 Jan 2022 00:01'	System	20 Nov 2020 07:06:03

**US3512248**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:56:44**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:06:03
Amendment Manager: User entered '05 Jan 2022 23:59'	System	20 Nov 2020 07:06:03

**US3512248**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:56:44**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:06:03
Amendment Manager: User entered 'Day 488'	System	20 Nov 2020 07:06:03



**US3512248**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:56:44**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:06:03
Amendment Manager: User entered '08 Jan 2022 00:01'	System	20 Nov 2020 07:06:03

**US3512248**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:56:44**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:06:03
Amendment Manager: User entered '12 Jan 2022 23:59'	System	20 Nov 2020 07:06:03

**US3512248**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:56:44**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:06:03
Amendment Manager: User entered 'Day 495'	System	20 Nov 2020 07:06:03

**US3512248**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:56:44**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:06:03
Amendment Manager: User entered '15 Jan 2022 00:01'	System	20 Nov 2020 07:06:03

**US3512248**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:56:44**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:06:03
Amendment Manager: User entered '19 Jan 2022 23:59'	System	20 Nov 2020 07:06:03

**US3512248**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:56:44**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:06:03
Amendment Manager: User entered 'Day 502'	System	20 Nov 2020 07:06:03

**US3512248**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:56:44**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:06:03
Amendment Manager: User entered '22 Jan 2022 00:01'	System	20 Nov 2020 07:06:03

**US3512248**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:56:44**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:06:03
Amendment Manager: User entered '26 Jan 2022 23:59'	System	20 Nov 2020 07:06:03



**US3512248**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:56:44**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:06:03
Amendment Manager: User entered 'Day 509'	System	20 Nov 2020 07:06:03

**US3512248**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:56:44**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:06:03
Amendment Manager: User entered '29 Jan 2022 00:01'	System	20 Nov 2020 07:06:03

**US3512248**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:56:44**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:06:03
Amendment Manager: User entered '02 Feb 2022 23:59'	System	20 Nov 2020 07:06:03

**US3512248**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:56:44**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:06:03
Amendment Manager: User entered 'Day 516'	System	20 Nov 2020 07:06:03

**US3512248**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:56:44**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:06:03
Amendment Manager: User entered '05 Feb 2022 00:01'	System	20 Nov 2020 07:06:03

**US3512248**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:56:44**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:06:03
Amendment Manager: User entered '09 Feb 2022 23:59'	System	20 Nov 2020 07:06:03

**US3512248**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:56:44**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:06:03
Amendment Manager: User entered 'Day 523'	System	20 Nov 2020 07:06:03

**US3512248**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:56:44**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:06:03
Amendment Manager: User entered '12 Feb 2022 00:01'	System	20 Nov 2020 07:06:03



**US3512248**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:56:44**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:06:03
Amendment Manager: User entered '16 Feb 2022 23:59'	System	20 Nov 2020 07:06:03

**US3512248**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:56:44**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:06:03
Amendment Manager: User entered 'Day 530'	System	20 Nov 2020 07:06:03

**US3512248**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:56:44**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:06:03
Amendment Manager: User entered '19 Feb 2022 00:01'	System	20 Nov 2020 07:06:03

**US3512248**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:56:44**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:06:03
Amendment Manager: User entered '23 Feb 2022 23:59'	System	20 Nov 2020 07:06:03

**US3512248**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:56:44**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:06:03
Amendment Manager: User entered 'Day 537'	System	20 Nov 2020 07:06:03

**US3512248**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:56:44**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:06:03
Amendment Manager: User entered '26 Feb 2022 00:01'	System	20 Nov 2020 07:06:03

**US3512248**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:56:44**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:06:03
Amendment Manager: User entered '02 Mar 2022 23:59'	System	20 Nov 2020 07:06:03

**US3512248**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:56:44**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:06:03
Amendment Manager: User entered 'Day 544'	System	20 Nov 2020 07:06:03



**US3512248**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:56:44**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:06:03
Amendment Manager: User entered '05 Mar 2022 00:01'	System	20 Nov 2020 07:06:03

**US3512248**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:56:44**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:06:03
Amendment Manager: User entered '09 Mar 2022 23:59'	System	20 Nov 2020 07:06:03

**US3512248**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:56:44**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:06:03
Amendment Manager: User entered 'Day 551'	System	20 Nov 2020 07:06:03

**US3512248**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:56:44**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:06:03
Amendment Manager: User entered '12 Mar 2022 00:01'	System	20 Nov 2020 07:06:03

**US3512248**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:56:44**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:06:03
Amendment Manager: User entered '16 Mar 2022 23:59'	System	20 Nov 2020 07:06:03

**US3512248**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:56:44**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:06:03
Amendment Manager: User entered 'Day 558'	System	20 Nov 2020 07:06:03

**US3512248**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:56:44**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:06:03
Amendment Manager: User entered '19 Mar 2022 00:01'	System	20 Nov 2020 07:06:03

**US3512248**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:56:44**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:06:03
Amendment Manager: User entered '23 Mar 2022 23:59'	System	20 Nov 2020 07:06:03



**US3512248**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:56:44**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:06:03
Amendment Manager: User entered 'Day 565'	System	20 Nov 2020 07:06:03

**US3512248**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:56:44**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:06:03
Amendment Manager: User entered '26 Mar 2022 00:01'	System	20 Nov 2020 07:06:03

**US3512248**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:56:44**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:06:03
Amendment Manager: User entered '30 Mar 2022 23:59'	System	20 Nov 2020 07:06:03

**US3512248**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:56:44**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:06:03
Amendment Manager: User entered 'Day 572'	System	20 Nov 2020 07:06:03

**US3512248**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:56:44**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:06:03
Amendment Manager: User entered '02 Apr 2022 00:01'	System	20 Nov 2020 07:06:03

**US3512248**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:56:44**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:06:03
Amendment Manager: User entered '06 Apr 2022 23:59'	System	20 Nov 2020 07:06:03

**US3512248**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:56:44**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:06:03
Amendment Manager: User entered 'Day 579'	System	20 Nov 2020 07:06:03

**US3512248**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:56:44**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:06:03
Amendment Manager: User entered '09 Apr 2022 00:01'	System	20 Nov 2020 07:06:03



**US3512248**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:56:44**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:06:03
Amendment Manager: User entered '13 Apr 2022 23:59'	System	20 Nov 2020 07:06:03

**US3512248**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:56:44**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:06:03
Amendment Manager: User entered 'Day 586'	System	20 Nov 2020 07:06:03

**US3512248**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:56:44**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:06:03
Amendment Manager: User entered '16 Apr 2022 00:01'	System	20 Nov 2020 07:06:03

**US3512248**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:56:44**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:06:03
Amendment Manager: User entered '20 Apr 2022 23:59'	System	20 Nov 2020 07:06:03

**US3512248**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:56:44**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:06:03
Amendment Manager: User entered 'Day 593'	System	20 Nov 2020 07:06:03

**US3512248**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:56:44**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:06:03
Amendment Manager: User entered '23 Apr 2022 00:01'	System	20 Nov 2020 07:06:03

**US3512248**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:56:44**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:06:03
Amendment Manager: User entered '27 Apr 2022 23:59'	System	20 Nov 2020 07:06:03

**US3512248**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:56:44**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:06:03
Amendment Manager: User entered 'Day 600'	System	20 Nov 2020 07:06:03



**US3512248**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:56:44**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:06:03
Amendment Manager: User entered '30 Apr 2022 00:01'	System	20 Nov 2020 07:06:03

**US3512248**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:56:44**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:06:03
Amendment Manager: User entered '04 May 2022 23:59'	System	20 Nov 2020 07:06:03

**US3512248**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:56:44**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:06:03
Amendment Manager: User entered 'Day 607'	System	20 Nov 2020 07:06:03

**US3512248**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:56:44**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:06:03
Amendment Manager: User entered '07 May 2022 00:01'	System	20 Nov 2020 07:06:03

**US3512248**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:56:44**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:06:03
Amendment Manager: User entered '11 May 2022 23:59'	System	20 Nov 2020 07:06:03

**US3512248**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:56:44**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:06:03
Amendment Manager: User entered 'Day 614'	System	20 Nov 2020 07:06:03

**US3512248**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:56:44**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:06:03
Amendment Manager: User entered '14 May 2022 00:01'	System	20 Nov 2020 07:06:03

**US3512248**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:56:44**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:06:03
Amendment Manager: User entered '18 May 2022 23:59'	System	20 Nov 2020 07:06:03



**US3512248**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:56:44**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:06:03
Amendment Manager: User entered 'Day 621'	System	20 Nov 2020 07:06:03

**US3512248**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:56:44**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:06:03
Amendment Manager: User entered '21 May 2022 00:01'	System	20 Nov 2020 07:06:03

**US3512248**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:56:44**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:06:03
Amendment Manager: User entered '25 May 2022 23:59'	System	20 Nov 2020 07:06:03

**US3512248**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:56:44**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:06:03
Amendment Manager: User entered 'Day 628'	System	20 Nov 2020 07:06:03

**US3512248**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:56:44**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:06:03
Amendment Manager: User entered '28 May 2022 00:01'	System	20 Nov 2020 07:06:03

**US3512248**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:56:44**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:06:03
Amendment Manager: User entered '01 Jun 2022 23:59'	System	20 Nov 2020 07:06:03

**US3512248**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:56:44**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:06:03
Amendment Manager: User entered 'Day 635'	System	20 Nov 2020 07:06:03

**US3512248**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:56:44**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:06:03
Amendment Manager: User entered '04 Jun 2022 00:01'	System	20 Nov 2020 07:06:03



**US3512248**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:56:44**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:06:03
Amendment Manager: User entered '08 Jun 2022 23:59'	System	20 Nov 2020 07:06:03

**US3512248**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:56:44**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:06:03
Amendment Manager: User entered 'Day 642'	System	20 Nov 2020 07:06:03

**US3512248**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:56:44**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:06:03
Amendment Manager: User entered '11 Jun 2022 00:01'	System	20 Nov 2020 07:06:03

**US3512248**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:56:44**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:06:03
Amendment Manager: User entered '15 Jun 2022 23:59'	System	20 Nov 2020 07:06:03

**US3512248**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:56:44**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:06:03
Amendment Manager: User entered 'Day 649'	System	20 Nov 2020 07:06:03

**US3512248**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:56:44**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:06:03
Amendment Manager: User entered '18 Jun 2022 00:01'	System	20 Nov 2020 07:06:03

**US3512248**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:56:44**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:06:03
Amendment Manager: User entered '22 Jun 2022 23:59'	System	20 Nov 2020 07:06:03

**US3512248**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:56:44**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:06:03
Amendment Manager: User entered 'Day 656'	System	20 Nov 2020 07:06:03



**US3512248**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:56:44**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:06:03
Amendment Manager: User entered '25 Jun 2022 00:01'	System	20 Nov 2020 07:06:03

**US3512248**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:56:44**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:06:03
Amendment Manager: User entered '29 Jun 2022 23:59'	System	20 Nov 2020 07:06:03

**US3512248**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:56:44**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:06:03
Amendment Manager: User entered 'Day 663'	System	20 Nov 2020 07:06:03

**US3512248**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:56:44**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:06:03
Amendment Manager: User entered '02 Jul 2022 00:01'	System	20 Nov 2020 07:06:03

**US3512248**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:56:44**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:06:03
Amendment Manager: User entered '06 Jul 2022 23:59'	System	20 Nov 2020 07:06:03

**US3512248**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:56:44**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:06:03
Amendment Manager: User entered 'Day 670'	System	20 Nov 2020 07:06:03

**US3512248**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:56:44**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:06:03
Amendment Manager: User entered '09 Jul 2022 00:01'	System	20 Nov 2020 07:06:03

**US3512248**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:56:44**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:06:03
Amendment Manager: User entered '13 Jul 2022 23:59'	System	20 Nov 2020 07:06:03



**US3512248**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:56:44**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:06:03
Amendment Manager: User entered 'Day 677'	System	20 Nov 2020 07:06:03

**US3512248**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:56:44**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:06:03
Amendment Manager: User entered '16 Jul 2022 00:01'	System	20 Nov 2020 07:06:03

**US3512248**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:56:44**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:06:03
Amendment Manager: User entered '20 Jul 2022 23:59'	System	20 Nov 2020 07:06:03

**US3512248**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:56:44**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:06:03
Amendment Manager: User entered 'Day 684'	System	20 Nov 2020 07:06:03

**US3512248**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:56:44**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:06:03
Amendment Manager: User entered '23 Jul 2022 00:01'	System	20 Nov 2020 07:06:03

**US3512248**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:56:44**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:06:03
Amendment Manager: User entered '27 Jul 2022 23:59'	System	20 Nov 2020 07:06:03

**US3512248**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:56:44**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:06:03
Amendment Manager: User entered 'Day 691'	System	20 Nov 2020 07:06:03

**US3512248**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:56:44**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:06:03
Amendment Manager: User entered '30 Jul 2022 00:01'	System	20 Nov 2020 07:06:03



**US3512248**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:56:44**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:06:03
Amendment Manager: User entered '03 Aug 2022 23:59'	System	20 Nov 2020 07:06:03

**US3512248**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:56:44**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:06:03
Amendment Manager: User entered 'Day 698'	System	20 Nov 2020 07:06:03

**US3512248**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:56:44**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:06:03
Amendment Manager: User entered '06 Aug 2022 00:01'	System	20 Nov 2020 07:06:03

**US3512248**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:56:44**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:06:03
Amendment Manager: User entered '10 Aug 2022 23:59'	System	20 Nov 2020 07:06:03

**US3512248**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:56:44**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:06:03
Amendment Manager: User entered 'Day 705'	System	20 Nov 2020 07:06:03

**US3512248**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:56:44**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:06:03
Amendment Manager: User entered '13 Aug 2022 00:01'	System	20 Nov 2020 07:06:03

**US3512248**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:56:44**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:06:03
Amendment Manager: User entered '17 Aug 2022 23:59'	System	20 Nov 2020 07:06:03

**US3512248**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:56:44**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:06:03
Amendment Manager: User entered 'Day 712'	System	20 Nov 2020 07:06:03



**US3512248**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:56:44**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:06:03
Amendment Manager: User entered '20 Aug 2022 00:01'	System	20 Nov 2020 07:06:03

**US3512248**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:56:44**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:06:03
Amendment Manager: User entered '24 Aug 2022 23:59'	System	20 Nov 2020 07:06:03

**US3512248**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:56:44**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:06:03
Amendment Manager: User entered 'Day 719'	System	20 Nov 2020 07:06:03

**US3512248**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:56:44**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:06:03
Amendment Manager: User entered '27 Aug 2022 00:01'	System	20 Nov 2020 07:06:03

**US3512248**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:56:44**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:06:03
Amendment Manager: User entered '31 Aug 2022 23:59'	System	20 Nov 2020 07:06:03

**US3512248**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:56:44**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:06:03
Amendment Manager: User entered 'Day 726'	System	20 Nov 2020 07:06:03

**US3512248**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:56:44**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:06:03
Amendment Manager: User entered '03 Sep 2022 00:01'	System	20 Nov 2020 07:06:03

**US3512248**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:56:44**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:06:03
Amendment Manager: User entered '07 Sep 2022 23:59'	System	20 Nov 2020 07:06:03



**US3512248**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:56:44**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:06:03
Amendment Manager: User entered 'Day 733'	System	20 Nov 2020 07:06:03

**US3512248**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:56:44**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:06:03
Amendment Manager: User entered '10 Sep 2022 00:01'	System	20 Nov 2020 07:06:03

**US3512248**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:56:44**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:06:03
Amendment Manager: User entered '14 Sep 2022 23:59'	System	20 Nov 2020 07:06:03

**US3512248**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:56:44**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:06:03
Amendment Manager: User entered 'Day 740'	System	20 Nov 2020 07:06:03

**US3512248**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:56:44**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:06:03
Amendment Manager: User entered '17 Sep 2022 00:01'	System	20 Nov 2020 07:06:03

**US3512248**

**Folder: New Safety Follow Up Diary (1)**

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**Generated On: 10 Jun 2021 07:56:44**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:06:03
Amendment Manager: User entered '21 Sep 2022 23:59'	System	20 Nov 2020 07:06:03

**US3512248**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:56:44**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:06:03
Amendment Manager: User entered 'Day 747'	System	20 Nov 2020 07:06:03

**US3512248**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:56:44**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:06:03
Amendment Manager: User entered '24 Sep 2022 00:01'	System	20 Nov 2020 07:06:03



**US3512248**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:56:44**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:06:03
Amendment Manager: User entered '28 Sep 2022 23:59'	System	20 Nov 2020 07:06:03

**US3512248**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:56:44**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:06:03
Amendment Manager: User entered 'Day 754'	System	20 Nov 2020 07:06:03

**US3512248**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:56:44**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:06:03
Amendment Manager: User entered '01 Oct 2022 00:01'	System	20 Nov 2020 07:06:03

**US3512248**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:56:44**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:06:03
Amendment Manager: User entered '05 Oct 2022 23:59'	System	20 Nov 2020 07:06:03

**US3512248**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:56:44**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:06:03
Amendment Manager: User entered 'Day 761'	System	20 Nov 2020 07:06:03

**US3512248**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:56:44**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:06:03
Amendment Manager: User entered '08 Oct 2022 00:01'	System	20 Nov 2020 07:06:03

**US3512248**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:56:44**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:06:03
Amendment Manager: User entered '12 Oct 2022 23:59'	System	20 Nov 2020 07:06:03

**US3512248**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:56:44**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:06:03
Amendment Manager: User entered 'Day 768'	System	20 Nov 2020 07:06:03



**US3512248**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:56:44**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:06:03
Amendment Manager: User entered '15 Oct 2022 00:01'	System	20 Nov 2020 07:06:03

**US3512248**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:56:44**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:06:03
Amendment Manager: User entered '19 Oct 2022 23:59'	System	20 Nov 2020 07:06:03

**US3512248**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:56:44**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:06:03
Amendment Manager: User entered 'Day 775'	System	20 Nov 2020 07:06:03

**US3512248**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:56:44**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:06:03
Amendment Manager: User entered '22 Oct 2022 00:01'	System	20 Nov 2020 07:06:03

**US3512248**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:56:44**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:06:03
Amendment Manager: User entered '26 Oct 2022 23:59'	System	20 Nov 2020 07:06:03

**US3512248**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:56:44**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:06:03
Amendment Manager: User entered 'Day 782'	System	20 Nov 2020 07:06:03

**US3512248**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:56:44**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:06:03
Amendment Manager: User entered '29 Oct 2022 00:01'	System	20 Nov 2020 07:06:03

**US3512248**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:56:44**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:06:03
Amendment Manager: User entered '02 Nov 2022 23:59'	System	20 Nov 2020 07:06:03



**US3512248**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:56:44**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:06:03
Amendment Manager: User entered 'Day 789'	System	20 Nov 2020 07:06:03

**US3512248**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:56:44**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:06:03
Amendment Manager: User entered '05 Nov 2022 00:01'	System	20 Nov 2020 07:06:03

**US3512248**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:56:44**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:06:03
Amendment Manager: User entered '09 Nov 2022 23:59'	System	20 Nov 2020 07:06:03

**US3512248**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:56:44**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:06:03
Amendment Manager: User entered 'Day 796'	System	20 Nov 2020 07:06:03

**US3512248**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:56:44**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:06:03
Amendment Manager: User entered '12 Nov 2022 00:01'	System	20 Nov 2020 07:06:03

**US3512248**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:56:44**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:06:03
Amendment Manager: User entered '16 Nov 2022 23:59'	System	20 Nov 2020 07:06:03

US3512248

**Folder: Cosmetic Injections and Dermal Fillers**

**Form: Cosmetic Injection\_ Dermal Filler eDiary (1)**

**Generated On: 10 Jun 2021 07:56:44**

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 14:44:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FCE43EC3-F1E0-47A1-B438-4D694934F821)', Time: '2021-03-02T18:29:53-05:00', User OID: 'PatientReportedOutcome (US3512248)', ODM File OID: '09bcea26-593f-45f3-9ae6-c2b36b9c67d5'	System	02 Mar 2021 23:30:05
User entered 'No (N)'	System	02 Mar 2021 23:30:05

**US3512248**

**Folder: Cosmetic Injections and Dermal Fillers**

**Form: Cosmetic Injection\_ Dermal Filler eDiary (1)**

**Generated On: 10 Jun 2021 07:56:44**

[Date & Time of Submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:44:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FCE43EC3-F1E0-47A1-B438-4D694934F821)', Time: '2021-03-02T18:29:59-05:00', User OID: 'PatientReportedOutcome (US3512248)', ODM File OID: '09bcea26-593f-45f3-9ae6-c2b36b9c67d5'	System	02 Mar 2021 23:30:05
User entered '02 Mar 2021 18:29:59'	System	02 Mar 2021 23:30:05



**US3512248**

**Folder: Safety Call Day 85 (1)**

**Form: Safety Call**

**Generated On: 10 Jun 2021 07:56:44**

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:23:03
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 22:12:02
DataPoint Verified.	(b) (4)	(b) (4), (b) (6)
User entered 'Yes (Y)'	Sheldon Warren (b) (4)	06 Dec 2020 22:48:29
	(b) (4)	

**US3512248**

**Folder: Safety Call Day 85 (1)**

**Form: Safety Call**

**Generated On: 10 Jun 2021 07:56:44**

[Date of Contact or Contact Attempt \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:23:03
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 22:12:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Dec 2020 15:58:07
User entered '6 Dec 2020'	Sheldon Warren (b) (4) (b) (4)	06 Dec 2020 22:48:29

**US3512248**

**Folder: Safety Call Day 85 (1)**

**Form: Safety Call**

**Generated On: 10 Jun 2021 07:56:44**

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:23:03
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 22:12:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Dec 2020 15:58:07
User entered 'Contact Made (CONTACT MADE)'	Sheldon Warren (b) (4) (b) (4)	06 Dec 2020 22:48:29

US3512248

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 10 Jun 2021 07:56:44

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:23:03
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 22:12:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Dec 2020 15:58:07
User entered empty.	Sheldon Warren (b) (4) (b) (4)	06 Dec 2020 22:48:29

**US3512248**

**Folder: Safety Call Day 85 (1)**

**Form: Continuing**

**Generated On: 10 Jun 2021 07:56:44**

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:23:03
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 22:12:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Dec 2020 15:58:12
User entered 'Yes (Y)'	Sheldon Warren (b) (4) (b) (4)	06 Dec 2020 22:48:40

**US3512248**

**Folder: Safety Call Day 85 (1)**

**Form: Continuing**

**Generated On: 10 Jun 2021 07:56:44**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:23:03
User entered 'I'	System	06 Dec 2020 22:48:40

**US3512248**

**Folder: Safety Call Day 119 (1)**

**Form: Safety Call**

**Generated On: 10 Jun 2021 07:56:44**

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:23:47
DataPoint Verified.	(b) (4), (b) (6)	10 Mar 2021 19:26:22
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 22:12:02
User entered 'Yes (Y)'	(b) (4) Sheldon Warren (b) (4) (b) (4)	07 Jan 2021 22:03:39

**US3512248**

**Folder: Safety Call Day 119 (1)**

**Form: Safety Call**

**Generated On: 10 Jun 2021 07:56:44**

[Date of Contact or Contact Attempt \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:23:47
DataPoint Verified.	(b) (4), (b) (6)	10 Mar 2021 19:26:22
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 22:12:02
User entered '7 Jan 2021'	(b) (4) Sheldon Warren (b) (4) (b) (4)	07 Jan 2021 22:03:39



**US3512248**

**Folder: Safety Call Day 119 (1)**

**Form: Safety Call**

**Generated On: 10 Jun 2021 07:56:44**

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:23:47
DataPoint Verified.	(b) (4), (b) (6)	10 Mar 2021 19:26:22
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 22:12:02
User entered 'Contact Made (CONTACT MADE)'	(b) (4) Sheldon Warren (b) (4) (b) (4)	07 Jan 2021 22:03:39

**US3512248**

**Folder: Safety Call Day 119 (1)**

**Form: Safety Call**

**Generated On: 10 Jun 2021 07:56:44**

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:23:47
DataPoint Verified.	(b) (4), (b) (6)	10 Mar 2021 19:26:22
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 22:12:02
User entered empty.	(b) (4) Sheldon Warren (b) (4) (b) (4)	07 Jan 2021 22:03:39

**US3512248**

**Folder: Safety Call Day 119 (1)**

**Form: Continuing**

**Generated On: 10 Jun 2021 07:56:44**

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:23:47
DataPoint Verified.	(b) (4), (b) (6)	10 Mar 2021 19:26:26
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 22:12:02
User entered 'Yes (Y)'	(b) (4) Sheldon Warren (b) (4) (b) (4)	07 Jan 2021 22:03:43

**US3512248**

**Folder: Safety Call Day 119 (1)**

**Form: Continuing**

**Generated On: 10 Jun 2021 07:56:44**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:23:47
User entered 'I'	System	07 Jan 2021 22:03:43

**US3512248**

**Folder: Safety Call Day 149 (1)**

**Form: Safety Call**

**Generated On: 10 Jun 2021 07:56:44**

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:23:47
DataPoint Verified.	(b) (4), (b) (6)	10 Mar 2021 19:25:33
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 22:12:02
User entered 'Yes (Y)'	(b) (4) Sheldon Warren (b) (4) (b) (4)	05 Feb 2021 00:16:09

**US3512248**

**Folder: Safety Call Day 149 (1)**

**Form: Safety Call**

**Generated On: 10 Jun 2021 07:56:44**

[Date of Contact or Contact Attempt \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:23:47
DataPoint Verified.	(b) (4), (b) (6)	10 Mar 2021 19:25:33
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 22:12:02
User entered '4 Feb 2021'	(b) (4) Sheldon Warren (b) (4) (b) (4)	05 Feb 2021 00:16:09

**US3512248**

**Folder: Safety Call Day 149 (1)**

**Form: Safety Call**

**Generated On: 10 Jun 2021 07:56:44**

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:23:47
DataPoint Verified.	(b) (4), (b) (6)	10 Mar 2021 19:25:33
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 22:12:02
User entered 'Contact Made (CONTACT MADE)'	(b) (4) Sheldon Warren (b) (4) (b) (4)	05 Feb 2021 00:16:09

US3512248

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 10 Jun 2021 07:56:44

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:23:47
DataPoint Verified.	(b) (4), (b) (6)	10 Mar 2021 19:25:33
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 22:12:02
User entered empty.	(b) (4) Sheldon Warren (b) (4) (b) (4)	05 Feb 2021 00:16:09



US3512248

Folder: Safety Call Day 149 (1)

Form: Continuing

Generated On: 10 Jun 2021 07:56:44

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:23:47
DataPoint Verified.	(b) (4), (b) (6)	10 Mar 2021 19:25:38
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 22:12:02
User entered 'Yes (Y)'	(b) (4) Sheldon Warren (b) (4) (b) (4)	05 Feb 2021 00:16:14

**US3512248**

**Folder: Safety Call Day 149 (1)**

**Form: Continuing**

**Generated On: 10 Jun 2021 07:56:44**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:23:47
User entered 'I'	System	05 Feb 2021 00:16:14

**US3512248**

**Folder: Safety Call Day 179 (1)**

**Form: Safety Call**

**Generated On: 10 Jun 2021 07:56:44**

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:23:47
DataPoint Verified.	(b) (4), (b) (6)	10 Mar 2021 19:25:59
User signature succeeded.	Michael Koren (b) (4)	05 Mar 2021 22:44:46
User entered 'Yes (Y)'	(b) (4) Sheldon Warren (b) (4) (b) (4)	04 Mar 2021 16:08:00

**US3512248**

**Folder: Safety Call Day 179 (1)**

**Form: Safety Call**

**Generated On: 10 Jun 2021 07:56:44**

[Date of Contact or Contact Attempt \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:23:47
DataPoint Verified.	(b) (4), (b) (6)	10 Mar 2021 19:25:59
User signature succeeded.	Michael Koren (b) (4)	05 Mar 2021 22:44:46
User entered '4 Mar 2021'	(b) (4) Sheldon Warren (b) (4) (b) (4)	04 Mar 2021 16:08:00

**US3512248**

**Folder: Safety Call Day 179 (1)**

**Form: Safety Call**

**Generated On: 10 Jun 2021 07:56:44**

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:23:47
DataPoint Verified.	(b) (4), (b) (6)	10 Mar 2021 19:25:59
User signature succeeded.	Michael Koren (b) (4)	05 Mar 2021 22:44:46
User entered 'Contact Made (CONTACT MADE)'	(b) (4) Sheldon Warren (b) (4) (b) (4)	04 Mar 2021 16:08:00

US3512248

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 10 Jun 2021 07:56:44

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:23:47
DataPoint Verified.	(b) (4), (b) (6)	10 Mar 2021 19:25:59
User signature succeeded.	Michael Koren (b) (4)	05 Mar 2021 22:44:46
User entered empty.	(b) (4) Sheldon Warren (b) (4) (b) (4)	04 Mar 2021 16:08:00

US3512248

Folder: Safety Call Day 179 (1)

Form: Continuing

Generated On: 10 Jun 2021 07:56:44

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:23:47
DataPoint Verified.	(b) (4), (b) (6)	10 Mar 2021 19:26:03
User signature succeeded.	Michael Koren (b) (4)	05 Mar 2021 22:44:46
User entered 'Yes (Y)'	(b) (4) Sheldon Warren (b) (4) (b) (4)	04 Mar 2021 16:07:46

**US3512248**

**Folder: Safety Call Day 179 (1)**

**Form: Continuing**

**Generated On: 10 Jun 2021 07:56:44**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:23:47
User entered 'I'	System	04 Mar 2021 16:07:46



**US3512248**

**Folder: Visit 4 Day 209 (1)**

**Form: Visit Date**

**Generated On: 10 Jun 2021 07:56:44**

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:21:08
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 19:44:41
User signature succeeded.	Michael Koren (b) (4)	31 Mar 2021 17:34:59
User entered 'Yes (Y)'	(b) (4) Brenda Anderson (b) (4)	29 Mar 2021 17:33:06
	(b) (4)	

**US3512248**

**Folder: Visit 4 Day 209 (1)**

**Form: Visit Date**

**Generated On: 10 Jun 2021 07:56:44**

[Visit date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:21:08
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 19:44:41
User signature succeeded.	Michael Koren (b) (4)	31 Mar 2021 17:34:59
User entered '25 Mar 2021'	(b) (4) Brenda Anderson (b) (4)	29 Mar 2021 17:33:06

**US3512248**

**Folder: Visit 4 Day 209 (1)**

**Form: Visit Date**

**Generated On: 10 Jun 2021 07:56:44**

[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 10:21:08
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 19:44:41
User signature succeeded.	Michael Koren (b) (4)	31 Mar 2021 17:34:59
User entered 'Clinic (Clinic)'	(b) (4) Brenda Anderson (b) (4) (b) (4)	29 Mar 2021 17:33:06

**US3512248**

**Folder: Visit 4 Day 209 (1)**

**Form: Visit Date**

**Generated On: 10 Jun 2021 07:56:44**

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:21:08
User entered 'VISIT4'	System	29 Mar 2021 17:33:06

**US3512248**

**Folder: Visit 4 Day 209 (1)**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 07:56:44**

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:21:08
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 19:44:48
User signature succeeded.	Michael Koren (b) (4)	31 Mar 2021 17:34:59
User entered 'No (N)'	(b) (4) Brenda Anderson (b) (4)	29 Mar 2021 17:33:36
	(b) (4)	

US3512248

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 07:56:44

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:21:08
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 19:44:48
User signature succeeded.	Michael Koren (b) (4)	31 Mar 2021 17:34:59
User entered empty.	(b) (4) Brenda Anderson (b) (4)	29 Mar 2021 17:33:36
	(b) (4)	

**US3512248**

**Folder: Visit 4 Day 209 (1)**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 07:56:44**

**Time of assessment (00:00-23:59)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:21:08
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 19:44:48
User signature succeeded.	Michael Koren (b) (4)	31 Mar 2021 17:34:59
User entered empty.	(b) (4) Brenda Anderson (b) (4)	29 Mar 2021 17:33:36

**US3512248**

**Folder: Visit 4 Day 209 (1)**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 07:56:44**

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:21:08
User entered empty.	System	29 Mar 2021 17:33:36



US3512248

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 07:56:44

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:21:08
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 19:44:48
User signature succeeded.	Michael Koren (b) (4)	31 Mar 2021 17:34:59
User entered empty.	(b) (4) Brenda Anderson (b) (4)	29 Mar 2021 17:33:36
	(b) (4)	

**US3512248**

**Folder: Visit 4 Day 209 (1)**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 07:56:44**

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:21:08
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 19:44:48
User signature succeeded.	Michael Koren (b) (4)	31 Mar 2021 17:34:59
User entered empty.	(b) (4) Brenda Anderson (b) (4)	29 Mar 2021 17:33:36
	(b) (4)	

**US3512248**

**Folder: Visit 4 Day 209 (1)**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 07:56:44**

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:21:08
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 19:44:48
User signature succeeded.	Michael Koren (b) (4)	31 Mar 2021 17:34:59
User entered empty.	(b) (4) Brenda Anderson (b) (4)	29 Mar 2021 17:33:36

**US3512248**

**Folder: Visit 4 Day 209 (1)**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 07:56:44**

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:21:08
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 19:44:48
User signature succeeded.	Michael Koren (b) (4)	31 Mar 2021 17:34:59
User entered empty.	(b) (4) Brenda Anderson (b) (4)	29 Mar 2021 17:33:36

**US3512248**

**Folder: Visit 4 Day 209 (1)**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 07:56:44**

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:21:08
User entered empty.	System	29 Mar 2021 17:33:36

**US3512248**

**Folder: Visit 4 Day 209 (1)**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 07:56:44**

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:21:08
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 19:44:48
User signature succeeded.	Michael Koren (b) (4)	31 Mar 2021 17:34:59
User entered empty.	(b) (4) Brenda Anderson (b) (4)	29 Mar 2021 17:33:36

US3512248

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 07:56:44

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:21:08
User entered empty.	System	29 Mar 2021 17:33:36

**US3512248**

**Folder: Visit 4 Day 209 (1)**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 07:56:44**

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:21:08
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 19:44:48
User signature succeeded.	Michael Koren (b) (4)	31 Mar 2021 17:34:59
User entered empty.	(b) (4) Brenda Anderson (b) (4)	29 Mar 2021 17:33:36
	(b) (4)	



US3512248

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 07:56:44

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:21:08
User entered empty.	System	29 Mar 2021 17:33:36

**US3512248**

**Folder: Visit 4 Day 209 (1)**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 07:56:44**

[Diastolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:21:08
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 19:44:48
User signature succeeded.	Michael Koren (b) (4)	31 Mar 2021 17:34:59
User entered empty.	(b) (4) Brenda Anderson (b) (4)	29 Mar 2021 17:33:36
	(b) (4)	

US3512248

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 07:56:44

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:21:08
User entered empty.	System	29 Mar 2021 17:33:36

**US3512248**

**Folder: Visit 4 Day 209 (1)**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 07:56:44**

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:21:08

**US3512248**

**Folder: Visit 4 Day 209 (1)**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 07:56:44**

[Weight \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:21:08

**US3512248**

**Folder: Visit 4 Day 209 (1)**

**Form: Physical Examination**

**Generated On: 10 Jun 2021 07:56:44**

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:21:08
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 19:44:52
User signature succeeded.	Michael Koren (b) (4)	31 Mar 2021 17:34:59
User entered 'No (N)'	(b) (4) Brenda Anderson (b) (4)	29 Mar 2021 17:33:45

**US3512248**

**Folder: Visit 4 Day 209 (1)**

**Form: Physical Examination**

**Generated On: 10 Jun 2021 07:56:44**

**Date of examination (dd MMM yyyy)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:21:08
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 19:44:52
User signature succeeded.	Michael Koren (b) (4)	31 Mar 2021 17:34:59
User entered empty.	(b) (4) Brenda Anderson (b) (4)	29 Mar 2021 17:33:45
	(b) (4)	

**US3512248**

**Folder: Visit 4 Day 209 (1)**

**Form: Immunogenicity Assessment**

**Generated On: 10 Jun 2021 07:56:44**

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:21:08
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 19:44:56
User signature succeeded.	Michael Koren (b) (4)	31 Mar 2021 17:34:59
User entered 'Yes (Y)'	(b) (4) Brenda Anderson (b) (4)	29 Mar 2021 17:34:00



**US3512248**

**Folder: Visit 4 Day 209 (1)**

**Form: Immunogenicity Assessment**

**Generated On: 10 Jun 2021 07:56:44**

**Collection date** (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:21:08
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 19:44:56
User signature succeeded.	Michael Koren (b) (4)	31 Mar 2021 17:34:59
User entered '25 Mar 2021'	(b) (4) Brenda Anderson (b) (4)	29 Mar 2021 17:34:00
	(b) (4)	

**US3512248**

**Folder: Visit 4 Day 209 (1)**

**Form: Immunogenicity Assessment**

**Generated On: 10 Jun 2021 07:56:44**

[Collection time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:21:08
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 19:44:56
User signature succeeded.	Michael Koren (b) (4)	31 Mar 2021 17:34:59
User entered '14:10'	(b) (4) Brenda Anderson (b) (4)	29 Mar 2021 17:34:00
	(b) (4)	

**US3512248**

**Folder: Visit 4 Day 209 (1)**

**Form: Immunogenicity Assessment**

**Generated On: 10 Jun 2021 07:56:44**

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:21:08
User entered '25 Mar 2021 14:10'	System	29 Mar 2021 17:34:00

**US3512248**

**Folder: Visit 4 Day 209 (1)**

**Form: Continuing**

**Generated On: 10 Jun 2021 07:56:44**

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:21:08
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 19:45:02
User signature succeeded.	Michael Koren (b) (4)	31 Mar 2021 17:34:59
User entered 'Yes (Y)'	(b) (4) Brenda Anderson (b) (4)	29 Mar 2021 17:34:06

**US3512248**

**Folder: Visit 4 Day 209 (1)**

**Form: Continuing**

**Generated On: 10 Jun 2021 07:56:44**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:21:08
User entered 'I'	System	29 Mar 2021 17:34:06

**US3512248**

**Folder: Safety Call Day 239 (1)**

**Form: Safety Call**

**Generated On: 10 Jun 2021 07:56:44**

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Sheldon Warren (b) (4) (b) (4)	03 May 2021 18:31:19

US3512248

Folder: Safety Call Day 239 (1)

Form: Safety Call

Generated On: 10 Jun 2021 07:56:44

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered '3 May 2021'	Sheldon Warren (b) (4) (b) (4)	03 May 2021 18:31:19

US3512248

Folder: Safety Call Day 239 (1)

Form: Safety Call

Generated On: 10 Jun 2021 07:56:44

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
User entered 'Contact Made (CONTACT MADE)'	Sheldon Warren (b) (4) (b) (4)	03 May 2021 18:31:19



**US3512248**

**Folder: Safety Call Day 239 (1)**

**Form: Safety Call**

**Generated On: 10 Jun 2021 07:56:44**

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
User entered empty.	Sheldon Warren (b) (4) (b) (4)	03 May 2021 18:31:19

US3512248

Folder: Safety Call Day 239 (1)

Form: Continuing

Generated On: 10 Jun 2021 07:56:44

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Sheldon Warren (b) (4) (b) (4)	03 May 2021 18:31:29

**US3512248**

**Folder: Safety Call Day 239 (1)**

**Form: Continuing**

**Generated On: 10 Jun 2021 07:56:44**

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered 'I'	System	03 May 2021 18:31:29

**US3512248**

**Folder: Covid-19 Assessment 19 Apr 2021**

**Form: COVID-19 Contact**

**Generated On: 10 Jun 2021 07:56:44**

[Date of Contact](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	26 Apr 2021 15:25:40
	(b) (4)	
User entered '19 Apr 2021'	Sheldon Warren (b) (4)	23 Apr 2021 19:02:49
	(b) (4)	

**US3512248**

**Folder: Covid-19 Assessment 19 Apr 2021**

**Form: COVID-19 Contact**

**Generated On: 10 Jun 2021 07:56:44**

[Time of Contact](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	26 Apr 2021 15:25:40
	(b) (4)	
User entered '19:00'	Sheldon Warren (b) (4)	23 Apr 2021 19:02:49
	(b) (4)	

**US3512248**

**Folder: Covid-19 Assessment 19 Apr 2021**

**Form: COVID-19 Contact**

**Generated On: 10 Jun 2021 07:56:44**

[Date and Time of Contact \(derived\)](#)

Audit	User	Time (GMT)
User entered '19 Apr 2021 19:00'	System	23 Apr 2021 19:02:49

US3512248

Folder: Covid-19 Assessment 19 Apr 2021

Form: COVID-19 Contact

Generated On: 10 Jun 2021 07:56:44

[Type of Contact](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	26 Apr 2021 15:25:40
	(b) (4)	
User entered 'Safety Call (Safety Call)' reason for change: Data Entry Error	Sheldon Warren (b) (4)	23 Apr 2021 19:05:03
	(b) (4)	
User entered 'Convalescent Tele-visit (Convalescent Tele-visit)'	Sheldon Warren (b) (4)	23 Apr 2021 19:02:49
	(b) (4)	

US3512248

Folder: Covid-19 Assessment 19 Apr 2021

Form: COVID-19 Contact

Generated On: 10 Jun 2021 07:56:44

[Has the subject reported symptoms of SARS-COV-2?](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	26 Apr 2021 15:25:40
	(b) (4)	
User entered 'Yes (Y)'	Sheldon Warren (b) (4)	23 Apr 2021 19:02:49
	(b) (4)	



US3512248

Folder: Covid-19 Assessment 19 Apr 2021

Form: Symptom Log (1)

Generated On: 10 Jun 2021 07:56:44

[Symptom Day](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	26 Apr 2021 15:25:40
	(b) (4)	
User entered 'Day 1 (Day 1)'	Sheldon Warren (b) (4)	23 Apr 2021 19:06:01
	(b) (4)	

US3512248

Folder: Covid-19 Assessment 19 Apr 2021

Form: Symptom Log (1)

Generated On: 10 Jun 2021 07:56:44

[Date](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	26 Apr 2021 15:25:40
	(b) (4)	
User entered '12 Apr 2021'	Sheldon Warren (b) (4)	23 Apr 2021 19:06:01
	(b) (4)	

US3512248

Folder: Covid-19 Assessment 19 Apr 2021

Form: Symptom Log (1)

Generated On: 10 Jun 2021 07:56:44

[Assessment Not Done](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	26 Apr 2021 15:25:40
	(b) (4)	
User entered '0'	Sheldon Warren (b) (4)	23 Apr 2021 19:06:01
	(b) (4)	

US3512248

Folder: Covid-19 Assessment 19 Apr 2021

Form: Symptom Log (1)

Generated On: 10 Jun 2021 07:56:44

[O2 Saturation](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4) (b) (4)	26 Apr 2021 15:25:40
User entered empty.	Sheldon Warren (b) (4) (b) (4)	23 Apr 2021 19:06:01

**US3512248**

**Folder: Covid-19 Assessment 19 Apr 2021**

**Form: Symptom Log (1)**

**Generated On: 10 Jun 2021 07:56:44**

[O2 Saturation Units](#)

Audit	User	Time (GMT)
User entered empty.	System	23 Apr 2021 19:06:01

US3512248

Folder: Covid-19 Assessment 19 Apr 2021

Form: Symptom Log (1)

Generated On: 10 Jun 2021 07:56:44

[Temperature](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	26 Apr 2021 15:25:40
	(b) (4)	
User entered empty.	Sheldon Warren (b) (4)	23 Apr 2021 19:06:01
	(b) (4)	

US3512248

Folder: Covid-19 Assessment 19 Apr 2021

Form: Symptom Log (1)

Generated On: 10 Jun 2021 07:56:44

[Chills](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	26 Apr 2021 15:25:40
	(b) (4)	
User entered 'None (None)'	Sheldon Warren (b) (4)	23 Apr 2021 19:06:01
	(b) (4)	

US3512248

Folder: Covid-19 Assessment 19 Apr 2021

Form: Symptom Log (1)

Generated On: 10 Jun 2021 07:56:44

[Cough](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	26 Apr 2021 15:25:40
	(b) (4)	
User entered 'Moderate (Moderate)'	Sheldon Warren (b) (4)	23 Apr 2021 19:06:01
	(b) (4)	



US3512248

Folder: Covid-19 Assessment 19 Apr 2021

Form: Symptom Log (1)

Generated On: 10 Jun 2021 07:56:44

[Shortness of Breath](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	26 Apr 2021 15:25:40
	(b) (4)	
User entered 'None (None)'	Sheldon Warren (b) (4)	23 Apr 2021 19:06:01
	(b) (4)	

US3512248

Folder: Covid-19 Assessment 19 Apr 2021

Form: Symptom Log (1)

Generated On: 10 Jun 2021 07:56:44

[Difficulty Breathing](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	26 Apr 2021 15:25:40
	(b) (4)	
User entered 'None (None)'	Sheldon Warren (b) (4)	23 Apr 2021 19:06:01
	(b) (4)	

US3512248

Folder: Covid-19 Assessment 19 Apr 2021

Form: Symptom Log (1)

Generated On: 10 Jun 2021 07:56:44

[Fatigue](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	26 Apr 2021 15:25:40
	(b) (4)	
User entered 'None (None)'	Sheldon Warren (b) (4)	23 Apr 2021 19:06:01
	(b) (4)	

US3512248

Folder: Covid-19 Assessment 19 Apr 2021

Form: Symptom Log (1)

Generated On: 10 Jun 2021 07:56:44

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	26 Apr 2021 15:25:40
	(b) (4)	
User entered 'None (None)'	Sheldon Warren (b) (4)	23 Apr 2021 19:06:01
	(b) (4)	

US3512248

Folder: Covid-19 Assessment 19 Apr 2021

Form: Symptom Log (1)

Generated On: 10 Jun 2021 07:56:44

[Body Aches](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	26 Apr 2021 15:25:40
	(b) (4)	
User entered 'None (None)'	Sheldon Warren (b) (4)	23 Apr 2021 19:06:01
	(b) (4)	

US3512248

Folder: Covid-19 Assessment 19 Apr 2021

Form: Symptom Log (1)

Generated On: 10 Jun 2021 07:56:44

[Headache](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	26 Apr 2021 15:25:40
	(b) (4)	
User entered 'None (None)'	Sheldon Warren (b) (4)	23 Apr 2021 19:06:01
	(b) (4)	

US3512248

Folder: Covid-19 Assessment 19 Apr 2021

Form: Symptom Log (1)

Generated On: 10 Jun 2021 07:56:44

[New Loss of Taste](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	26 Apr 2021 15:25:40
	(b) (4)	
User entered 'None (None)'	Sheldon Warren (b) (4)	23 Apr 2021 19:06:01
	(b) (4)	

US3512248

Folder: Covid-19 Assessment 19 Apr 2021

Form: Symptom Log (1)

Generated On: 10 Jun 2021 07:56:44

[New Loss of Smell](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	26 Apr 2021 15:25:40
	(b) (4)	
User entered 'None (None)'	Sheldon Warren (b) (4)	23 Apr 2021 19:06:01
	(b) (4)	



US3512248

Folder: Covid-19 Assessment 19 Apr 2021

Form: Symptom Log (1)

Generated On: 10 Jun 2021 07:56:44

[Nasal Congestion](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	26 Apr 2021 15:25:40
	(b) (4)	
User entered 'Mild (Mild)'	Sheldon Warren (b) (4)	23 Apr 2021 19:06:01
	(b) (4)	

US3512248

Folder: Covid-19 Assessment 19 Apr 2021

Form: Symptom Log (1)

Generated On: 10 Jun 2021 07:56:44

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	26 Apr 2021 15:25:40
	(b) (4)	
User entered 'Moderate (Moderate)'	Sheldon Warren (b) (4)	23 Apr 2021 19:06:01
	(b) (4)	

US3512248

Folder: Covid-19 Assessment 19 Apr 2021

Form: Symptom Log (1)

Generated On: 10 Jun 2021 07:56:44

[Nausea](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	26 Apr 2021 15:25:40
	(b) (4)	
User entered 'None (None)'	Sheldon Warren (b) (4)	23 Apr 2021 19:06:01
	(b) (4)	

US3512248

Folder: Covid-19 Assessment 19 Apr 2021

Form: Symptom Log (1)

Generated On: 10 Jun 2021 07:56:44

[Vomiting](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	26 Apr 2021 15:25:40
	(b) (4)	
User entered 'None (None)'	Sheldon Warren (b) (4)	23 Apr 2021 19:06:01
	(b) (4)	

US3512248

Folder: Covid-19 Assessment 19 Apr 2021

Form: Symptom Log (1)

Generated On: 10 Jun 2021 07:56:44

[Diarrhea](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	26 Apr 2021 15:25:40
	(b) (4)	
User entered 'None (None)'	Sheldon Warren (b) (4)	23 Apr 2021 19:06:01
	(b) (4)	

US3512248

Folder: Covid-19 Assessment 19 Apr 2021

Form: Symptom Log (1)

Generated On: 10 Jun 2021 07:56:44

[Sore Throat](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	26 Apr 2021 15:25:40
	(b) (4)	
User entered 'None (None)'	Sheldon Warren (b) (4)	23 Apr 2021 19:06:01
	(b) (4)	

US3512248

Folder: Covid-19 Assessment 19 Apr 2021

Form: Symptom Log (2)

Generated On: 10 Jun 2021 07:56:44

[Symptom Day](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	26 Apr 2021 15:25:40
	(b) (4)	
User entered 'Day 2 (Day 2)'	Sheldon Warren (b) (4)	23 Apr 2021 19:06:39
	(b) (4)	

US3512248

Folder: Covid-19 Assessment 19 Apr 2021

Form: Symptom Log (2)

Generated On: 10 Jun 2021 07:56:44

[Date](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	26 Apr 2021 15:25:40
	(b) (4)	
User entered '13 Apr 2021'	Sheldon Warren (b) (4)	23 Apr 2021 19:06:39
	(b) (4)	



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Folder: Covid-19 Assessment 19 Apr 2021

Form: Symptom Log (2)

Generated On: 10 Jun 2021 07:56:44

[Assessment Not Done](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	26 Apr 2021 15:25:40
	(b) (4)	
User entered '0'	Sheldon Warren (b) (4)	23 Apr 2021 19:06:39
	(b) (4)	

US3512248

Folder: Covid-19 Assessment 19 Apr 2021

Form: Symptom Log (2)

Generated On: 10 Jun 2021 07:56:44

[O2 Saturation](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4) (b) (4)	26 Apr 2021 15:25:40
User entered empty.	Sheldon Warren (b) (4) (b) (4)	23 Apr 2021 19:06:39

**US3512248**

**Folder: Covid-19 Assessment 19 Apr 2021**

**Form: Symptom Log (2)**

**Generated On: 10 Jun 2021 07:56:44**

[O2 Saturation Units](#)

Audit	User	Time (GMT)
User entered empty.	System	23 Apr 2021 19:06:39

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Folder: Covid-19 Assessment 19 Apr 2021

Form: Symptom Log (2)

Generated On: 10 Jun 2021 07:56:44

[Temperature](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	26 Apr 2021 15:25:40
	(b) (4)	
User entered empty.	Sheldon Warren (b) (4)	23 Apr 2021 19:06:39
	(b) (4)	

US3512248

Folder: Covid-19 Assessment 19 Apr 2021

Form: Symptom Log (2)

Generated On: 10 Jun 2021 07:56:44

[Chills](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	26 Apr 2021 15:25:40
	(b) (4)	
User entered 'None (None)'	Sheldon Warren (b) (4)	23 Apr 2021 19:06:39
	(b) (4)	

US3512248

Folder: Covid-19 Assessment 19 Apr 2021

Form: Symptom Log (2)

Generated On: 10 Jun 2021 07:56:44

[Cough](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	26 Apr 2021 15:25:40
	(b) (4)	
User entered 'Moderate (Moderate)'	Sheldon Warren (b) (4)	23 Apr 2021 19:06:39
	(b) (4)	

US3512248

Folder: Covid-19 Assessment 19 Apr 2021

Form: Symptom Log (2)

Generated On: 10 Jun 2021 07:56:44

[Shortness of Breath](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	26 Apr 2021 15:25:40
	(b) (4)	
User entered 'None (None)'	Sheldon Warren (b) (4)	23 Apr 2021 19:06:39
	(b) (4)	

US3512248

Folder: Covid-19 Assessment 19 Apr 2021

Form: Symptom Log (2)

Generated On: 10 Jun 2021 07:56:44

[Difficulty Breathing](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	26 Apr 2021 15:25:40
	(b) (4)	
User entered 'None (None)'	Sheldon Warren (b) (4)	23 Apr 2021 19:06:39
	(b) (4)	



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Folder: Covid-19 Assessment 19 Apr 2021

Form: Symptom Log (2)

Generated On: 10 Jun 2021 07:56:44

[Fatigue](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	26 Apr 2021 15:25:40
	(b) (4)	
User entered 'None (None)'	Sheldon Warren (b) (4)	23 Apr 2021 19:06:39
	(b) (4)	

US3512248

Folder: Covid-19 Assessment 19 Apr 2021

Form: Symptom Log (2)

Generated On: 10 Jun 2021 07:56:44

Muscle Aches (Myalgia)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	26 Apr 2021 15:25:40
	(b) (4)	
User entered 'None (None)'	Sheldon Warren (b) (4)	23 Apr 2021 19:06:39
	(b) (4)	

US3512248

Folder: Covid-19 Assessment 19 Apr 2021

Form: Symptom Log (2)

Generated On: 10 Jun 2021 07:56:44

[Body Aches](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	26 Apr 2021 15:25:40
	(b) (4)	
User entered 'None (None)'	Sheldon Warren (b) (4)	23 Apr 2021 19:06:39
	(b) (4)	

US3512248

Folder: Covid-19 Assessment 19 Apr 2021

Form: Symptom Log (2)

Generated On: 10 Jun 2021 07:56:44

[Headache](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	26 Apr 2021 15:25:40
	(b) (4)	
User entered 'None (None)'	Sheldon Warren (b) (4)	23 Apr 2021 19:06:39
	(b) (4)	

US3512248

Folder: Covid-19 Assessment 19 Apr 2021

Form: Symptom Log (2)

Generated On: 10 Jun 2021 07:56:44

[New Loss of Taste](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	26 Apr 2021 15:25:40
	(b) (4)	
User entered 'None (None)'	Sheldon Warren (b) (4)	23 Apr 2021 19:06:39
	(b) (4)	

US3512248

Folder: Covid-19 Assessment 19 Apr 2021

Form: Symptom Log (2)

Generated On: 10 Jun 2021 07:56:44

[New Loss of Smell](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	26 Apr 2021 15:25:40
	(b) (4)	
User entered 'None (None)'	Sheldon Warren (b) (4)	23 Apr 2021 19:06:39
	(b) (4)	

US3512248

Folder: Covid-19 Assessment 19 Apr 2021

Form: Symptom Log (2)

Generated On: 10 Jun 2021 07:56:44

[Nasal Congestion](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	26 Apr 2021 15:25:40
	(b) (4)	
User entered 'Mild (Mild)'	Sheldon Warren (b) (4)	23 Apr 2021 19:06:39
	(b) (4)	

US3512248

Folder: Covid-19 Assessment 19 Apr 2021

Form: Symptom Log (2)

Generated On: 10 Jun 2021 07:56:44

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	26 Apr 2021 15:25:40
	(b) (4)	
User entered 'Moderate (Moderate)'	Sheldon Warren (b) (4)	23 Apr 2021 19:06:39
	(b) (4)	



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Folder: Covid-19 Assessment 19 Apr 2021

Form: Symptom Log (2)

Generated On: 10 Jun 2021 07:56:44

[Nausea](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	26 Apr 2021 15:25:40
	(b) (4)	
User entered 'None (None)'	Sheldon Warren (b) (4)	23 Apr 2021 19:06:39
	(b) (4)	

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Folder: Covid-19 Assessment 19 Apr 2021

Form: Symptom Log (2)

Generated On: 10 Jun 2021 07:56:44

[Vomiting](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	26 Apr 2021 15:25:40
	(b) (4)	
User entered 'None (None)'	Sheldon Warren (b) (4)	23 Apr 2021 19:06:39
	(b) (4)	

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Folder: Covid-19 Assessment 19 Apr 2021

Form: Symptom Log (2)

Generated On: 10 Jun 2021 07:56:44

[Diarrhea](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	26 Apr 2021 15:25:40
	(b) (4)	
User entered 'None (None)'	Sheldon Warren (b) (4)	23 Apr 2021 19:06:39
	(b) (4)	

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Folder: Covid-19 Assessment 19 Apr 2021

Form: Symptom Log (2)

Generated On: 10 Jun 2021 07:56:44

[Sore Throat](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	26 Apr 2021 15:25:40
	(b) (4)	
User entered 'None (None)'	Sheldon Warren (b) (4)	23 Apr 2021 19:06:39
	(b) (4)	

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Folder: Covid-19 Assessment 19 Apr 2021

Form: Symptom Log (3)

Generated On: 10 Jun 2021 07:56:44

[Symptom Day](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	26 Apr 2021 15:25:40
	(b) (4)	
User entered 'Day 3 (Day 3)'	Sheldon Warren (b) (4)	23 Apr 2021 19:07:15
	(b) (4)	

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Folder: Covid-19 Assessment 19 Apr 2021

Form: Symptom Log (3)

Generated On: 10 Jun 2021 07:56:44

[Date](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	26 Apr 2021 15:25:40
	(b) (4)	
User entered '14 Apr 2021'	Sheldon Warren (b) (4)	23 Apr 2021 19:07:15
	(b) (4)	

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Folder: Covid-19 Assessment 19 Apr 2021

Form: Symptom Log (3)

Generated On: 10 Jun 2021 07:56:44

[Assessment Not Done](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	26 Apr 2021 15:25:40
	(b) (4)	
User entered '0'	Sheldon Warren (b) (4)	23 Apr 2021 19:07:15
	(b) (4)	

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Folder: Covid-19 Assessment 19 Apr 2021

Form: Symptom Log (3)

Generated On: 10 Jun 2021 07:56:44

[O2 Saturation](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4) (b) (4)	26 Apr 2021 15:25:40
User entered empty.	Sheldon Warren (b) (4) (b) (4)	23 Apr 2021 19:07:15



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**Folder: Covid-19 Assessment 19 Apr 2021**

**Form: Symptom Log (3)**

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[O2 Saturation Units](#)

Audit	User	Time (GMT)
User entered empty.	System	23 Apr 2021 19:07:15

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Folder: Covid-19 Assessment 19 Apr 2021

Form: Symptom Log (3)

Generated On: 10 Jun 2021 07:56:44

[Temperature](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	26 Apr 2021 15:25:40
	(b) (4)	
User entered empty.	Sheldon Warren (b) (4)	23 Apr 2021 19:07:15
	(b) (4)	

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Folder: Covid-19 Assessment 19 Apr 2021

Form: Symptom Log (3)

Generated On: 10 Jun 2021 07:56:44

[Chills](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	26 Apr 2021 15:25:40
	(b) (4)	
User entered 'None (None)'	Sheldon Warren (b) (4)	23 Apr 2021 19:07:15
	(b) (4)	

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Form: Symptom Log (3)

Generated On: 10 Jun 2021 07:56:44

[Cough](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	26 Apr 2021 15:25:40
	(b) (4)	
User entered 'Moderate (Moderate)'	Sheldon Warren (b) (4)	23 Apr 2021 19:07:15
	(b) (4)	

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Folder: Covid-19 Assessment 19 Apr 2021

Form: Symptom Log (3)

Generated On: 10 Jun 2021 07:56:44

[Shortness of Breath](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	26 Apr 2021 15:25:40
	(b) (4)	
User entered 'None (None)'	Sheldon Warren (b) (4)	23 Apr 2021 19:07:15
	(b) (4)	

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Folder: Covid-19 Assessment 19 Apr 2021

Form: Symptom Log (3)

Generated On: 10 Jun 2021 07:56:44

[Difficulty Breathing](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	26 Apr 2021 15:25:40
	(b) (4)	
User entered 'None (None)'	Sheldon Warren (b) (4)	23 Apr 2021 19:07:15
	(b) (4)	

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Folder: Covid-19 Assessment 19 Apr 2021

Form: Symptom Log (3)

Generated On: 10 Jun 2021 07:56:44

[Fatigue](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	26 Apr 2021 15:25:40
	(b) (4)	
User entered 'None (None)'	Sheldon Warren (b) (4)	23 Apr 2021 19:07:15
	(b) (4)	

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Folder: Covid-19 Assessment 19 Apr 2021

Form: Symptom Log (3)

Generated On: 10 Jun 2021 07:56:44

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	26 Apr 2021 15:25:40
	(b) (4)	
User entered 'None (None)'	Sheldon Warren (b) (4)	23 Apr 2021 19:07:15
	(b) (4)	



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Folder: Covid-19 Assessment 19 Apr 2021

Form: Symptom Log (3)

Generated On: 10 Jun 2021 07:56:44

[Body Aches](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	26 Apr 2021 15:25:40
	(b) (4)	
User entered 'None (None)'	Sheldon Warren (b) (4)	23 Apr 2021 19:07:15
	(b) (4)	

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Folder: Covid-19 Assessment 19 Apr 2021

Form: Symptom Log (3)

Generated On: 10 Jun 2021 07:56:44

[Headache](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	26 Apr 2021 15:25:40
	(b) (4)	
User entered 'None (None)'	Sheldon Warren (b) (4)	23 Apr 2021 19:07:15
	(b) (4)	

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Folder: Covid-19 Assessment 19 Apr 2021

Form: Symptom Log (3)

Generated On: 10 Jun 2021 07:56:44

[New Loss of Taste](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	26 Apr 2021 15:25:40
	(b) (4)	
User entered 'None (None)'	Sheldon Warren (b) (4)	23 Apr 2021 19:07:15
	(b) (4)	

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Folder: Covid-19 Assessment 19 Apr 2021

Form: Symptom Log (3)

Generated On: 10 Jun 2021 07:56:44

[New Loss of Smell](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	26 Apr 2021 15:25:40
	(b) (4)	
User entered 'None (None)'	Sheldon Warren (b) (4)	23 Apr 2021 19:07:15
	(b) (4)	

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Folder: Covid-19 Assessment 19 Apr 2021

Form: Symptom Log (3)

Generated On: 10 Jun 2021 07:56:44

[Nasal Congestion](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	26 Apr 2021 15:25:40
	(b) (4)	
User entered 'Mild (Mild)'	Sheldon Warren (b) (4)	23 Apr 2021 19:07:15
	(b) (4)	

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Folder: Covid-19 Assessment 19 Apr 2021

Form: Symptom Log (3)

Generated On: 10 Jun 2021 07:56:44

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	26 Apr 2021 15:25:40
	(b) (4)	
User entered 'Moderate (Moderate)'	Sheldon Warren (b) (4)	23 Apr 2021 19:07:15
	(b) (4)	

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Folder: Covid-19 Assessment 19 Apr 2021

Form: Symptom Log (3)

Generated On: 10 Jun 2021 07:56:44

[Nausea](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	26 Apr 2021 15:25:40
	(b) (4)	
User entered 'None (None)'	Sheldon Warren (b) (4)	23 Apr 2021 19:07:15
	(b) (4)	

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Folder: Covid-19 Assessment 19 Apr 2021

Form: Symptom Log (3)

Generated On: 10 Jun 2021 07:56:44

[Vomiting](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	26 Apr 2021 15:25:40
	(b) (4)	
User entered 'None (None)'	Sheldon Warren (b) (4)	23 Apr 2021 19:07:15
	(b) (4)	



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Folder: Covid-19 Assessment 19 Apr 2021

Form: Symptom Log (3)

Generated On: 10 Jun 2021 07:56:44

[Diarrhea](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	26 Apr 2021 15:25:40
	(b) (4)	
User entered 'None (None)'	Sheldon Warren (b) (4)	23 Apr 2021 19:07:15
	(b) (4)	

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Folder: Covid-19 Assessment 19 Apr 2021

Form: Symptom Log (3)

Generated On: 10 Jun 2021 07:56:44

[Sore Throat](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	26 Apr 2021 15:25:40
	(b) (4)	
User entered 'None (None)'	Sheldon Warren (b) (4)	23 Apr 2021 19:07:15
	(b) (4)	

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Folder: Covid-19 Assessment 19 Apr 2021

Form: Symptom Log (4)

Generated On: 10 Jun 2021 07:56:44

[Symptom Day](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	26 Apr 2021 15:25:40
	(b) (4)	
User entered 'Day 4 (Day 4)'	Sheldon Warren (b) (4)	23 Apr 2021 19:07:55
	(b) (4)	

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Folder: Covid-19 Assessment 19 Apr 2021

Form: Symptom Log (4)

Generated On: 10 Jun 2021 07:56:44

[Date](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	26 Apr 2021 15:25:40
	(b) (4)	
User entered '15 Apr 2021'	Sheldon Warren (b) (4)	23 Apr 2021 19:07:55
	(b) (4)	

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Folder: Covid-19 Assessment 19 Apr 2021

Form: Symptom Log (4)

Generated On: 10 Jun 2021 07:56:44

[Assessment Not Done](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	26 Apr 2021 15:25:40
	(b) (4)	
User entered '0'	Sheldon Warren (b) (4)	23 Apr 2021 19:07:55
	(b) (4)	

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Folder: Covid-19 Assessment 19 Apr 2021

Form: Symptom Log (4)

Generated On: 10 Jun 2021 07:56:44

[O2 Saturation](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4) (b) (4)	26 Apr 2021 15:25:40
User entered empty.	Sheldon Warren (b) (4) (b) (4)	23 Apr 2021 19:07:55

**US3512248**

**Folder: Covid-19 Assessment 19 Apr 2021**

**Form: Symptom Log (4)**

**Generated On: 10 Jun 2021 07:56:44**

[O2 Saturation Units](#)

Audit	User	Time (GMT)
User entered empty.	System	23 Apr 2021 19:07:55

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Folder: Covid-19 Assessment 19 Apr 2021

Form: Symptom Log (4)

Generated On: 10 Jun 2021 07:56:44

[Temperature](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	26 Apr 2021 15:25:40
	(b) (4)	
User entered empty.	Sheldon Warren (b) (4)	23 Apr 2021 19:07:55
	(b) (4)	



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Folder: Covid-19 Assessment 19 Apr 2021

Form: Symptom Log (4)

Generated On: 10 Jun 2021 07:56:44

[Chills](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	26 Apr 2021 15:25:40
	(b) (4)	
User entered 'None (None)'	Sheldon Warren (b) (4)	23 Apr 2021 19:07:55
	(b) (4)	

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Folder: Covid-19 Assessment 19 Apr 2021

Form: Symptom Log (4)

Generated On: 10 Jun 2021 07:56:44

[Cough](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	26 Apr 2021 15:25:40
	(b) (4)	
User entered 'Moderate (Moderate)'	Sheldon Warren (b) (4)	23 Apr 2021 19:07:55
	(b) (4)	

US3512248

Folder: Covid-19 Assessment 19 Apr 2021

Form: Symptom Log (4)

Generated On: 10 Jun 2021 07:56:44

[Shortness of Breath](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	26 Apr 2021 15:25:40
	(b) (4)	
User entered 'None (None)'	Sheldon Warren (b) (4)	23 Apr 2021 19:07:55
	(b) (4)	

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Folder: Covid-19 Assessment 19 Apr 2021

Form: Symptom Log (4)

Generated On: 10 Jun 2021 07:56:44

[Difficulty Breathing](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	26 Apr 2021 15:25:40
	(b) (4)	
User entered 'None (None)'	Sheldon Warren (b) (4)	23 Apr 2021 19:07:55
	(b) (4)	

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Folder: Covid-19 Assessment 19 Apr 2021

Form: Symptom Log (4)

Generated On: 10 Jun 2021 07:56:44

[Fatigue](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	26 Apr 2021 15:25:40
	(b) (4)	
User entered 'None (None)'	Sheldon Warren (b) (4)	23 Apr 2021 19:07:55
	(b) (4)	

US3512248

Folder: Covid-19 Assessment 19 Apr 2021

Form: Symptom Log (4)

Generated On: 10 Jun 2021 07:56:44

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	26 Apr 2021 15:25:40
	(b) (4)	
User entered 'None (None)'	Sheldon Warren (b) (4)	23 Apr 2021 19:07:55
	(b) (4)	

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Folder: Covid-19 Assessment 19 Apr 2021

Form: Symptom Log (4)

Generated On: 10 Jun 2021 07:56:44

[Body Aches](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	26 Apr 2021 15:25:40
	(b) (4)	
User entered 'None (None)'	Sheldon Warren (b) (4)	23 Apr 2021 19:07:55
	(b) (4)	

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Folder: Covid-19 Assessment 19 Apr 2021

Form: Symptom Log (4)

Generated On: 10 Jun 2021 07:56:44

[Headache](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	26 Apr 2021 15:25:40
	(b) (4)	
User entered 'None (None)'	Sheldon Warren (b) (4)	23 Apr 2021 19:07:55
	(b) (4)	



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Folder: Covid-19 Assessment 19 Apr 2021

Form: Symptom Log (4)

Generated On: 10 Jun 2021 07:56:44

[New Loss of Taste](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	26 Apr 2021 15:25:40
	(b) (4)	
User entered 'None (None)'	Sheldon Warren (b) (4)	23 Apr 2021 19:07:55
	(b) (4)	

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Folder: Covid-19 Assessment 19 Apr 2021

Form: Symptom Log (4)

Generated On: 10 Jun 2021 07:56:44

[New Loss of Smell](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	26 Apr 2021 15:25:40
	(b) (4)	
User entered 'None (None)'	Sheldon Warren (b) (4)	23 Apr 2021 19:07:55
	(b) (4)	

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Folder: Covid-19 Assessment 19 Apr 2021

Form: Symptom Log (4)

Generated On: 10 Jun 2021 07:56:44

[Nasal Congestion](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	26 Apr 2021 15:25:40
	(b) (4)	
User entered 'Mild (Mild)'	Sheldon Warren (b) (4)	23 Apr 2021 19:07:55
	(b) (4)	

US3512248

Folder: Covid-19 Assessment 19 Apr 2021

Form: Symptom Log (4)

Generated On: 10 Jun 2021 07:56:44

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	26 Apr 2021 15:25:40
	(b) (4)	
User entered 'Moderate (Moderate)'	Sheldon Warren (b) (4)	23 Apr 2021 19:07:55
	(b) (4)	

US3512248

Folder: Covid-19 Assessment 19 Apr 2021

Form: Symptom Log (4)

Generated On: 10 Jun 2021 07:56:44

[Nausea](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	26 Apr 2021 15:25:40
	(b) (4)	
User entered 'None (None)'	Sheldon Warren (b) (4)	23 Apr 2021 19:07:55
	(b) (4)	

US3512248

Folder: Covid-19 Assessment 19 Apr 2021

Form: Symptom Log (4)

Generated On: 10 Jun 2021 07:56:44

[Vomiting](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	26 Apr 2021 15:25:40
	(b) (4)	
User entered 'None (None)'	Sheldon Warren (b) (4)	23 Apr 2021 19:07:55
	(b) (4)	

US3512248

Folder: Covid-19 Assessment 19 Apr 2021

Form: Symptom Log (4)

Generated On: 10 Jun 2021 07:56:44

[Diarrhea](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	26 Apr 2021 15:25:40
	(b) (4)	
User entered 'None (None)'	Sheldon Warren (b) (4)	23 Apr 2021 19:07:55
	(b) (4)	

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Folder: Covid-19 Assessment 19 Apr 2021

Form: Symptom Log (4)

Generated On: 10 Jun 2021 07:56:44

[Sore Throat](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	26 Apr 2021 15:25:40
	(b) (4)	
User entered 'None (None)'	Sheldon Warren (b) (4)	23 Apr 2021 19:07:55
	(b) (4)	



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Form: Symptom Log (5)

Generated On: 10 Jun 2021 07:56:44

[Symptom Day](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	26 Apr 2021 15:25:40
	(b) (4)	
User entered 'Day 5 (Day 5)'	Sheldon Warren (b) (4)	23 Apr 2021 19:08:32
	(b) (4)	

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Folder: Covid-19 Assessment 19 Apr 2021

Form: Symptom Log (5)

Generated On: 10 Jun 2021 07:56:44

[Date](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	26 Apr 2021 15:25:40
	(b) (4)	
User entered '16 Apr 2021'	Sheldon Warren (b) (4)	23 Apr 2021 19:08:32
	(b) (4)	

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Folder: Covid-19 Assessment 19 Apr 2021

Form: Symptom Log (5)

Generated On: 10 Jun 2021 07:56:44

[Assessment Not Done](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	26 Apr 2021 15:25:40
	(b) (4)	
User entered '0'	Sheldon Warren (b) (4)	23 Apr 2021 19:08:32
	(b) (4)	

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Folder: Covid-19 Assessment 19 Apr 2021

Form: Symptom Log (5)

Generated On: 10 Jun 2021 07:56:44

[O2 Saturation](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4) (b) (4)	26 Apr 2021 15:25:40
User entered empty.	Sheldon Warren (b) (4) (b) (4)	23 Apr 2021 19:08:32

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**Folder: Covid-19 Assessment 19 Apr 2021**

**Form: Symptom Log (5)**

**Generated On: 10 Jun 2021 07:56:44**

[O2 Saturation Units](#)

Audit	User	Time (GMT)
User entered empty.	System	23 Apr 2021 19:08:32

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Folder: Covid-19 Assessment 19 Apr 2021

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[Temperature](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	26 Apr 2021 15:25:40
	(b) (4)	
User entered empty.	Sheldon Warren (b) (4)	23 Apr 2021 19:08:32
	(b) (4)	

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Folder: Covid-19 Assessment 19 Apr 2021

Form: Symptom Log (5)

Generated On: 10 Jun 2021 07:56:44

[Chills](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	26 Apr 2021 15:25:40
	(b) (4)	
User entered 'None (None)'	Sheldon Warren (b) (4)	23 Apr 2021 19:08:32
	(b) (4)	

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Folder: Covid-19 Assessment 19 Apr 2021

Form: Symptom Log (5)

Generated On: 10 Jun 2021 07:56:44

[Cough](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	26 Apr 2021 15:25:40
	(b) (4)	
User entered 'Moderate (Moderate)'	Sheldon Warren (b) (4)	23 Apr 2021 19:08:32
	(b) (4)	



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Folder: Covid-19 Assessment 19 Apr 2021

Form: Symptom Log (5)

Generated On: 10 Jun 2021 07:56:44

[Shortness of Breath](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	26 Apr 2021 15:25:40
	(b) (4)	
User entered 'None (None)'	Sheldon Warren (b) (4)	23 Apr 2021 19:08:32
	(b) (4)	

US3512248

Folder: Covid-19 Assessment 19 Apr 2021

Form: Symptom Log (5)

Generated On: 10 Jun 2021 07:56:44

[Difficulty Breathing](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	26 Apr 2021 15:25:40
	(b) (4)	
User entered 'None (None)'	Sheldon Warren (b) (4)	23 Apr 2021 19:08:32
	(b) (4)	

US3512248

Folder: Covid-19 Assessment 19 Apr 2021

Form: Symptom Log (5)

Generated On: 10 Jun 2021 07:56:44

[Fatigue](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	26 Apr 2021 15:25:40
	(b) (4)	
User entered 'None (None)'	Sheldon Warren (b) (4)	23 Apr 2021 19:08:32
	(b) (4)	

US3512248

Folder: Covid-19 Assessment 19 Apr 2021

Form: Symptom Log (5)

Generated On: 10 Jun 2021 07:56:44

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	26 Apr 2021 15:25:40
	(b) (4)	
User entered 'None (None)'	Sheldon Warren (b) (4)	23 Apr 2021 19:08:32
	(b) (4)	

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Folder: Covid-19 Assessment 19 Apr 2021

Form: Symptom Log (5)

Generated On: 10 Jun 2021 07:56:44

[Body Aches](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	26 Apr 2021 15:25:40
	(b) (4)	
User entered 'None (None)'	Sheldon Warren (b) (4)	23 Apr 2021 19:08:32
	(b) (4)	

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Folder: Covid-19 Assessment 19 Apr 2021

Form: Symptom Log (5)

Generated On: 10 Jun 2021 07:56:44

[Headache](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	26 Apr 2021 15:25:40
	(b) (4)	
User entered 'None (None)'	Sheldon Warren (b) (4)	23 Apr 2021 19:08:32
	(b) (4)	

US3512248

Folder: Covid-19 Assessment 19 Apr 2021

Form: Symptom Log (5)

Generated On: 10 Jun 2021 07:56:44

[New Loss of Taste](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	26 Apr 2021 15:25:40
	(b) (4)	
User entered 'None (None)'	Sheldon Warren (b) (4)	23 Apr 2021 19:08:32
	(b) (4)	

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Folder: Covid-19 Assessment 19 Apr 2021

Form: Symptom Log (5)

Generated On: 10 Jun 2021 07:56:44

[New Loss of Smell](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	26 Apr 2021 15:25:40
	(b) (4)	
User entered 'None (None)'	Sheldon Warren (b) (4)	23 Apr 2021 19:08:32
	(b) (4)	



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Folder: Covid-19 Assessment 19 Apr 2021

Form: Symptom Log (5)

Generated On: 10 Jun 2021 07:56:44

[Nasal Congestion](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	26 Apr 2021 15:25:40
	(b) (4)	
User entered 'Mild (Mild)'	Sheldon Warren (b) (4)	23 Apr 2021 19:08:32
	(b) (4)	

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Folder: Covid-19 Assessment 19 Apr 2021

Form: Symptom Log (5)

Generated On: 10 Jun 2021 07:56:44

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	26 Apr 2021 15:25:40
	(b) (4)	
User entered 'Moderate (Moderate)'	Sheldon Warren (b) (4)	23 Apr 2021 19:08:32
	(b) (4)	

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Folder: Covid-19 Assessment 19 Apr 2021

Form: Symptom Log (5)

Generated On: 10 Jun 2021 07:56:44

[Nausea](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	26 Apr 2021 15:25:40
	(b) (4)	
User entered 'None (None)'	Sheldon Warren (b) (4)	23 Apr 2021 19:08:32
	(b) (4)	

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Folder: Covid-19 Assessment 19 Apr 2021

Form: Symptom Log (5)

Generated On: 10 Jun 2021 07:56:44

[Vomiting](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	26 Apr 2021 15:25:40
	(b) (4)	
User entered 'None (None)'	Sheldon Warren (b) (4)	23 Apr 2021 19:08:32
	(b) (4)	

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Folder: Covid-19 Assessment 19 Apr 2021

Form: Symptom Log (5)

Generated On: 10 Jun 2021 07:56:44

[Diarrhea](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	26 Apr 2021 15:25:40
	(b) (4)	
User entered 'None (None)'	Sheldon Warren (b) (4)	23 Apr 2021 19:08:32
	(b) (4)	

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[Sore Throat](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	26 Apr 2021 15:25:40
	(b) (4)	
User entered 'None (None)'	Sheldon Warren (b) (4)	23 Apr 2021 19:08:32
	(b) (4)	

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[Symptom Day](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	26 Apr 2021 15:25:40
	(b) (4)	
User entered 'Day 6 (Day 6)'	Sheldon Warren (b) (4)	23 Apr 2021 19:09:16
	(b) (4)	

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[Date](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	26 Apr 2021 15:25:40
	(b) (4)	
User entered '17 Apr 2021'	Sheldon Warren (b) (4)	23 Apr 2021 19:09:16
	(b) (4)	



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Folder: Covid-19 Assessment 19 Apr 2021

Form: Symptom Log (6)

Generated On: 10 Jun 2021 07:56:44

[Assessment Not Done](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	26 Apr 2021 15:25:40
	(b) (4)	
User entered '0'	Sheldon Warren (b) (4)	23 Apr 2021 19:09:16
	(b) (4)	

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Folder: Covid-19 Assessment 19 Apr 2021

Form: Symptom Log (6)

Generated On: 10 Jun 2021 07:56:44

[O2 Saturation](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	26 Apr 2021 15:25:40
	(b) (4)	
User entered empty.	Sheldon Warren (b) (4)	23 Apr 2021 19:09:16
	(b) (4)	

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**Folder: Covid-19 Assessment 19 Apr 2021**

**Form: Symptom Log (6)**

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[O2 Saturation Units](#)

Audit	User	Time (GMT)
User entered empty.	System	23 Apr 2021 19:09:16

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Folder: Covid-19 Assessment 19 Apr 2021

Form: Symptom Log (6)

Generated On: 10 Jun 2021 07:56:44

[Temperature](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	26 Apr 2021 15:25:40
	(b) (4)	
User entered empty.	Sheldon Warren (b) (4)	23 Apr 2021 19:09:16
	(b) (4)	

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Form: Symptom Log (6)

Generated On: 10 Jun 2021 07:56:44

[Chills](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	26 Apr 2021 15:25:40
	(b) (4)	
User entered 'None (None)'	Sheldon Warren (b) (4)	23 Apr 2021 19:09:16
	(b) (4)	

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Folder: Covid-19 Assessment 19 Apr 2021

Form: Symptom Log (6)

Generated On: 10 Jun 2021 07:56:44

[Cough](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	26 Apr 2021 15:25:40
	(b) (4)	
User entered 'Mild (Mild)'	Sheldon Warren (b) (4)	23 Apr 2021 19:09:16
	(b) (4)	

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Folder: Covid-19 Assessment 19 Apr 2021

Form: Symptom Log (6)

Generated On: 10 Jun 2021 07:56:44

[Shortness of Breath](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	26 Apr 2021 15:25:40
	(b) (4)	
User entered 'None (None)'	Sheldon Warren (b) (4)	23 Apr 2021 19:09:16
	(b) (4)	

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Folder: Covid-19 Assessment 19 Apr 2021

Form: Symptom Log (6)

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[Difficulty Breathing](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	26 Apr 2021 15:25:40
	(b) (4)	
User entered 'None (None)'	Sheldon Warren (b) (4)	23 Apr 2021 19:09:16
	(b) (4)	



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Form: Symptom Log (6)

Generated On: 10 Jun 2021 07:56:44

[Fatigue](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	26 Apr 2021 15:25:40
	(b) (4)	
User entered 'None (None)'	Sheldon Warren (b) (4)	23 Apr 2021 19:09:16
	(b) (4)	

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Folder: Covid-19 Assessment 19 Apr 2021

Form: Symptom Log (6)

Generated On: 10 Jun 2021 07:56:44

Muscle Aches (Myalgia)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	26 Apr 2021 15:25:40
	(b) (4)	
User entered 'None (None)'	Sheldon Warren (b) (4)	23 Apr 2021 19:09:16
	(b) (4)	

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Folder: Covid-19 Assessment 19 Apr 2021

Form: Symptom Log (6)

Generated On: 10 Jun 2021 07:56:44

[Body Aches](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	26 Apr 2021 15:25:40
	(b) (4)	
User entered 'None (None)'	Sheldon Warren (b) (4)	23 Apr 2021 19:09:16
	(b) (4)	

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Folder: Covid-19 Assessment 19 Apr 2021

Form: Symptom Log (6)

Generated On: 10 Jun 2021 07:56:44

[Headache](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	26 Apr 2021 15:25:40
	(b) (4)	
User entered 'None (None)'	Sheldon Warren (b) (4)	23 Apr 2021 19:09:16
	(b) (4)	

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Folder: Covid-19 Assessment 19 Apr 2021

Form: Symptom Log (6)

Generated On: 10 Jun 2021 07:56:44

[New Loss of Taste](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	26 Apr 2021 15:25:40
	(b) (4)	
User entered 'None (None)'	Sheldon Warren (b) (4)	23 Apr 2021 19:09:16
	(b) (4)	

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Folder: Covid-19 Assessment 19 Apr 2021

Form: Symptom Log (6)

Generated On: 10 Jun 2021 07:56:44

[New Loss of Smell](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	26 Apr 2021 15:25:40
	(b) (4)	
User entered 'None (None)'	Sheldon Warren (b) (4)	23 Apr 2021 19:09:16
	(b) (4)	

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Folder: Covid-19 Assessment 19 Apr 2021

Form: Symptom Log (6)

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[Nasal Congestion](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	26 Apr 2021 15:25:40
	(b) (4)	
User entered 'Mild (Mild)'	Sheldon Warren (b) (4)	23 Apr 2021 19:09:16
	(b) (4)	

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Form: Symptom Log (6)

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[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	26 Apr 2021 15:25:40
	(b) (4)	
User entered 'Mild (Mild)'	Sheldon Warren (b) (4)	23 Apr 2021 19:09:16
	(b) (4)	



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Form: Symptom Log (6)

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[Nausea](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	26 Apr 2021 15:25:40
	(b) (4)	
User entered 'None (None)'	Sheldon Warren (b) (4)	23 Apr 2021 19:09:16
	(b) (4)	

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Form: Symptom Log (6)

Generated On: 10 Jun 2021 07:56:44

[Vomiting](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	26 Apr 2021 15:25:40
	(b) (4)	
User entered 'None (None)'	Sheldon Warren (b) (4)	23 Apr 2021 19:09:16
	(b) (4)	

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Folder: Covid-19 Assessment 19 Apr 2021

Form: Symptom Log (6)

Generated On: 10 Jun 2021 07:56:44

[Diarrhea](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	26 Apr 2021 15:25:40
	(b) (4)	
User entered 'None (None)'	Sheldon Warren (b) (4)	23 Apr 2021 19:09:16
	(b) (4)	

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Form: Symptom Log (6)

Generated On: 10 Jun 2021 07:56:44

[Sore Throat](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	26 Apr 2021 15:25:40
	(b) (4)	
User entered 'None (None)'	Sheldon Warren (b) (4)	23 Apr 2021 19:09:16
	(b) (4)	

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Form: Symptom Log (7)

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[Symptom Day](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	26 Apr 2021 15:25:40
	(b) (4)	
User entered 'Day 7 (Day 7)'	Sheldon Warren (b) (4)	23 Apr 2021 19:09:54
	(b) (4)	

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Form: Symptom Log (7)

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[Date](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	26 Apr 2021 15:25:40
	(b) (4)	
User entered '18 Apr 2021'	Sheldon Warren (b) (4)	23 Apr 2021 19:09:54
	(b) (4)	

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Folder: Covid-19 Assessment 19 Apr 2021

Form: Symptom Log (7)

Generated On: 10 Jun 2021 07:56:44

[Assessment Not Done](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	26 Apr 2021 15:25:40
	(b) (4)	
User entered '0'	Sheldon Warren (b) (4)	23 Apr 2021 19:09:54
	(b) (4)	

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Folder: Covid-19 Assessment 19 Apr 2021

Form: Symptom Log (7)

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[O2 Saturation](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	26 Apr 2021 15:25:40
	(b) (4)	
User entered '96'	Sheldon Warren (b) (4)	23 Apr 2021 19:09:54
	(b) (4)	



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**Folder: Covid-19 Assessment 19 Apr 2021**

**Form: Symptom Log (7)**

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[O2 Saturation Units](#)

Audit	User	Time (GMT)
User entered '%'	System	23 Apr 2021 19:09:54

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Folder: Covid-19 Assessment 19 Apr 2021

Form: Symptom Log (7)

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[Temperature](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	26 Apr 2021 15:25:40
	(b) (4)	
User entered empty.	Sheldon Warren (b) (4)	23 Apr 2021 19:09:54
	(b) (4)	

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Form: Symptom Log (7)

Generated On: 10 Jun 2021 07:56:44

[Chills](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	26 Apr 2021 15:25:40
	(b) (4)	
User entered 'None (None)'	Sheldon Warren (b) (4)	23 Apr 2021 19:09:54
	(b) (4)	

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Folder: Covid-19 Assessment 19 Apr 2021

Form: Symptom Log (7)

Generated On: 10 Jun 2021 07:56:44

[Cough](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	26 Apr 2021 15:25:40
	(b) (4)	
User entered 'Mild (Mild)'	Sheldon Warren (b) (4)	23 Apr 2021 19:09:54
	(b) (4)	

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Folder: Covid-19 Assessment 19 Apr 2021

Form: Symptom Log (7)

Generated On: 10 Jun 2021 07:56:44

[Shortness of Breath](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	26 Apr 2021 15:25:40
	(b) (4)	
User entered 'None (None)'	Sheldon Warren (b) (4)	23 Apr 2021 19:09:54
	(b) (4)	

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Folder: Covid-19 Assessment 19 Apr 2021

Form: Symptom Log (7)

Generated On: 10 Jun 2021 07:56:44

[Difficulty Breathing](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	26 Apr 2021 15:25:40
	(b) (4)	
User entered 'None (None)'	Sheldon Warren (b) (4)	23 Apr 2021 19:09:54
	(b) (4)	

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Folder: Covid-19 Assessment 19 Apr 2021

Form: Symptom Log (7)

Generated On: 10 Jun 2021 07:56:44

[Fatigue](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	26 Apr 2021 15:25:40
	(b) (4)	
User entered 'None (None)'	Sheldon Warren (b) (4)	23 Apr 2021 19:09:54
	(b) (4)	

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Folder: Covid-19 Assessment 19 Apr 2021

Form: Symptom Log (7)

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[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	26 Apr 2021 15:25:40
	(b) (4)	
User entered 'None (None)'	Sheldon Warren (b) (4)	23 Apr 2021 19:09:54
	(b) (4)	



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Form: Symptom Log (7)

Generated On: 10 Jun 2021 07:56:44

[Body Aches](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	26 Apr 2021 15:25:40
	(b) (4)	
User entered 'None (None)'	Sheldon Warren (b) (4)	23 Apr 2021 19:09:54
	(b) (4)	

US3512248

Folder: Covid-19 Assessment 19 Apr 2021

Form: Symptom Log (7)

Generated On: 10 Jun 2021 07:56:44

[Headache](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	26 Apr 2021 15:25:40
	(b) (4)	
User entered 'None (None)'	Sheldon Warren (b) (4)	23 Apr 2021 19:09:54
	(b) (4)	

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Form: Symptom Log (7)

Generated On: 10 Jun 2021 07:56:44

[New Loss of Taste](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	26 Apr 2021 15:25:40
	(b) (4)	
User entered 'None (None)'	Sheldon Warren (b) (4)	23 Apr 2021 19:09:54
	(b) (4)	

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Folder: Covid-19 Assessment 19 Apr 2021

Form: Symptom Log (7)

Generated On: 10 Jun 2021 07:56:44

[New Loss of Smell](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	26 Apr 2021 15:25:40
	(b) (4)	
User entered 'None (None)'	Sheldon Warren (b) (4)	23 Apr 2021 19:09:54
	(b) (4)	

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Folder: Covid-19 Assessment 19 Apr 2021

Form: Symptom Log (7)

Generated On: 10 Jun 2021 07:56:44

[Nasal Congestion](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	26 Apr 2021 15:25:40
	(b) (4)	
User entered 'Mild (Mild)'	Sheldon Warren (b) (4)	23 Apr 2021 19:09:54
	(b) (4)	

US3512248

Folder: Covid-19 Assessment 19 Apr 2021

Form: Symptom Log (7)

Generated On: 10 Jun 2021 07:56:44

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	26 Apr 2021 15:25:40
	(b) (4)	
User entered 'Mild (Mild)'	Sheldon Warren (b) (4)	23 Apr 2021 19:09:54
	(b) (4)	

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Folder: Covid-19 Assessment 19 Apr 2021

Form: Symptom Log (7)

Generated On: 10 Jun 2021 07:56:44

[Nausea](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	26 Apr 2021 15:25:40
	(b) (4)	
User entered 'None (None)'	Sheldon Warren (b) (4)	23 Apr 2021 19:09:54
	(b) (4)	

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Folder: Covid-19 Assessment 19 Apr 2021

Form: Symptom Log (7)

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[Vomiting](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	26 Apr 2021 15:25:40
	(b) (4)	
User entered 'None (None)'	Sheldon Warren (b) (4)	23 Apr 2021 19:09:54
	(b) (4)	



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Form: Symptom Log (7)

Generated On: 10 Jun 2021 07:56:44

[Diarrhea](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	26 Apr 2021 15:25:40
	(b) (4)	
User entered 'None (None)'	Sheldon Warren (b) (4)	23 Apr 2021 19:09:54
	(b) (4)	

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Folder: Covid-19 Assessment 19 Apr 2021

Form: Symptom Log (7)

Generated On: 10 Jun 2021 07:56:44

[Sore Throat](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	26 Apr 2021 15:25:40
	(b) (4)	
User entered 'None (None)'	Sheldon Warren (b) (4)	23 Apr 2021 19:09:54
	(b) (4)	

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Form: Symptom Log (8)

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[Symptom Day](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	26 Apr 2021 15:25:40
	(b) (4)	
User entered 'Day 8 (Day 8)'	Sheldon Warren (b) (4)	23 Apr 2021 19:10:40
	(b) (4)	

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Form: Symptom Log (8)

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[Date](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	26 Apr 2021 15:25:40
	(b) (4)	
User entered '19 Apr 2021'	Sheldon Warren (b) (4)	23 Apr 2021 19:10:40
	(b) (4)	

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Folder: Covid-19 Assessment 19 Apr 2021

Form: Symptom Log (8)

Generated On: 10 Jun 2021 07:56:44

[Assessment Not Done](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	26 Apr 2021 15:25:40
	(b) (4)	
User entered '0'	Sheldon Warren (b) (4)	23 Apr 2021 19:10:40
	(b) (4)	

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Folder: Covid-19 Assessment 19 Apr 2021

Form: Symptom Log (8)

Generated On: 10 Jun 2021 07:56:44

[O2 Saturation](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4) (b) (4)	26 Apr 2021 15:25:40
User entered empty.	Sheldon Warren (b) (4) (b) (4)	23 Apr 2021 19:10:40

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**Folder: Covid-19 Assessment 19 Apr 2021**

**Form: Symptom Log (8)**

**Generated On: 10 Jun 2021 07:56:44**

[O2 Saturation Units](#)

Audit	User	Time (GMT)
User entered empty.	System	23 Apr 2021 19:10:40

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Folder: Covid-19 Assessment 19 Apr 2021

Form: Symptom Log (8)

Generated On: 10 Jun 2021 07:56:44

[Temperature](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	26 Apr 2021 15:25:40
	(b) (4)	
User entered empty.	Sheldon Warren (b) (4)	23 Apr 2021 19:10:40
	(b) (4)	



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Folder: Covid-19 Assessment 19 Apr 2021

Form: Symptom Log (8)

Generated On: 10 Jun 2021 07:56:44

[Chills](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	26 Apr 2021 15:25:40
	(b) (4)	
User entered 'None (None)'	Sheldon Warren (b) (4)	23 Apr 2021 19:10:40
	(b) (4)	

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Folder: Covid-19 Assessment 19 Apr 2021

Form: Symptom Log (8)

Generated On: 10 Jun 2021 07:56:44

[Cough](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	26 Apr 2021 15:25:40
	(b) (4)	
User entered 'Mild (Mild)'	Sheldon Warren (b) (4)	23 Apr 2021 19:10:40
	(b) (4)	

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Folder: Covid-19 Assessment 19 Apr 2021

Form: Symptom Log (8)

Generated On: 10 Jun 2021 07:56:44

[Shortness of Breath](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	26 Apr 2021 15:25:40
	(b) (4)	
User entered 'None (None)'	Sheldon Warren (b) (4)	23 Apr 2021 19:10:40
	(b) (4)	

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Folder: Covid-19 Assessment 19 Apr 2021

Form: Symptom Log (8)

Generated On: 10 Jun 2021 07:56:44

[Difficulty Breathing](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	26 Apr 2021 15:25:40
	(b) (4)	
User entered 'None (None)'	Sheldon Warren (b) (4)	23 Apr 2021 19:10:40
	(b) (4)	

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Folder: Covid-19 Assessment 19 Apr 2021

Form: Symptom Log (8)

Generated On: 10 Jun 2021 07:56:44

[Fatigue](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	26 Apr 2021 15:25:40
	(b) (4)	
User entered 'None (None)'	Sheldon Warren (b) (4)	23 Apr 2021 19:10:40
	(b) (4)	

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Folder: Covid-19 Assessment 19 Apr 2021

Form: Symptom Log (8)

Generated On: 10 Jun 2021 07:56:44

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	26 Apr 2021 15:25:40
	(b) (4)	
User entered 'None (None)'	Sheldon Warren (b) (4)	23 Apr 2021 19:10:40
	(b) (4)	

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Folder: Covid-19 Assessment 19 Apr 2021

Form: Symptom Log (8)

Generated On: 10 Jun 2021 07:56:44

[Body Aches](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	26 Apr 2021 15:25:40
	(b) (4)	
User entered 'None (None)'	Sheldon Warren (b) (4)	23 Apr 2021 19:10:40
	(b) (4)	

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Form: Symptom Log (8)

Generated On: 10 Jun 2021 07:56:44

[Headache](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	26 Apr 2021 15:25:40
	(b) (4)	
User entered 'None (None)'	Sheldon Warren (b) (4)	23 Apr 2021 19:10:40
	(b) (4)	



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Folder: Covid-19 Assessment 19 Apr 2021

Form: Symptom Log (8)

Generated On: 10 Jun 2021 07:56:44

[New Loss of Taste](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	26 Apr 2021 15:25:40
	(b) (4)	
User entered 'None (None)'	Sheldon Warren (b) (4)	23 Apr 2021 19:10:40
	(b) (4)	

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Folder: Covid-19 Assessment 19 Apr 2021

Form: Symptom Log (8)

Generated On: 10 Jun 2021 07:56:44

[New Loss of Smell](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	26 Apr 2021 15:25:40
	(b) (4)	
User entered 'None (None)'	Sheldon Warren (b) (4)	23 Apr 2021 19:10:40
	(b) (4)	

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Folder: Covid-19 Assessment 19 Apr 2021

Form: Symptom Log (8)

Generated On: 10 Jun 2021 07:56:44

[Nasal Congestion](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	26 Apr 2021 15:25:40
	(b) (4)	
User entered 'Mild (Mild)'	Sheldon Warren (b) (4)	23 Apr 2021 19:10:40
	(b) (4)	

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Folder: Covid-19 Assessment 19 Apr 2021

Form: Symptom Log (8)

Generated On: 10 Jun 2021 07:56:44

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	26 Apr 2021 15:25:40
	(b) (4)	
User entered 'Mild (Mild)'	Sheldon Warren (b) (4)	23 Apr 2021 19:10:40
	(b) (4)	

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Folder: Covid-19 Assessment 19 Apr 2021

Form: Symptom Log (8)

Generated On: 10 Jun 2021 07:56:44

[Nausea](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	26 Apr 2021 15:25:40
	(b) (4)	
User entered 'None (None)'	Sheldon Warren (b) (4)	23 Apr 2021 19:10:40
	(b) (4)	

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Folder: Covid-19 Assessment 19 Apr 2021

Form: Symptom Log (8)

Generated On: 10 Jun 2021 07:56:44

[Vomiting](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	26 Apr 2021 15:25:40
	(b) (4)	
User entered 'None (None)'	Sheldon Warren (b) (4)	23 Apr 2021 19:10:40
	(b) (4)	

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Folder: Covid-19 Assessment 19 Apr 2021

Form: Symptom Log (8)

Generated On: 10 Jun 2021 07:56:44

[Diarrhea](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	26 Apr 2021 15:25:40
	(b) (4)	
User entered 'None (None)'	Sheldon Warren (b) (4)	23 Apr 2021 19:10:40
	(b) (4)	

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Form: Symptom Log (8)

Generated On: 10 Jun 2021 07:56:44

[Sore Throat](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	26 Apr 2021 15:25:40
	(b) (4)	
User entered 'None (None)'	Sheldon Warren (b) (4)	23 Apr 2021 19:10:40
	(b) (4)	



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Form: Symptom Log (9)

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[Symptom Day](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	26 Apr 2021 15:25:40
	(b) (4)	
User entered 'Day 9 (Day 9)'	Sheldon Warren (b) (4)	23 Apr 2021 19:11:25
	(b) (4)	

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Folder: Covid-19 Assessment 19 Apr 2021

Form: Symptom Log (9)

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[Date](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	26 Apr 2021 15:25:40
	(b) (4)	
User entered '20 Apr 2021'	Sheldon Warren (b) (4)	23 Apr 2021 19:11:25
	(b) (4)	

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Folder: Covid-19 Assessment 19 Apr 2021

Form: Symptom Log (9)

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[Assessment Not Done](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	26 Apr 2021 15:25:40
	(b) (4)	
User entered '0'	Sheldon Warren (b) (4)	23 Apr 2021 19:11:25
	(b) (4)	

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Form: Symptom Log (9)

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[O2 Saturation](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	26 Apr 2021 15:25:40
	(b) (4)	
User entered '99'	Sheldon Warren (b) (4)	23 Apr 2021 19:11:25
	(b) (4)	

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**Folder: Covid-19 Assessment 19 Apr 2021**

**Form: Symptom Log (9)**

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[O2 Saturation Units](#)

Audit	User	Time (GMT)
User entered '%'	System	23 Apr 2021 19:11:25

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Folder: Covid-19 Assessment 19 Apr 2021

Form: Symptom Log (9)

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[Temperature](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	26 Apr 2021 15:25:40
	(b) (4)	
User entered '98.3' F	Sheldon Warren (b) (4)	23 Apr 2021 19:11:25
	(b) (4)	

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Form: Symptom Log (9)

Generated On: 10 Jun 2021 07:56:44

[Chills](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	26 Apr 2021 15:25:40
	(b) (4)	
User entered 'None (None)'	Sheldon Warren (b) (4)	23 Apr 2021 19:11:25
	(b) (4)	

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Folder: Covid-19 Assessment 19 Apr 2021

Form: Symptom Log (9)

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[Cough](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	26 Apr 2021 15:25:40
	(b) (4)	
User entered 'Mild (Mild)'	Sheldon Warren (b) (4)	23 Apr 2021 19:11:25
	(b) (4)	



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Form: Symptom Log (9)

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[Shortness of Breath](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	26 Apr 2021 15:25:40
	(b) (4)	
User entered 'None (None)'	Sheldon Warren (b) (4)	23 Apr 2021 19:11:25
	(b) (4)	

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Folder: Covid-19 Assessment 19 Apr 2021

Form: Symptom Log (9)

Generated On: 10 Jun 2021 07:56:44

[Difficulty Breathing](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	26 Apr 2021 15:25:40
	(b) (4)	
User entered 'None (None)'	Sheldon Warren (b) (4)	23 Apr 2021 19:11:25
	(b) (4)	

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Folder: Covid-19 Assessment 19 Apr 2021

Form: Symptom Log (9)

Generated On: 10 Jun 2021 07:56:44

[Fatigue](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	26 Apr 2021 15:25:40
	(b) (4)	
User entered 'None (None)'	Sheldon Warren (b) (4)	23 Apr 2021 19:11:25
	(b) (4)	

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Folder: Covid-19 Assessment 19 Apr 2021

Form: Symptom Log (9)

Generated On: 10 Jun 2021 07:56:44

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	26 Apr 2021 15:25:40
	(b) (4)	
User entered 'None (None)'	Sheldon Warren (b) (4)	23 Apr 2021 19:11:25
	(b) (4)	

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Folder: Covid-19 Assessment 19 Apr 2021

Form: Symptom Log (9)

Generated On: 10 Jun 2021 07:56:44

[Body Aches](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	26 Apr 2021 15:25:40
	(b) (4)	
User entered 'None (None)'	Sheldon Warren (b) (4)	23 Apr 2021 19:11:25
	(b) (4)	

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Form: Symptom Log (9)

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[Headache](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	26 Apr 2021 15:25:40
	(b) (4)	
User entered 'None (None)'	Sheldon Warren (b) (4)	23 Apr 2021 19:11:25
	(b) (4)	

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Form: Symptom Log (9)

Generated On: 10 Jun 2021 07:56:44

[New Loss of Taste](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	26 Apr 2021 15:25:40
	(b) (4)	
User entered 'None (None)'	Sheldon Warren (b) (4)	23 Apr 2021 19:11:25
	(b) (4)	

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Form: Symptom Log (9)

Generated On: 10 Jun 2021 07:56:44

[New Loss of Smell](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	26 Apr 2021 15:25:40
	(b) (4)	
User entered 'None (None)'	Sheldon Warren (b) (4)	23 Apr 2021 19:11:25
	(b) (4)	



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Form: Symptom Log (9)

Generated On: 10 Jun 2021 07:56:44

[Nasal Congestion](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	26 Apr 2021 15:25:40
	(b) (4)	
User entered 'Mild (Mild)'	Sheldon Warren (b) (4)	23 Apr 2021 19:11:25
	(b) (4)	

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Form: Symptom Log (9)

Generated On: 10 Jun 2021 07:56:44

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	26 Apr 2021 15:25:40
	(b) (4)	
User entered 'Mild (Mild)'	Sheldon Warren (b) (4)	23 Apr 2021 19:11:25
	(b) (4)	

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Folder: Covid-19 Assessment 19 Apr 2021

Form: Symptom Log (9)

Generated On: 10 Jun 2021 07:56:44

[Nausea](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	26 Apr 2021 15:25:40
	(b) (4)	
User entered 'None (None)'	Sheldon Warren (b) (4)	23 Apr 2021 19:11:25
	(b) (4)	

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Form: Symptom Log (9)

Generated On: 10 Jun 2021 07:56:44

[Vomiting](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	26 Apr 2021 15:25:40
	(b) (4)	
User entered 'None (None)'	Sheldon Warren (b) (4)	23 Apr 2021 19:11:25
	(b) (4)	

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Form: Symptom Log (9)

Generated On: 10 Jun 2021 07:56:44

[Diarrhea](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	26 Apr 2021 15:25:40
	(b) (4)	
User entered 'None (None)'	Sheldon Warren (b) (4)	23 Apr 2021 19:11:25
	(b) (4)	

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Form: Symptom Log (9)

Generated On: 10 Jun 2021 07:56:44

[Sore Throat](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	26 Apr 2021 15:25:40
	(b) (4)	
User entered 'None (None)'	Sheldon Warren (b) (4)	23 Apr 2021 19:11:25
	(b) (4)	

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Form: Symptom Log (10)

Generated On: 10 Jun 2021 07:56:44

[Symptom Day](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	26 Apr 2021 15:25:40
	(b) (4)	
User entered 'Day 10 (Day 10)'	Sheldon Warren (b) (4)	23 Apr 2021 19:12:04
	(b) (4)	

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Form: Symptom Log (10)

Generated On: 10 Jun 2021 07:56:44

[Date](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	26 Apr 2021 15:25:40
	(b) (4)	
User entered '21 Apr 2021'	Sheldon Warren (b) (4)	23 Apr 2021 19:12:04
	(b) (4)	



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Form: Symptom Log (10)

Generated On: 10 Jun 2021 07:56:44

[Assessment Not Done](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	26 Apr 2021 15:25:40
	(b) (4)	
User entered '0'	Sheldon Warren (b) (4)	23 Apr 2021 19:12:04
	(b) (4)	

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Folder: Covid-19 Assessment 19 Apr 2021

Form: Symptom Log (10)

Generated On: 10 Jun 2021 07:56:44

[O2 Saturation](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	26 Apr 2021 15:25:40
	(b) (4)	
User entered '98'	Sheldon Warren (b) (4)	23 Apr 2021 19:12:04
	(b) (4)	

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**Folder: Covid-19 Assessment 19 Apr 2021**

**Form: Symptom Log (10)**

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[O2 Saturation Units](#)

Audit	User	Time (GMT)
User entered '%'	System	23 Apr 2021 19:12:04

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Folder: Covid-19 Assessment 19 Apr 2021

Form: Symptom Log (10)

Generated On: 10 Jun 2021 07:56:44

[Temperature](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	26 Apr 2021 15:25:40
	(b) (4)	
User entered '98.4' F	Sheldon Warren (b) (4)	23 Apr 2021 19:12:04
	(b) (4)	

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[Chills](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	26 Apr 2021 15:25:40
	(b) (4)	
User entered 'None (None)'	Sheldon Warren (b) (4)	23 Apr 2021 19:12:04
	(b) (4)	

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Folder: Covid-19 Assessment 19 Apr 2021

Form: Symptom Log (10)

Generated On: 10 Jun 2021 07:56:44

[Cough](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	26 Apr 2021 15:25:40
	(b) (4)	
User entered 'Mild (Mild)'	Sheldon Warren (b) (4)	23 Apr 2021 19:12:04
	(b) (4)	

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Form: Symptom Log (10)

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[Shortness of Breath](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	26 Apr 2021 15:25:40
	(b) (4)	
User entered 'None (None)'	Sheldon Warren (b) (4)	23 Apr 2021 19:12:04
	(b) (4)	

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Form: Symptom Log (10)

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[Difficulty Breathing](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	26 Apr 2021 15:25:40
	(b) (4)	
User entered 'None (None)'	Sheldon Warren (b) (4)	23 Apr 2021 19:12:04
	(b) (4)	



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[Fatigue](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	26 Apr 2021 15:25:40
	(b) (4)	
User entered 'None (None)'	Sheldon Warren (b) (4)	23 Apr 2021 19:12:04
	(b) (4)	

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[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	26 Apr 2021 15:25:40
	(b) (4)	
User entered 'None (None)'	Sheldon Warren (b) (4)	23 Apr 2021 19:12:04
	(b) (4)	

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Form: Symptom Log (10)

Generated On: 10 Jun 2021 07:56:44

[Body Aches](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	26 Apr 2021 15:25:40
	(b) (4)	
User entered 'None (None)'	Sheldon Warren (b) (4)	23 Apr 2021 19:12:04
	(b) (4)	

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Form: Symptom Log (10)

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[Headache](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	26 Apr 2021 15:25:40
	(b) (4)	
User entered 'None (None)'	Sheldon Warren (b) (4)	23 Apr 2021 19:12:04
	(b) (4)	

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[New Loss of Taste](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	26 Apr 2021 15:25:40
	(b) (4)	
User entered 'None (None)'	Sheldon Warren (b) (4)	23 Apr 2021 19:12:04
	(b) (4)	

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Form: Symptom Log (10)

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[New Loss of Smell](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	26 Apr 2021 15:25:40
	(b) (4)	
User entered 'None (None)'	Sheldon Warren (b) (4)	23 Apr 2021 19:12:04
	(b) (4)	

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Form: Symptom Log (10)

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[Nasal Congestion](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	26 Apr 2021 15:25:40
	(b) (4)	
User entered 'Mild (Mild)'	Sheldon Warren (b) (4)	23 Apr 2021 19:12:04
	(b) (4)	

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Folder: Covid-19 Assessment 19 Apr 2021

Form: Symptom Log (10)

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[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	26 Apr 2021 15:25:40
	(b) (4)	
User entered 'Mild (Mild)'	Sheldon Warren (b) (4)	23 Apr 2021 19:12:04
	(b) (4)	



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[Nausea](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	26 Apr 2021 15:25:40
	(b) (4)	
User entered 'None (None)'	Sheldon Warren (b) (4)	23 Apr 2021 19:12:04
	(b) (4)	

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Folder: Covid-19 Assessment 19 Apr 2021

Form: Symptom Log (10)

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[Vomiting](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	26 Apr 2021 15:25:40
	(b) (4)	
User entered 'None (None)'	Sheldon Warren (b) (4)	23 Apr 2021 19:12:04
	(b) (4)	

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Folder: Covid-19 Assessment 19 Apr 2021

Form: Symptom Log (10)

Generated On: 10 Jun 2021 07:56:44

[Diarrhea](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	26 Apr 2021 15:25:40
	(b) (4)	
User entered 'None (None)'	Sheldon Warren (b) (4)	23 Apr 2021 19:12:04
	(b) (4)	

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Folder: Covid-19 Assessment 19 Apr 2021

Form: Symptom Log (10)

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[Sore Throat](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	26 Apr 2021 15:25:40
	(b) (4)	
User entered 'None (None)'	Sheldon Warren (b) (4)	23 Apr 2021 19:12:04
	(b) (4)	

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[Symptom Day](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	26 Apr 2021 15:25:40
	(b) (4)	
User entered 'Day 11 (Day 11)'	Sheldon Warren (b) (4)	23 Apr 2021 19:12:49
	(b) (4)	

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Folder: Covid-19 Assessment 19 Apr 2021

Form: Symptom Log (11)

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[Date](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	26 Apr 2021 15:25:40
	(b) (4)	
User entered '22 Apr 2021'	Sheldon Warren (b) (4)	23 Apr 2021 19:12:49
	(b) (4)	

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Folder: Covid-19 Assessment 19 Apr 2021

Form: Symptom Log (11)

Generated On: 10 Jun 2021 07:56:44

[Assessment Not Done](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	26 Apr 2021 15:25:40
	(b) (4)	
User entered '0'	Sheldon Warren (b) (4)	23 Apr 2021 19:12:49
	(b) (4)	

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[O2 Saturation](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	26 Apr 2021 15:25:40
	(b) (4)	
User entered '96'	Sheldon Warren (b) (4)	23 Apr 2021 19:12:49
	(b) (4)	



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**Form: Symptom Log (11)**

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[O2 Saturation Units](#)

Audit	User	Time (GMT)
User entered '%'	System	23 Apr 2021 19:12:49

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[Temperature](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	26 Apr 2021 15:25:40
	(b) (4)	
User entered '97.8' F	Sheldon Warren (b) (4)	23 Apr 2021 19:12:49
	(b) (4)	

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Folder: Covid-19 Assessment 19 Apr 2021

Form: Symptom Log (11)

Generated On: 10 Jun 2021 07:56:44

[Chills](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	26 Apr 2021 15:25:40
	(b) (4)	
User entered 'None (None)'	Sheldon Warren (b) (4)	23 Apr 2021 19:12:49
	(b) (4)	

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Folder: Covid-19 Assessment 19 Apr 2021

Form: Symptom Log (11)

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[Cough](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	26 Apr 2021 15:25:40
	(b) (4)	
User entered 'None (None)'	Sheldon Warren (b) (4)	23 Apr 2021 19:12:49
	(b) (4)	

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Form: Symptom Log (11)

Generated On: 10 Jun 2021 07:56:44

[Shortness of Breath](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	26 Apr 2021 15:25:40
	(b) (4)	
User entered 'None (None)'	Sheldon Warren (b) (4)	23 Apr 2021 19:12:49
	(b) (4)	

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Form: Symptom Log (11)

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[Difficulty Breathing](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	26 Apr 2021 15:25:40
	(b) (4)	
User entered 'None (None)'	Sheldon Warren (b) (4)	23 Apr 2021 19:12:49
	(b) (4)	

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Folder: Covid-19 Assessment 19 Apr 2021

Form: Symptom Log (11)

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[Fatigue](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	26 Apr 2021 15:25:40
	(b) (4)	
User entered 'None (None)'	Sheldon Warren (b) (4)	23 Apr 2021 19:12:49
	(b) (4)	

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Form: Symptom Log (11)

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Muscle Aches (Myalgia)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	26 Apr 2021 15:25:40
	(b) (4)	
User entered 'None (None)'	Sheldon Warren (b) (4)	23 Apr 2021 19:12:49
	(b) (4)	



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[Body Aches](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	26 Apr 2021 15:25:40
	(b) (4)	
User entered 'None (None)'	Sheldon Warren (b) (4)	23 Apr 2021 19:12:49
	(b) (4)	

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[Headache](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	26 Apr 2021 15:25:40
	(b) (4)	
User entered 'None (None)'	Sheldon Warren (b) (4)	23 Apr 2021 19:12:49
	(b) (4)	

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Folder: Covid-19 Assessment 19 Apr 2021

Form: Symptom Log (11)

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[New Loss of Taste](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	26 Apr 2021 15:25:40
	(b) (4)	
User entered 'None (None)'	Sheldon Warren (b) (4)	23 Apr 2021 19:12:49
	(b) (4)	

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Folder: Covid-19 Assessment 19 Apr 2021

Form: Symptom Log (11)

Generated On: 10 Jun 2021 07:56:44

[New Loss of Smell](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	26 Apr 2021 15:25:40
	(b) (4)	
User entered 'None (None)'	Sheldon Warren (b) (4)	23 Apr 2021 19:12:49
	(b) (4)	

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**Folder: Covid-19 Assessment 19 Apr 2021**

**Form: Symptom Log (11)**

**Generated On: 10 Jun 2021 07:56:44**

[Nasal Congestion](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	26 Apr 2021 15:25:40
	(b) (4)	
User entered 'None (None)'	Sheldon Warren (b) (4)	23 Apr 2021 19:12:49
	(b) (4)	

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Form: Symptom Log (11)

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[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	26 Apr 2021 15:25:40
	(b) (4)	
User entered 'None (None)'	Sheldon Warren (b) (4)	23 Apr 2021 19:12:49
	(b) (4)	

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Folder: Covid-19 Assessment 19 Apr 2021

Form: Symptom Log (11)

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[Nausea](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	26 Apr 2021 15:25:40
	(b) (4)	
User entered 'None (None)'	Sheldon Warren (b) (4)	23 Apr 2021 19:12:49
	(b) (4)	

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[Vomiting](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	26 Apr 2021 15:25:40
	(b) (4)	
User entered 'None (None)'	Sheldon Warren (b) (4)	23 Apr 2021 19:12:49
	(b) (4)	



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[Diarrhea](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	26 Apr 2021 15:25:40
	(b) (4)	
User entered 'None (None)'	Sheldon Warren (b) (4)	23 Apr 2021 19:12:49
	(b) (4)	

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[Sore Throat](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	26 Apr 2021 15:25:40
	(b) (4)	
User entered 'None (None)'	Sheldon Warren (b) (4)	23 Apr 2021 19:12:49
	(b) (4)	

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[Symptom Day](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	26 Apr 2021 15:25:40
	(b) (4)	
User entered 'Day 12 (Day 12)'	Sheldon Warren (b) (4)	23 Apr 2021 19:13:19
	(b) (4)	

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Form: Symptom Log (12)

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[Date](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	26 Apr 2021 15:25:40
	(b) (4)	
User entered '23 Apr 2021'	Sheldon Warren (b) (4)	23 Apr 2021 19:13:19
	(b) (4)	

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Form: Symptom Log (12)

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[Assessment Not Done](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	26 Apr 2021 15:25:40
	(b) (4)	
User entered '0'	Sheldon Warren (b) (4)	23 Apr 2021 19:13:19
	(b) (4)	

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[O2 Saturation](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	26 Apr 2021 15:25:40
	(b) (4)	
User entered '98'	Sheldon Warren (b) (4)	23 Apr 2021 19:13:19
	(b) (4)	

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[O2 Saturation Units](#)

Audit	User	Time (GMT)
User entered '%'	System	23 Apr 2021 19:13:19

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[Temperature](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	26 Apr 2021 15:25:40
	(b) (4)	
User entered '95.8' F	Sheldon Warren (b) (4)	23 Apr 2021 19:13:19
	(b) (4)	



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[Chills](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	26 Apr 2021 15:25:40
	(b) (4)	
User entered 'None (None)'	Sheldon Warren (b) (4)	23 Apr 2021 19:13:19
	(b) (4)	

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Form: Symptom Log (12)

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[Cough](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	26 Apr 2021 15:25:40
	(b) (4)	
User entered 'None (None)'	Sheldon Warren (b) (4)	23 Apr 2021 19:13:19
	(b) (4)	

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Form: Symptom Log (12)

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[Shortness of Breath](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	26 Apr 2021 15:25:40
	(b) (4)	
User entered 'None (None)'	Sheldon Warren (b) (4)	23 Apr 2021 19:13:19
	(b) (4)	

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[Difficulty Breathing](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	26 Apr 2021 15:25:40
	(b) (4)	
User entered 'None (None)'	Sheldon Warren (b) (4)	23 Apr 2021 19:13:19
	(b) (4)	

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Form: Symptom Log (12)

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[Fatigue](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	26 Apr 2021 15:25:40
	(b) (4)	
User entered 'None (None)'	Sheldon Warren (b) (4)	23 Apr 2021 19:13:19
	(b) (4)	

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Folder: Covid-19 Assessment 19 Apr 2021

Form: Symptom Log (12)

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[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	26 Apr 2021 15:25:40
	(b) (4)	
User entered 'None (None)'	Sheldon Warren (b) (4)	23 Apr 2021 19:13:19
	(b) (4)	

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[Body Aches](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	26 Apr 2021 15:25:40
	(b) (4)	
User entered 'None (None)'	Sheldon Warren (b) (4)	23 Apr 2021 19:13:19
	(b) (4)	

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[Headache](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	26 Apr 2021 15:25:40
	(b) (4)	
User entered 'None (None)'	Sheldon Warren (b) (4)	23 Apr 2021 19:13:19
	(b) (4)	



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[New Loss of Taste](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	26 Apr 2021 15:25:40
	(b) (4)	
User entered 'None (None)'	Sheldon Warren (b) (4)	23 Apr 2021 19:13:19
	(b) (4)	

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Form: Symptom Log (12)

Generated On: 10 Jun 2021 07:56:44

[New Loss of Smell](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	26 Apr 2021 15:25:40
	(b) (4)	
User entered 'None (None)'	Sheldon Warren (b) (4)	23 Apr 2021 19:13:19
	(b) (4)	

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Form: Symptom Log (12)

Generated On: 10 Jun 2021 07:56:44

[Nasal Congestion](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	26 Apr 2021 15:25:40
	(b) (4)	
User entered 'None (None)'	Sheldon Warren (b) (4)	23 Apr 2021 19:13:19
	(b) (4)	

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[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	26 Apr 2021 15:25:40
	(b) (4)	
User entered 'None (None)'	Sheldon Warren (b) (4)	23 Apr 2021 19:13:19
	(b) (4)	

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Form: Symptom Log (12)

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[Nausea](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	26 Apr 2021 15:25:40
	(b) (4)	
User entered 'None (None)'	Sheldon Warren (b) (4)	23 Apr 2021 19:13:19
	(b) (4)	

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Form: Symptom Log (12)

Generated On: 10 Jun 2021 07:56:44

[Vomiting](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	26 Apr 2021 15:25:40
	(b) (4)	
User entered 'None (None)'	Sheldon Warren (b) (4)	23 Apr 2021 19:13:19
	(b) (4)	

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Form: Symptom Log (12)

Generated On: 10 Jun 2021 07:56:44

[Diarrhea](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	26 Apr 2021 15:25:40
	(b) (4)	
User entered 'None (None)'	Sheldon Warren (b) (4)	23 Apr 2021 19:13:19
	(b) (4)	

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Folder: Covid-19 Assessment 19 Apr 2021

Form: Symptom Log (12)

Generated On: 10 Jun 2021 07:56:44

[Sore Throat](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	26 Apr 2021 15:25:40
	(b) (4)	
User entered 'None (None)'	Sheldon Warren (b) (4)	23 Apr 2021 19:13:19
	(b) (4)	



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Form: Symptom Log (13)

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[Symptom Day](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	28 Apr 2021 21:04:50
	(b) (4)	
User entered 'Day 13 (Day 13)'	Sheldon Warren (b) (4)	26 Apr 2021 21:31:00
	(b) (4)	

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Folder: Covid-19 Assessment 19 Apr 2021

Form: Symptom Log (13)

Generated On: 10 Jun 2021 07:56:44

[Date](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	28 Apr 2021 21:04:50
	(b) (4)	
User entered '24 Apr 2021'	Sheldon Warren (b) (4)	26 Apr 2021 21:31:00
	(b) (4)	

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Folder: Covid-19 Assessment 19 Apr 2021

Form: Symptom Log (13)

Generated On: 10 Jun 2021 07:56:44

[Assessment Not Done](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	28 Apr 2021 21:04:50
	(b) (4)	
User entered '0'	Sheldon Warren (b) (4)	26 Apr 2021 21:31:00
	(b) (4)	

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Folder: Covid-19 Assessment 19 Apr 2021

Form: Symptom Log (13)

Generated On: 10 Jun 2021 07:56:44

[O2 Saturation](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	28 Apr 2021 21:04:50
	(b) (4)	
User entered '98'	Sheldon Warren (b) (4)	26 Apr 2021 21:31:00
	(b) (4)	

**US3512248**

**Folder: Covid-19 Assessment 19 Apr 2021**

**Form: Symptom Log (13)**

**Generated On: 10 Jun 2021 07:56:44**

[O2 Saturation Units](#)

Audit	User	Time (GMT)
User entered '%'	System	26 Apr 2021 21:31:00

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Form: Symptom Log (13)

Generated On: 10 Jun 2021 07:56:44

[Temperature](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	28 Apr 2021 21:04:50
	(b) (4)	
User entered '97.2' F	Sheldon Warren (b) (4)	26 Apr 2021 21:31:00
	(b) (4)	

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Folder: Covid-19 Assessment 19 Apr 2021

Form: Symptom Log (13)

Generated On: 10 Jun 2021 07:56:44

[Chills](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	28 Apr 2021 21:04:50
	(b) (4)	
User entered 'None (None)'	Sheldon Warren (b) (4)	26 Apr 2021 21:31:00
	(b) (4)	

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Folder: Covid-19 Assessment 19 Apr 2021

Form: Symptom Log (13)

Generated On: 10 Jun 2021 07:56:44

[Cough](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	28 Apr 2021 21:04:50
	(b) (4)	
User entered 'None (None)'	Sheldon Warren (b) (4)	26 Apr 2021 21:31:00
	(b) (4)	



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Folder: Covid-19 Assessment 19 Apr 2021

Form: Symptom Log (13)

Generated On: 10 Jun 2021 07:56:44

[Shortness of Breath](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	28 Apr 2021 21:04:50
	(b) (4)	
User entered 'None (None)'	Sheldon Warren (b) (4)	26 Apr 2021 21:31:00
	(b) (4)	

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Folder: Covid-19 Assessment 19 Apr 2021

Form: Symptom Log (13)

Generated On: 10 Jun 2021 07:56:44

[Difficulty Breathing](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	28 Apr 2021 21:04:50
	(b) (4)	
User entered 'None (None)'	Sheldon Warren (b) (4)	26 Apr 2021 21:31:00
	(b) (4)	

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Folder: Covid-19 Assessment 19 Apr 2021

Form: Symptom Log (13)

Generated On: 10 Jun 2021 07:56:44

[Fatigue](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	28 Apr 2021 21:04:50
	(b) (4)	
User entered 'None (None)'	Sheldon Warren (b) (4)	26 Apr 2021 21:31:00
	(b) (4)	

US3512248

Folder: Covid-19 Assessment 19 Apr 2021

Form: Symptom Log (13)

Generated On: 10 Jun 2021 07:56:44

Muscle Aches (Myalgia)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	28 Apr 2021 21:04:50
	(b) (4)	
User entered 'None (None)'	Sheldon Warren (b) (4)	26 Apr 2021 21:31:00
	(b) (4)	

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Folder: Covid-19 Assessment 19 Apr 2021

Form: Symptom Log (13)

Generated On: 10 Jun 2021 07:56:44

[Body Aches](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	28 Apr 2021 21:04:50
	(b) (4)	
User entered 'None (None)'	Sheldon Warren (b) (4)	26 Apr 2021 21:31:00
	(b) (4)	

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Folder: Covid-19 Assessment 19 Apr 2021

Form: Symptom Log (13)

Generated On: 10 Jun 2021 07:56:44

[Headache](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	28 Apr 2021 21:04:50
	(b) (4)	
User entered 'None (None)'	Sheldon Warren (b) (4)	26 Apr 2021 21:31:00
	(b) (4)	

US3512248

Folder: Covid-19 Assessment 19 Apr 2021

Form: Symptom Log (13)

Generated On: 10 Jun 2021 07:56:44

[New Loss of Taste](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	28 Apr 2021 21:04:50
	(b) (4)	
User entered 'None (None)'	Sheldon Warren (b) (4)	26 Apr 2021 21:31:00
	(b) (4)	

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Folder: Covid-19 Assessment 19 Apr 2021

Form: Symptom Log (13)

Generated On: 10 Jun 2021 07:56:44

[New Loss of Smell](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	28 Apr 2021 21:04:50
	(b) (4)	
User entered 'None (None)'	Sheldon Warren (b) (4)	26 Apr 2021 21:31:00
	(b) (4)	



**US3512248**

**Folder: Covid-19 Assessment 19 Apr 2021**

**Form: Symptom Log (13)**

**Generated On: 10 Jun 2021 07:56:44**

[Nasal Congestion](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	28 Apr 2021 21:04:50
	(b) (4)	
User entered 'None (None)'	Sheldon Warren (b) (4)	26 Apr 2021 21:31:00
	(b) (4)	

US3512248

Folder: Covid-19 Assessment 19 Apr 2021

Form: Symptom Log (13)

Generated On: 10 Jun 2021 07:56:44

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	28 Apr 2021 21:04:50
	(b) (4)	
User entered 'None (None)'	Sheldon Warren (b) (4)	26 Apr 2021 21:31:00
	(b) (4)	

**US3512248**

**Folder: Covid-19 Assessment 19 Apr 2021**

**Form: Symptom Log (13)**

**Generated On: 10 Jun 2021 07:56:44**

[Nausea](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	28 Apr 2021 21:04:50
	(b) (4)	
User entered 'None (None)'	Sheldon Warren (b) (4)	26 Apr 2021 21:31:00
	(b) (4)	

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Folder: Covid-19 Assessment 19 Apr 2021

Form: Symptom Log (13)

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[Vomiting](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	28 Apr 2021 21:04:50
	(b) (4)	
User entered 'None (None)'	Sheldon Warren (b) (4)	26 Apr 2021 21:31:00
	(b) (4)	

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Folder: Covid-19 Assessment 19 Apr 2021

Form: Symptom Log (13)

Generated On: 10 Jun 2021 07:56:44

[Diarrhea](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	28 Apr 2021 21:04:50
	(b) (4)	
User entered 'None (None)'	Sheldon Warren (b) (4)	26 Apr 2021 21:31:00
	(b) (4)	

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Folder: Covid-19 Assessment 19 Apr 2021

Form: Symptom Log (13)

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[Sore Throat](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	28 Apr 2021 21:04:50
	(b) (4)	
User entered 'None (None)'	Sheldon Warren (b) (4)	26 Apr 2021 21:31:00
	(b) (4)	

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Form: Symptom Log (14)

Generated On: 10 Jun 2021 07:56:44

[Symptom Day](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	28 Apr 2021 21:04:50
	(b) (4)	
User entered 'Day 14 (Day 14)'	Sheldon Warren (b) (4)	26 Apr 2021 21:31:42
	(b) (4)	

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Folder: Covid-19 Assessment 19 Apr 2021

Form: Symptom Log (14)

Generated On: 10 Jun 2021 07:56:44

[Date](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	28 Apr 2021 21:04:50
	(b) (4)	
User entered '25 Apr 2021'	Sheldon Warren (b) (4)	26 Apr 2021 21:31:42
	(b) (4)	



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Folder: Covid-19 Assessment 19 Apr 2021

Form: Symptom Log (14)

Generated On: 10 Jun 2021 07:56:44

[Assessment Not Done](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	28 Apr 2021 21:04:50
	(b) (4)	
User entered '0'	Sheldon Warren (b) (4)	26 Apr 2021 21:31:42
	(b) (4)	

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Form: Symptom Log (14)

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[O2 Saturation](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	28 Apr 2021 21:04:50
	(b) (4)	
User entered '98'	Sheldon Warren (b) (4)	26 Apr 2021 21:31:42
	(b) (4)	

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**Folder: Covid-19 Assessment 19 Apr 2021**

**Form: Symptom Log (14)**

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[O2 Saturation Units](#)

Audit	User	Time (GMT)
User entered '%'	System	26 Apr 2021 21:31:42

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Form: Symptom Log (14)

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[Temperature](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	28 Apr 2021 21:04:50
	(b) (4)	
User entered '96.8' F	Sheldon Warren (b) (4)	26 Apr 2021 21:31:42
	(b) (4)	

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Folder: Covid-19 Assessment 19 Apr 2021

Form: Symptom Log (14)

Generated On: 10 Jun 2021 07:56:44

[Chills](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	28 Apr 2021 21:04:50
	(b) (4)	
User entered 'None (None)'	Sheldon Warren (b) (4)	26 Apr 2021 21:31:42
	(b) (4)	

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Folder: Covid-19 Assessment 19 Apr 2021

Form: Symptom Log (14)

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[Cough](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	28 Apr 2021 21:04:50
	(b) (4)	
User entered 'None (None)'	Sheldon Warren (b) (4)	26 Apr 2021 21:31:42
	(b) (4)	

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Form: Symptom Log (14)

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[Shortness of Breath](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	28 Apr 2021 21:04:50
	(b) (4)	
User entered 'None (None)'	Sheldon Warren (b) (4)	26 Apr 2021 21:31:42
	(b) (4)	

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Folder: Covid-19 Assessment 19 Apr 2021

Form: Symptom Log (14)

Generated On: 10 Jun 2021 07:56:44

[Difficulty Breathing](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	28 Apr 2021 21:04:50
	(b) (4)	
User entered 'None (None)'	Sheldon Warren (b) (4)	26 Apr 2021 21:31:42
	(b) (4)	



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Form: Symptom Log (14)

Generated On: 10 Jun 2021 07:56:44

[Fatigue](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	28 Apr 2021 21:04:50
	(b) (4)	
User entered 'None (None)'	Sheldon Warren (b) (4)	26 Apr 2021 21:31:42
	(b) (4)	

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Folder: Covid-19 Assessment 19 Apr 2021

Form: Symptom Log (14)

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[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	28 Apr 2021 21:04:50
	(b) (4)	
User entered 'None (None)'	Sheldon Warren (b) (4)	26 Apr 2021 21:31:42
	(b) (4)	

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Folder: Covid-19 Assessment 19 Apr 2021

Form: Symptom Log (14)

Generated On: 10 Jun 2021 07:56:44

[Body Aches](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	28 Apr 2021 21:04:50
	(b) (4)	
User entered 'None (None)'	Sheldon Warren (b) (4)	26 Apr 2021 21:31:42
	(b) (4)	

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Folder: Covid-19 Assessment 19 Apr 2021

Form: Symptom Log (14)

Generated On: 10 Jun 2021 07:56:44

[Headache](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	28 Apr 2021 21:04:50
	(b) (4)	
User entered 'None (None)'	Sheldon Warren (b) (4)	26 Apr 2021 21:31:42
	(b) (4)	

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Folder: Covid-19 Assessment 19 Apr 2021

Form: Symptom Log (14)

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[New Loss of Taste](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	28 Apr 2021 21:04:50
	(b) (4)	
User entered 'None (None)'	Sheldon Warren (b) (4)	26 Apr 2021 21:31:42
	(b) (4)	

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Folder: Covid-19 Assessment 19 Apr 2021

Form: Symptom Log (14)

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[New Loss of Smell](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	28 Apr 2021 21:04:50
	(b) (4)	
User entered 'None (None)'	Sheldon Warren (b) (4)	26 Apr 2021 21:31:42
	(b) (4)	

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Form: Symptom Log (14)

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[Nasal Congestion](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	28 Apr 2021 21:04:50
	(b) (4)	
User entered 'None (None)'	Sheldon Warren (b) (4)	26 Apr 2021 21:31:42
	(b) (4)	

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Form: Symptom Log (14)

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[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	28 Apr 2021 21:04:50
	(b) (4)	
User entered 'None (None)'	Sheldon Warren (b) (4)	26 Apr 2021 21:31:42
	(b) (4)	



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[Nausea](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	28 Apr 2021 21:04:50
	(b) (4)	
User entered 'None (None)'	Sheldon Warren (b) (4)	26 Apr 2021 21:31:42
	(b) (4)	

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[Vomiting](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	28 Apr 2021 21:04:50
	(b) (4)	
User entered 'None (None)'	Sheldon Warren (b) (4)	26 Apr 2021 21:31:42
	(b) (4)	

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[Diarrhea](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	28 Apr 2021 21:04:50
	(b) (4)	
User entered 'None (None)'	Sheldon Warren (b) (4)	26 Apr 2021 21:31:42
	(b) (4)	

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[Sore Throat](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	28 Apr 2021 21:04:50
	(b) (4)	
User entered 'None (None)'	Sheldon Warren (b) (4)	26 Apr 2021 21:31:42
	(b) (4)	

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Form: Symptom Log (15)

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[Symptom Day](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	28 Apr 2021 21:04:50
	(b) (4)	
User entered 'Day 15 (Day 15)'	Sheldon Warren (b) (4)	26 Apr 2021 21:32:25
	(b) (4)	

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Folder: Covid-19 Assessment 19 Apr 2021

Form: Symptom Log (15)

Generated On: 10 Jun 2021 07:56:44

[Date](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	28 Apr 2021 21:04:50
	(b) (4)	
User entered '26 Apr 2021'	Sheldon Warren (b) (4)	26 Apr 2021 21:32:25
	(b) (4)	

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Form: Symptom Log (15)

Generated On: 10 Jun 2021 07:56:44

[Assessment Not Done](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	28 Apr 2021 21:04:50
	(b) (4)	
User entered '0'	Sheldon Warren (b) (4)	26 Apr 2021 21:32:25
	(b) (4)	

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Form: Symptom Log (15)

Generated On: 10 Jun 2021 07:56:44

[O2 Saturation](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	28 Apr 2021 21:04:50
	(b) (4)	
User entered '98'	Sheldon Warren (b) (4)	26 Apr 2021 21:32:25
	(b) (4)	



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**Folder: Covid-19 Assessment 19 Apr 2021**

**Form: Symptom Log (15)**

**Generated On: 10 Jun 2021 07:56:44**

[O2 Saturation Units](#)

Audit	User	Time (GMT)
User entered '%'	System	26 Apr 2021 21:32:25

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Folder: Covid-19 Assessment 19 Apr 2021

Form: Symptom Log (15)

Generated On: 10 Jun 2021 07:56:44

[Temperature](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	28 Apr 2021 21:04:50
	(b) (4)	
User entered '97.5' F	Sheldon Warren (b) (4)	26 Apr 2021 21:32:25
	(b) (4)	

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Folder: Covid-19 Assessment 19 Apr 2021

Form: Symptom Log (15)

Generated On: 10 Jun 2021 07:56:44

[Chills](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	28 Apr 2021 21:04:50
	(b) (4)	
User entered 'None (None)'	Sheldon Warren (b) (4)	26 Apr 2021 21:32:25
	(b) (4)	

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Folder: Covid-19 Assessment 19 Apr 2021

Form: Symptom Log (15)

Generated On: 10 Jun 2021 07:56:44

[Cough](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	28 Apr 2021 21:04:50
	(b) (4)	
User entered 'None (None)'	Sheldon Warren (b) (4)	26 Apr 2021 21:32:25
	(b) (4)	

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Folder: Covid-19 Assessment 19 Apr 2021

Form: Symptom Log (15)

Generated On: 10 Jun 2021 07:56:44

[Shortness of Breath](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	28 Apr 2021 21:04:50
	(b) (4)	
User entered 'None (None)'	Sheldon Warren (b) (4)	26 Apr 2021 21:32:25
	(b) (4)	

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Folder: Covid-19 Assessment 19 Apr 2021

Form: Symptom Log (15)

Generated On: 10 Jun 2021 07:56:44

[Difficulty Breathing](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	28 Apr 2021 21:04:50
	(b) (4)	
User entered 'None (None)'	Sheldon Warren (b) (4)	26 Apr 2021 21:32:25
	(b) (4)	

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Folder: Covid-19 Assessment 19 Apr 2021

Form: Symptom Log (15)

Generated On: 10 Jun 2021 07:56:44

[Fatigue](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	28 Apr 2021 21:04:50
	(b) (4)	
User entered 'None (None)'	Sheldon Warren (b) (4)	26 Apr 2021 21:32:25
	(b) (4)	

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Folder: Covid-19 Assessment 19 Apr 2021

Form: Symptom Log (15)

Generated On: 10 Jun 2021 07:56:44

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	28 Apr 2021 21:04:50
	(b) (4)	
User entered 'None (None)'	Sheldon Warren (b) (4)	26 Apr 2021 21:32:25
	(b) (4)	



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Form: Symptom Log (15)

Generated On: 10 Jun 2021 07:56:44

[Body Aches](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	28 Apr 2021 21:04:50
	(b) (4)	
User entered 'None (None)'	Sheldon Warren (b) (4)	26 Apr 2021 21:32:25
	(b) (4)	

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Folder: Covid-19 Assessment 19 Apr 2021

Form: Symptom Log (15)

Generated On: 10 Jun 2021 07:56:44

[Headache](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	28 Apr 2021 21:04:50
	(b) (4)	
User entered 'None (None)'	Sheldon Warren (b) (4)	26 Apr 2021 21:32:25
	(b) (4)	

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Folder: Covid-19 Assessment 19 Apr 2021

Form: Symptom Log (15)

Generated On: 10 Jun 2021 07:56:44

[New Loss of Taste](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	28 Apr 2021 21:04:50
	(b) (4)	
User entered 'None (None)'	Sheldon Warren (b) (4)	26 Apr 2021 21:32:25
	(b) (4)	

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Form: Symptom Log (15)

Generated On: 10 Jun 2021 07:56:44

[New Loss of Smell](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	28 Apr 2021 21:04:50
	(b) (4)	
User entered 'None (None)'	Sheldon Warren (b) (4)	26 Apr 2021 21:32:25
	(b) (4)	

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Folder: Covid-19 Assessment 19 Apr 2021

Form: Symptom Log (15)

Generated On: 10 Jun 2021 07:56:44

[Nasal Congestion](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	28 Apr 2021 21:04:50
	(b) (4)	
User entered 'None (None)'	Sheldon Warren (b) (4)	26 Apr 2021 21:32:25
	(b) (4)	

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Form: Symptom Log (15)

Generated On: 10 Jun 2021 07:56:44

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	28 Apr 2021 21:04:50
	(b) (4)	
User entered 'None (None)'	Sheldon Warren (b) (4)	26 Apr 2021 21:32:25
	(b) (4)	

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Folder: Covid-19 Assessment 19 Apr 2021

Form: Symptom Log (15)

Generated On: 10 Jun 2021 07:56:44

[Nausea](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	28 Apr 2021 21:04:50
	(b) (4)	
User entered 'None (None)'	Sheldon Warren (b) (4)	26 Apr 2021 21:32:25
	(b) (4)	

US3512248

Folder: Covid-19 Assessment 19 Apr 2021

Form: Symptom Log (15)

Generated On: 10 Jun 2021 07:56:44

[Vomiting](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	28 Apr 2021 21:04:50
	(b) (4)	
User entered 'None (None)'	Sheldon Warren (b) (4)	26 Apr 2021 21:32:25
	(b) (4)	



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Folder: Covid-19 Assessment 19 Apr 2021

Form: Symptom Log (15)

Generated On: 10 Jun 2021 07:56:44

[Diarrhea](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	28 Apr 2021 21:04:50
	(b) (4)	
User entered 'None (None)'	Sheldon Warren (b) (4)	26 Apr 2021 21:32:25
	(b) (4)	

US3512248

Folder: Covid-19 Assessment 19 Apr 2021

Form: Symptom Log (15)

Generated On: 10 Jun 2021 07:56:44

[Sore Throat](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	28 Apr 2021 21:04:50
	(b) (4)	
User entered 'None (None)'	Sheldon Warren (b) (4)	26 Apr 2021 21:32:25
	(b) (4)	

US3512248

Folder: Covid-19 Assessment 19 Apr 2021

Form: Symptom Log (16)

Generated On: 10 Jun 2021 07:56:44

[Symptom Day](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	28 Apr 2021 21:04:50
	(b) (4)	
User entered 'Day 16 (Day 16)'	Sheldon Warren (b) (4)	27 Apr 2021 16:37:46
	(b) (4)	

US3512248

Folder: Covid-19 Assessment 19 Apr 2021

Form: Symptom Log (16)

Generated On: 10 Jun 2021 07:56:44

[Date](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	28 Apr 2021 21:04:50
	(b) (4)	
User entered '27 Apr 2021'	Sheldon Warren (b) (4)	27 Apr 2021 16:37:46
	(b) (4)	

US3512248

Folder: Covid-19 Assessment 19 Apr 2021

Form: Symptom Log (16)

Generated On: 10 Jun 2021 07:56:44

[Assessment Not Done](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	28 Apr 2021 21:04:50
	(b) (4)	
User entered '0'	Sheldon Warren (b) (4)	27 Apr 2021 16:37:46
	(b) (4)	

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Folder: Covid-19 Assessment 19 Apr 2021

Form: Symptom Log (16)

Generated On: 10 Jun 2021 07:56:44

[O2 Saturation](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	28 Apr 2021 21:04:50
	(b) (4)	
User entered '96'	Sheldon Warren (b) (4)	27 Apr 2021 16:37:46
	(b) (4)	

**US3512248**

**Folder: Covid-19 Assessment 19 Apr 2021**

**Form: Symptom Log (16)**

**Generated On: 10 Jun 2021 07:56:44**

[O2 Saturation Units](#)

Audit	User	Time (GMT)
User entered '%'	System	27 Apr 2021 16:37:46

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Folder: Covid-19 Assessment 19 Apr 2021

Form: Symptom Log (16)

Generated On: 10 Jun 2021 07:56:44

[Temperature](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	28 Apr 2021 21:04:50
	(b) (4)	
User entered '97.8' F	Sheldon Warren (b) (4)	27 Apr 2021 16:37:46
	(b) (4)	



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Folder: Covid-19 Assessment 19 Apr 2021

Form: Symptom Log (16)

Generated On: 10 Jun 2021 07:56:44

[Chills](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	28 Apr 2021 21:04:50
	(b) (4)	
User entered 'None (None)'	Sheldon Warren (b) (4)	27 Apr 2021 16:37:46
	(b) (4)	

US3512248

Folder: Covid-19 Assessment 19 Apr 2021

Form: Symptom Log (16)

Generated On: 10 Jun 2021 07:56:44

[Cough](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	28 Apr 2021 21:04:50
	(b) (4)	
User entered 'None (None)'	Sheldon Warren (b) (4)	27 Apr 2021 16:37:46
	(b) (4)	

US3512248

Folder: Covid-19 Assessment 19 Apr 2021

Form: Symptom Log (16)

Generated On: 10 Jun 2021 07:56:44

[Shortness of Breath](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	28 Apr 2021 21:04:50
	(b) (4)	
User entered 'None (None)'	Sheldon Warren (b) (4)	27 Apr 2021 16:37:46
	(b) (4)	

US3512248

Folder: Covid-19 Assessment 19 Apr 2021

Form: Symptom Log (16)

Generated On: 10 Jun 2021 07:56:44

[Difficulty Breathing](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	28 Apr 2021 21:04:50
	(b) (4)	
User entered 'None (None)'	Sheldon Warren (b) (4)	27 Apr 2021 16:37:46
	(b) (4)	

US3512248

Folder: Covid-19 Assessment 19 Apr 2021

Form: Symptom Log (16)

Generated On: 10 Jun 2021 07:56:44

[Fatigue](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	28 Apr 2021 21:04:50
	(b) (4)	
User entered 'None (None)'	Sheldon Warren (b) (4)	27 Apr 2021 16:37:46
	(b) (4)	

US3512248

Folder: Covid-19 Assessment 19 Apr 2021

Form: Symptom Log (16)

Generated On: 10 Jun 2021 07:56:44

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	28 Apr 2021 21:04:50
	(b) (4)	
User entered 'None (None)'	Sheldon Warren (b) (4)	27 Apr 2021 16:37:46
	(b) (4)	

US3512248

Folder: Covid-19 Assessment 19 Apr 2021

Form: Symptom Log (16)

Generated On: 10 Jun 2021 07:56:44

[Body Aches](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	28 Apr 2021 21:04:50
	(b) (4)	
User entered 'None (None)'	Sheldon Warren (b) (4)	27 Apr 2021 16:37:46
	(b) (4)	

US3512248

Folder: Covid-19 Assessment 19 Apr 2021

Form: Symptom Log (16)

Generated On: 10 Jun 2021 07:56:44

[Headache](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	28 Apr 2021 21:04:50
	(b) (4)	
User entered 'None (None)'	Sheldon Warren (b) (4)	27 Apr 2021 16:37:46
	(b) (4)	



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Folder: Covid-19 Assessment 19 Apr 2021

Form: Symptom Log (16)

Generated On: 10 Jun 2021 07:56:44

[New Loss of Taste](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	28 Apr 2021 21:04:50
	(b) (4)	
User entered 'None (None)'	Sheldon Warren (b) (4)	27 Apr 2021 16:37:46
	(b) (4)	

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Folder: Covid-19 Assessment 19 Apr 2021

Form: Symptom Log (16)

Generated On: 10 Jun 2021 07:56:44

[New Loss of Smell](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	28 Apr 2021 21:04:50
	(b) (4)	
User entered 'None (None)'	Sheldon Warren (b) (4)	27 Apr 2021 16:37:46
	(b) (4)	

**US3512248**

**Folder: Covid-19 Assessment 19 Apr 2021**

**Form: Symptom Log (16)**

**Generated On: 10 Jun 2021 07:56:44**

[Nasal Congestion](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	28 Apr 2021 21:04:50
	(b) (4)	
User entered 'None (None)'	Sheldon Warren (b) (4)	27 Apr 2021 16:37:46
	(b) (4)	

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Folder: Covid-19 Assessment 19 Apr 2021

Form: Symptom Log (16)

Generated On: 10 Jun 2021 07:56:44

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	28 Apr 2021 21:04:50
	(b) (4)	
User entered 'None (None)'	Sheldon Warren (b) (4)	27 Apr 2021 16:37:46
	(b) (4)	

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Folder: Covid-19 Assessment 19 Apr 2021

Form: Symptom Log (16)

Generated On: 10 Jun 2021 07:56:44

[Nausea](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	28 Apr 2021 21:04:50
	(b) (4)	
User entered 'None (None)'	Sheldon Warren (b) (4)	27 Apr 2021 16:37:46
	(b) (4)	

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Folder: Covid-19 Assessment 19 Apr 2021

Form: Symptom Log (16)

Generated On: 10 Jun 2021 07:56:44

[Vomiting](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	28 Apr 2021 21:04:50
	(b) (4)	
User entered 'None (None)'	Sheldon Warren (b) (4)	27 Apr 2021 16:37:46
	(b) (4)	

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Folder: Covid-19 Assessment 19 Apr 2021

Form: Symptom Log (16)

Generated On: 10 Jun 2021 07:56:44

[Diarrhea](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	28 Apr 2021 21:04:50
	(b) (4)	
User entered 'None (None)'	Sheldon Warren (b) (4)	27 Apr 2021 16:37:46
	(b) (4)	

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Folder: Covid-19 Assessment 19 Apr 2021

Form: Symptom Log (16)

Generated On: 10 Jun 2021 07:56:44

[Sore Throat](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	28 Apr 2021 21:04:50
	(b) (4)	
User entered 'None (None)'	Sheldon Warren (b) (4)	27 Apr 2021 16:37:46
	(b) (4)	



**US3512248**

**Folder: Covid-19 Assessment 19 Apr 2021**

**Form: COVID Diagnostic Test**

**Generated On: 10 Jun 2021 07:56:44**

[Date of Visit](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	26 Apr 2021 15:25:40
	(b) (4)	
User entered '20 Apr 2021'	Sheldon Warren (b) (4)	23 Apr 2021 19:14:11
	(b) (4)	

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Folder: Covid-19 Assessment 19 Apr 2021

Form: COVID Diagnostic Test

Generated On: 10 Jun 2021 07:56:44

[Was the Subject Tested For SARS-CoV-2 by RT-PCR?](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	26 Apr 2021 15:25:40
	(b) (4)	
User entered 'Yes (Y)'	Sheldon Warren (b) (4)	23 Apr 2021 19:14:11
	(b) (4)	

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Folder: Covid-19 Assessment 19 Apr 2021

Form: COVID Diagnostic Test

Generated On: 10 Jun 2021 07:56:44

[Did Subject Test Positive For SARS-CoV-2 by RT-PCR?](#)

Audit	User	Time (GMT)
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4), (b) (6)	29 Apr 2021 13:58:30
User signature succeeded.	Michael Koren (b) (4)	26 Apr 2021 15:25:40
Query 'Data is required. Please complete.' answered with 'will update information when results are returned to the clinic' (Site from System).	(b) (4)	
	Sheldon Warren (b) (4)	23 Apr 2021 19:14:35
User opened query 'Data is required. Please complete.' (Site from System).	(b) (4)	
User entered empty.	System	23 Apr 2021 19:14:11
	Sheldon Warren (b) (4)	23 Apr 2021 19:14:11
	(b) (4)	

**US3512248**

**Folder: Covid-19 Assessment 19 Apr 2021**

**Form: COVID Diagnostic Test**

**Generated On: 10 Jun 2021 07:56:44**

[Date of Test](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	26 Apr 2021 15:25:40
	(b) (4)	
User entered '20 Apr 2021'	Sheldon Warren (b) (4)	23 Apr 2021 19:14:11
	(b) (4)	

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Folder: Covid-19 Assessment 19 Apr 2021

Form: COVID Diagnostic Test

Generated On: 10 Jun 2021 07:56:44

[Type of Test Performed](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	26 Apr 2021 15:25:40
User entered 'Nasopharyngeal Swab (Nasopharyngeal Swab)'	(b) (4) Sheldon Warren (b) (4)	23 Apr 2021 19:14:11

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Folder: Covid-19 Assessment 19 Apr 2021

Form: COVID Diagnostic Test

Generated On: 10 Jun 2021 07:56:44

[Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4) (b) (4)	26 Apr 2021 15:25:40
User entered empty.	Sheldon Warren (b) (4) (b) (4)	23 Apr 2021 19:14:11

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Folder: Covid-19 Assessment 19 Apr 2021

Form: COVID Diagnostic Test

Generated On: 10 Jun 2021 07:56:44

[Was this diagnostic test performed at a lab other than the Study Central Lab?](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	26 Apr 2021 15:25:40
	(b) (4)	
User entered 'No (N)'	Sheldon Warren (b) (4)	23 Apr 2021 19:14:11
	(b) (4)	

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Folder: Covid-19 Assessment 19 Apr 2021

Form: COVID Diagnostic Test

Generated On: 10 Jun 2021 07:56:44

[Lab/ Institution Test Performed](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4) (b) (4)	26 Apr 2021 15:25:40
User entered empty.	Sheldon Warren (b) (4) (b) (4)	23 Apr 2021 19:14:11



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**Folder: Covid-19 Assessment 19 Apr 2021**

**Form: COVID Diagnostic Test**

**Generated On: 10 Jun 2021 07:56:44**

[CLIA Certified?](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	26 Apr 2021 15:25:40
	(b) (4)	
User entered empty.	Sheldon Warren (b) (4)	23 Apr 2021 19:14:11
	(b) (4)	

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**Folder: Covid-19 Assessment 26 Jan 2021**

**Form: COVID-19 Contact**

**Generated On: 10 Jun 2021 07:56:44**

[Date of Contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:25:31
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 19:45:53
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 22:12:02
User entered '26 Jan 2021'	(b) (4) Brenda Anderson (b) (4)	27 Jan 2021 12:29:25

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Folder: Covid-19 Assessment 26 Jan 2021

Form: COVID-19 Contact

Generated On: 10 Jun 2021 07:56:44

[Time of Contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:25:31
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 19:45:53
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 22:12:02
User entered '10:14'	(b) (4) Brenda Anderson (b) (4)	27 Jan 2021 12:29:25

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Folder: Covid-19 Assessment 26 Jan 2021

Form: COVID-19 Contact

Generated On: 10 Jun 2021 07:56:44

[Date and Time of Contact \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:25:31
User entered '26 Jan 2021 10:14'	System	27 Jan 2021 12:29:25

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Folder: Covid-19 Assessment 26 Jan 2021

Form: COVID-19 Contact

Generated On: 10 Jun 2021 07:56:44

[Type of Contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:25:31
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 19:45:53
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 22:12:02
User entered 'Clinical Visit - Unscheduled (Clinical Visit - Unscheduled)'	(b) (4) Brenda Anderson (b) (4)	27 Jan 2021 12:29:25

**US3512248**

**Folder: Covid-19 Assessment 26 Jan 2021**

**Form: COVID-19 Contact**

**Generated On: 10 Jun 2021 07:56:44**

[Has the subject reported symptoms of SARS-COV-2?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:25:31
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 19:45:53
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 22:12:02
User entered 'Yes (Y)'	(b) (4) Brenda Anderson (b) (4)	27 Jan 2021 12:29:25

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Folder: Covid-19 Assessment 26 Jan 2021

Form: Symptom Log (1)

Generated On: 10 Jun 2021 07:56:44

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:25:37
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 22:12:02
User entered 'Day 1 (Day 1)'	Brenda Anderson (b) (4)	27 Jan 2021 12:32:17

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Folder: Covid-19 Assessment 26 Jan 2021

Form: Symptom Log (1)

Generated On: 10 Jun 2021 07:56:44

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:25:37
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 19:46:06
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 22:12:02
User entered '23 Jan 2021'	(b) (4) Brenda Anderson (b) (4)	27 Jan 2021 12:32:17



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Folder: Covid-19 Assessment 26 Jan 2021

Form: Symptom Log (1)

Generated On: 10 Jun 2021 07:56:44

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:25:37
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 19:46:06
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 22:12:02
User entered '0'	(b) (4) Brenda Anderson (b) (4)	27 Jan 2021 12:32:17

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Folder: Covid-19 Assessment 26 Jan 2021

Form: Symptom Log (1)

Generated On: 10 Jun 2021 07:56:44

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:25:37
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 19:46:06
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 22:12:02
User entered missing code ND - Not Done.	(b) (4) Brenda Anderson (b) (4)	27 Jan 2021 12:32:17

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Folder: Covid-19 Assessment 26 Jan 2021

Form: Symptom Log (1)

Generated On: 10 Jun 2021 07:56:44

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:25:37
User entered '%'	System	27 Jan 2021 12:32:17

US3512248

Folder: Covid-19 Assessment 26 Jan 2021

Form: Symptom Log (1)

Generated On: 10 Jun 2021 07:56:44

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:25:37
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 19:46:06
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 22:12:02
User entered missing code ND - Not Done.	(b) (4) Brenda Anderson (b) (4)	27 Jan 2021 12:32:17

US3512248

Folder: Covid-19 Assessment 26 Jan 2021

Form: Symptom Log (1)

Generated On: 10 Jun 2021 07:56:44

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:25:37
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 19:46:06
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 22:12:02
User entered 'None (None)'	(b) (4) Brenda Anderson (b) (4)	27 Jan 2021 12:32:17

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Folder: Covid-19 Assessment 26 Jan 2021

Form: Symptom Log (1)

Generated On: 10 Jun 2021 07:56:44

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:25:37
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 19:46:06
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 22:12:02
User entered 'Mild (Mild)'	(b) (4) Brenda Anderson (b) (4)	27 Jan 2021 12:32:17

US3512248

Folder: Covid-19 Assessment 26 Jan 2021

Form: Symptom Log (1)

Generated On: 10 Jun 2021 07:56:44

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:25:37
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 19:46:06
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 22:12:02
User entered 'None (None)'	(b) (4) Brenda Anderson (b) (4)	27 Jan 2021 12:32:17

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Folder: Covid-19 Assessment 26 Jan 2021

Form: Symptom Log (1)

Generated On: 10 Jun 2021 07:56:44

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:25:37
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 19:46:06
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 22:12:02
User entered 'None (None)'	(b) (4) Brenda Anderson (b) (4)	27 Jan 2021 12:32:17



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Folder: Covid-19 Assessment 26 Jan 2021

Form: Symptom Log (1)

Generated On: 10 Jun 2021 07:56:44

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:25:37
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 19:46:06
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 22:12:02
User entered 'None (None)'	(b) (4) Brenda Anderson (b) (4)	27 Jan 2021 12:32:17

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Folder: Covid-19 Assessment 26 Jan 2021

Form: Symptom Log (1)

Generated On: 10 Jun 2021 07:56:44

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:25:37
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 19:46:06
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 22:12:02
User entered 'None (None)'	(b) (4) Brenda Anderson (b) (4)	27 Jan 2021 12:32:17

US3512248

Folder: Covid-19 Assessment 26 Jan 2021

Form: Symptom Log (1)

Generated On: 10 Jun 2021 07:56:44

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:25:37
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 19:46:06
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 22:12:02
User entered 'None (None)'	(b) (4) Brenda Anderson (b) (4)	27 Jan 2021 12:32:17

US3512248

Folder: Covid-19 Assessment 26 Jan 2021

Form: Symptom Log (1)

Generated On: 10 Jun 2021 07:56:44

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:25:37
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 19:46:06
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 22:12:02
User entered 'None (None)'	Brenda Anderson (b) (4)	27 Jan 2021 12:32:17

US3512248

Folder: Covid-19 Assessment 26 Jan 2021

Form: Symptom Log (1)

Generated On: 10 Jun 2021 07:56:44

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:25:37
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 19:46:06
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 22:12:02
User entered 'None (None)'	(b) (4) Brenda Anderson (b) (4)	27 Jan 2021 12:32:17

US3512248

Folder: Covid-19 Assessment 26 Jan 2021

Form: Symptom Log (1)

Generated On: 10 Jun 2021 07:56:44

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:25:37
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 19:46:06
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 22:12:02
User entered 'None (None)'	(b) (4) Brenda Anderson (b) (4)	27 Jan 2021 12:32:17

US3512248

Folder: Covid-19 Assessment 26 Jan 2021

Form: Symptom Log (1)

Generated On: 10 Jun 2021 07:56:44

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:25:37
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 19:46:06
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 22:12:02
User entered 'None (None)'	(b) (4) Brenda Anderson (b) (4)	27 Jan 2021 12:32:17

US3512248

Folder: Covid-19 Assessment 26 Jan 2021

Form: Symptom Log (1)

Generated On: 10 Jun 2021 07:56:44

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:25:37
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 19:46:06
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 22:12:02
User entered 'None (None)'	(b) (4) Brenda Anderson (b) (4)	27 Jan 2021 12:32:17



US3512248

Folder: Covid-19 Assessment 26 Jan 2021

Form: Symptom Log (1)

Generated On: 10 Jun 2021 07:56:44

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:25:37
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 19:46:06
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 22:12:02
User entered 'None (None)'	(b) (4) Brenda Anderson (b) (4)	27 Jan 2021 12:32:17

US3512248

Folder: Covid-19 Assessment 26 Jan 2021

Form: Symptom Log (1)

Generated On: 10 Jun 2021 07:56:44

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:25:37
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 19:46:06
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 22:12:02
User entered 'None (None)'	(b) (4) Brenda Anderson (b) (4)	27 Jan 2021 12:32:17

US3512248

Folder: Covid-19 Assessment 26 Jan 2021

Form: Symptom Log (1)

Generated On: 10 Jun 2021 07:56:44

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:25:37
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 19:46:06
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 22:12:02
User entered 'None (None)'	(b) (4) Brenda Anderson (b) (4)	27 Jan 2021 12:32:17

US3512248

Folder: Covid-19 Assessment 26 Jan 2021

Form: Symptom Log (1)

Generated On: 10 Jun 2021 07:56:44

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:25:37
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 19:46:06
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 22:12:02
User entered 'None (None)'	(b) (4) Brenda Anderson (b) (4)	27 Jan 2021 12:32:17

US3512248

Folder: Covid-19 Assessment 26 Jan 2021

Form: Symptom Log (2)

Generated On: 10 Jun 2021 07:56:44

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:25:37
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 22:12:02
User entered 'Day 2 (Day 2)'	Brenda Anderson (b) (4)	27 Jan 2021 12:32:17

US3512248

Folder: Covid-19 Assessment 26 Jan 2021

Form: Symptom Log (2)

Generated On: 10 Jun 2021 07:56:44

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:25:37
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 19:46:06
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 22:12:02
User entered '24 Jan 2021'	(b) (4) Brenda Anderson (b) (4)	27 Jan 2021 12:32:17

US3512248

Folder: Covid-19 Assessment 26 Jan 2021

Form: Symptom Log (2)

Generated On: 10 Jun 2021 07:56:44

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:25:37
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 19:46:06
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 22:12:02
User entered '0'	(b) (4) Brenda Anderson (b) (4)	27 Jan 2021 12:32:17

US3512248

Folder: Covid-19 Assessment 26 Jan 2021

Form: Symptom Log (2)

Generated On: 10 Jun 2021 07:56:44

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:25:37
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 19:46:06
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 22:12:02
User entered missing code ND - Not Done.	(b) (4) Brenda Anderson (b) (4)	27 Jan 2021 12:32:17



**US3512248**

**Folder: Covid-19 Assessment 26 Jan 2021**

**Form: Symptom Log (2)**

**Generated On: 10 Jun 2021 07:56:44**

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:25:37
User entered '%'	System	27 Jan 2021 12:32:17

US3512248

Folder: Covid-19 Assessment 26 Jan 2021

Form: Symptom Log (2)

Generated On: 10 Jun 2021 07:56:44

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:25:37
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 19:46:06
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 22:12:02
User entered missing code ND - Not Done.	(b) (4) Brenda Anderson (b) (4)	27 Jan 2021 12:32:17

US3512248

Folder: Covid-19 Assessment 26 Jan 2021

Form: Symptom Log (2)

Generated On: 10 Jun 2021 07:56:44

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:25:37
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 19:46:06
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 22:12:02
User entered 'None (None)'	(b) (4) Brenda Anderson (b) (4)	27 Jan 2021 12:32:17

US3512248

Folder: Covid-19 Assessment 26 Jan 2021

Form: Symptom Log (2)

Generated On: 10 Jun 2021 07:56:44

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:25:37
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 19:46:06
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 22:12:02
User entered 'Mild (Mild)'	(b) (4) Brenda Anderson (b) (4) (b) (4)	27 Jan 2021 12:32:17

US3512248

Folder: Covid-19 Assessment 26 Jan 2021

Form: Symptom Log (2)

Generated On: 10 Jun 2021 07:56:44

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:25:37
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 19:46:06
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 22:12:02
User entered 'None (None)'	Brenda Anderson (b) (4)	27 Jan 2021 12:32:17

US3512248

Folder: Covid-19 Assessment 26 Jan 2021

Form: Symptom Log (2)

Generated On: 10 Jun 2021 07:56:44

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:25:37
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 19:46:06
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 22:12:02
User entered 'None (None)'	(b) (4) Brenda Anderson (b) (4)	27 Jan 2021 12:32:17

US3512248

Folder: Covid-19 Assessment 26 Jan 2021

Form: Symptom Log (2)

Generated On: 10 Jun 2021 07:56:44

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:25:37
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 19:46:06
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 22:12:02
User entered 'None (None)'	(b) (4) Brenda Anderson (b) (4)	27 Jan 2021 12:32:17

US3512248

Folder: Covid-19 Assessment 26 Jan 2021

Form: Symptom Log (2)

Generated On: 10 Jun 2021 07:56:44

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:25:37
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 19:46:06
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 22:12:02
User entered 'None (None)'	(b) (4) Brenda Anderson (b) (4)	27 Jan 2021 12:32:17



US3512248

Folder: Covid-19 Assessment 26 Jan 2021

Form: Symptom Log (2)

Generated On: 10 Jun 2021 07:56:44

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:25:37
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 19:46:06
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 22:12:02
User entered 'None (None)'	(b) (4) Brenda Anderson (b) (4)	27 Jan 2021 12:32:17

US3512248

Folder: Covid-19 Assessment 26 Jan 2021

Form: Symptom Log (2)

Generated On: 10 Jun 2021 07:56:44

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:25:37
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 19:46:06
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 22:12:02
User entered 'None (None)'	(b) (4) Brenda Anderson (b) (4)	27 Jan 2021 12:32:17

US3512248

Folder: Covid-19 Assessment 26 Jan 2021

Form: Symptom Log (2)

Generated On: 10 Jun 2021 07:56:44

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:25:37
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 19:46:06
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 22:12:02
User entered 'None (None)'	(b) (4) Brenda Anderson (b) (4)	27 Jan 2021 12:32:17

US3512248

Folder: Covid-19 Assessment 26 Jan 2021

Form: Symptom Log (2)

Generated On: 10 Jun 2021 07:56:44

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:25:37
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 19:46:06
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 22:12:02
User entered 'None (None)'	(b) (4) Brenda Anderson (b) (4)	27 Jan 2021 12:32:17

US3512248

Folder: Covid-19 Assessment 26 Jan 2021

Form: Symptom Log (2)

Generated On: 10 Jun 2021 07:56:44

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:25:37
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 19:46:06
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 22:12:02
User entered 'None (None)'	(b) (4) Brenda Anderson (b) (4)	27 Jan 2021 12:32:17

US3512248

Folder: Covid-19 Assessment 26 Jan 2021

Form: Symptom Log (2)

Generated On: 10 Jun 2021 07:56:44

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:25:37
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 19:46:06
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 22:12:02
User entered 'None (None)'	(b) (4) Brenda Anderson (b) (4)	27 Jan 2021 12:32:17

US3512248

Folder: Covid-19 Assessment 26 Jan 2021

Form: Symptom Log (2)

Generated On: 10 Jun 2021 07:56:44

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:25:37
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 19:46:06
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 22:12:02
User entered 'None (None)'	(b) (4) Brenda Anderson (b) (4)	27 Jan 2021 12:32:17

US3512248

Folder: Covid-19 Assessment 26 Jan 2021

Form: Symptom Log (2)

Generated On: 10 Jun 2021 07:56:44

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:25:37
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 19:46:06
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 22:12:02
User entered 'None (None)'	(b) (4) Brenda Anderson (b) (4)	27 Jan 2021 12:32:17



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Folder: Covid-19 Assessment 26 Jan 2021

Form: Symptom Log (2)

Generated On: 10 Jun 2021 07:56:44

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:25:37
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 19:46:06
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 22:12:02
User entered 'None (None)'	Brenda Anderson (b) (4)	27 Jan 2021 12:32:17

US3512248

Folder: Covid-19 Assessment 26 Jan 2021

Form: Symptom Log (2)

Generated On: 10 Jun 2021 07:56:44

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:25:37
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 19:46:06
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 22:12:02
User entered 'None (None)'	(b) (4) Brenda Anderson (b) (4)	27 Jan 2021 12:32:17

US3512248

Folder: Covid-19 Assessment 26 Jan 2021

Form: Symptom Log (3)

Generated On: 10 Jun 2021 07:56:44

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:25:37
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 22:12:02
User entered 'Day 3 (Day 3)'	Brenda Anderson (b) (4)	27 Jan 2021 12:32:17

US3512248

Folder: Covid-19 Assessment 26 Jan 2021

Form: Symptom Log (3)

Generated On: 10 Jun 2021 07:56:44

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:25:37
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 19:46:06
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 22:12:02
User entered '25 Jan 2021'	(b) (4) Brenda Anderson (b) (4)	27 Jan 2021 12:32:17

US3512248

Folder: Covid-19 Assessment 26 Jan 2021

Form: Symptom Log (3)

Generated On: 10 Jun 2021 07:56:44

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:25:37
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 19:46:06
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 22:12:02
User entered '0'	(b) (4) Brenda Anderson (b) (4)	27 Jan 2021 12:32:17

US3512248

Folder: Covid-19 Assessment 26 Jan 2021

Form: Symptom Log (3)

Generated On: 10 Jun 2021 07:56:44

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:25:37
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 19:46:06
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 22:12:02
User entered missing code ND - Not Done.	(b) (4) Brenda Anderson (b) (4)	27 Jan 2021 12:32:17

US3512248

Folder: Covid-19 Assessment 26 Jan 2021

Form: Symptom Log (3)

Generated On: 10 Jun 2021 07:56:44

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:25:37
User entered '%'	System	27 Jan 2021 12:32:17

US3512248

Folder: Covid-19 Assessment 26 Jan 2021

Form: Symptom Log (3)

Generated On: 10 Jun 2021 07:56:44

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:25:37
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 19:46:06
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 22:12:02
User entered '97.2' F	(b) (4) Brenda Anderson (b) (4)	27 Jan 2021 12:32:17



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Folder: Covid-19 Assessment 26 Jan 2021

Form: Symptom Log (3)

Generated On: 10 Jun 2021 07:56:44

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:25:37
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 19:46:06
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 22:12:02
User entered 'None (None)'	(b) (4) Brenda Anderson (b) (4)	27 Jan 2021 12:32:17

US3512248

Folder: Covid-19 Assessment 26 Jan 2021

Form: Symptom Log (3)

Generated On: 10 Jun 2021 07:56:44

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:25:37
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 19:46:06
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 22:12:02
User entered 'Mild (Mild)'	(b) (4) Brenda Anderson (b) (4) (b) (4)	27 Jan 2021 12:32:17

US3512248

Folder: Covid-19 Assessment 26 Jan 2021

Form: Symptom Log (3)

Generated On: 10 Jun 2021 07:56:44

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:25:37
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 19:46:06
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 22:12:02
User entered 'None (None)'	(b) (4) Brenda Anderson (b) (4)	27 Jan 2021 12:32:17

US3512248

Folder: Covid-19 Assessment 26 Jan 2021

Form: Symptom Log (3)

Generated On: 10 Jun 2021 07:56:44

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:25:37
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 19:46:06
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 22:12:02
User entered 'None (None)'	(b) (4) Brenda Anderson (b) (4)	27 Jan 2021 12:32:17

US3512248

Folder: Covid-19 Assessment 26 Jan 2021

Form: Symptom Log (3)

Generated On: 10 Jun 2021 07:56:44

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:25:37
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 19:46:06
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 22:12:02
User entered 'None (None)'	(b) (4) Brenda Anderson (b) (4)	27 Jan 2021 12:32:17

US3512248

Folder: Covid-19 Assessment 26 Jan 2021

Form: Symptom Log (3)

Generated On: 10 Jun 2021 07:56:44

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:25:37
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 19:46:06
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 22:12:02
User entered 'None (None)'	(b) (4) Brenda Anderson (b) (4)	27 Jan 2021 12:32:17

US3512248

Folder: Covid-19 Assessment 26 Jan 2021

Form: Symptom Log (3)

Generated On: 10 Jun 2021 07:56:44

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:25:37
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 19:46:06
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 22:12:02
User entered 'None (None)'	(b) (4) Brenda Anderson (b) (4)	27 Jan 2021 12:32:17

US3512248

Folder: Covid-19 Assessment 26 Jan 2021

Form: Symptom Log (3)

Generated On: 10 Jun 2021 07:56:44

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:25:37
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 19:46:06
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 22:12:02
User entered 'Mild (Mild)'	(b) (4) Brenda Anderson (b) (4)	27 Jan 2021 12:32:17



US3512248

Folder: Covid-19 Assessment 26 Jan 2021

Form: Symptom Log (3)

Generated On: 10 Jun 2021 07:56:44

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:25:37
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 19:46:06
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 22:12:02
User entered 'None (None)'	(b) (4) Brenda Anderson (b) (4)	27 Jan 2021 12:32:17

US3512248

Folder: Covid-19 Assessment 26 Jan 2021

Form: Symptom Log (3)

Generated On: 10 Jun 2021 07:56:44

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:25:37
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 19:46:06
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 22:12:02
User entered 'None (None)'	(b) (4) Brenda Anderson (b) (4)	27 Jan 2021 12:32:17

US3512248

Folder: Covid-19 Assessment 26 Jan 2021

Form: Symptom Log (3)

Generated On: 10 Jun 2021 07:56:44

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:25:37
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 19:46:06
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 22:12:02
User entered 'None (None)' reason for change: Data Entry Error	(b) (4)	
	Brenda Anderson (b) (4)	27 Jan 2021 12:33:50
User entered 'Mild (Mild)'	(b) (4)	
	Brenda Anderson (b) (4)	27 Jan 2021 12:32:17
	(b) (4)	

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Folder: Covid-19 Assessment 26 Jan 2021

Form: Symptom Log (3)

Generated On: 10 Jun 2021 07:56:44

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:25:37
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 19:46:06
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 22:12:02
User entered 'None (None)' reason for change: Data Entry Error	(b) (4)	
	Brenda Anderson (b) (4)	27 Jan 2021 12:33:50
User entered 'Mild (Mild)'	(b) (4)	
	Brenda Anderson (b) (4)	27 Jan 2021 12:32:17
	(b) (4)	

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Folder: Covid-19 Assessment 26 Jan 2021

Form: Symptom Log (3)

Generated On: 10 Jun 2021 07:56:44

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:25:37
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 19:46:06
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 22:12:02
User entered 'None (None)'	(b) (4) Brenda Anderson (b) (4)	27 Jan 2021 12:32:17

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Folder: Covid-19 Assessment 26 Jan 2021

Form: Symptom Log (3)

Generated On: 10 Jun 2021 07:56:44

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:25:37
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 19:46:06
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 22:12:02
User entered 'None (None)'	(b) (4) Brenda Anderson (b) (4)	27 Jan 2021 12:32:17

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Folder: Covid-19 Assessment 26 Jan 2021

Form: Symptom Log (3)

Generated On: 10 Jun 2021 07:56:44

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:25:37
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 19:46:06
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 22:12:02
User entered 'None (None)'	(b) (4) Brenda Anderson (b) (4)	27 Jan 2021 12:32:17

US3512248

Folder: Covid-19 Assessment 26 Jan 2021

Form: Symptom Log (3)

Generated On: 10 Jun 2021 07:56:44

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:25:37
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 19:46:06
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 22:12:02
User entered 'Mild (Mild)'	(b) (4) Brenda Anderson (b) (4)	27 Jan 2021 12:32:17



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Folder: Covid-19 Assessment 26 Jan 2021

Form: Symptom Log (4)

Generated On: 10 Jun 2021 07:56:44

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:25:37
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 22:12:02
User entered 'Day 4 (Day 4)'	Brenda Anderson (b) (4)	27 Jan 2021 12:33:50

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Folder: Covid-19 Assessment 26 Jan 2021

Form: Symptom Log (4)

Generated On: 10 Jun 2021 07:56:44

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:25:37
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 19:46:06
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 22:12:02
User entered '26 Jan 2021'	(b) (4) Brenda Anderson (b) (4)	27 Jan 2021 12:33:50

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Folder: Covid-19 Assessment 26 Jan 2021

Form: Symptom Log (4)

Generated On: 10 Jun 2021 07:56:44

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:25:37
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 19:46:06
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 22:12:02
User entered '0'	(b) (4) Brenda Anderson (b) (4)	27 Jan 2021 12:33:50

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Folder: Covid-19 Assessment 26 Jan 2021

Form: Symptom Log (4)

Generated On: 10 Jun 2021 07:56:44

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:25:37
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 19:46:06
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 22:12:02
User entered '99'	(b) (4) Brenda Anderson (b) (4)	27 Jan 2021 12:33:50

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Folder: Covid-19 Assessment 26 Jan 2021

Form: Symptom Log (4)

Generated On: 10 Jun 2021 07:56:44

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:25:37
User entered '%'	System	27 Jan 2021 12:33:50

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Folder: Covid-19 Assessment 26 Jan 2021

Form: Symptom Log (4)

Generated On: 10 Jun 2021 07:56:44

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:25:37
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 19:46:06
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 22:12:02
User entered '97.3' F	(b) (4) Brenda Anderson (b) (4)	27 Jan 2021 12:33:50

US3512248

Folder: Covid-19 Assessment 26 Jan 2021

Form: Symptom Log (4)

Generated On: 10 Jun 2021 07:56:44

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:25:37
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 19:46:06
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 22:12:02
User entered 'None (None)'	(b) (4) Brenda Anderson (b) (4)	27 Jan 2021 12:33:50

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Folder: Covid-19 Assessment 26 Jan 2021

Form: Symptom Log (4)

Generated On: 10 Jun 2021 07:56:44

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:25:37
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 19:46:06
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 22:12:02
User entered 'Mild (Mild)'	(b) (4) Brenda Anderson (b) (4)	27 Jan 2021 12:33:50



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Folder: Covid-19 Assessment 26 Jan 2021

Form: Symptom Log (4)

Generated On: 10 Jun 2021 07:56:44

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:25:37
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 19:46:06
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 22:12:02
User entered 'None (None)'	(b) (4) Brenda Anderson (b) (4)	27 Jan 2021 12:33:50

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Folder: Covid-19 Assessment 26 Jan 2021

Form: Symptom Log (4)

Generated On: 10 Jun 2021 07:56:44

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:25:37
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 19:46:06
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 22:12:02
User entered 'None (None)'	(b) (4) Brenda Anderson (b) (4)	27 Jan 2021 12:33:50

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Folder: Covid-19 Assessment 26 Jan 2021

Form: Symptom Log (4)

Generated On: 10 Jun 2021 07:56:44

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:25:37
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 19:46:06
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 22:12:02
User entered 'None (None)'	(b) (4) Brenda Anderson (b) (4)	27 Jan 2021 12:33:50

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Folder: Covid-19 Assessment 26 Jan 2021

Form: Symptom Log (4)

Generated On: 10 Jun 2021 07:56:44

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:25:37
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 19:46:06
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 22:12:02
User entered 'None (None)'	(b) (4) Brenda Anderson (b) (4)	27 Jan 2021 12:33:50

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Folder: Covid-19 Assessment 26 Jan 2021

Form: Symptom Log (4)

Generated On: 10 Jun 2021 07:56:44

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:25:37
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 19:46:06
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 22:12:02
User entered 'None (None)'	(b) (4) Brenda Anderson (b) (4)	27 Jan 2021 12:33:50

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Folder: Covid-19 Assessment 26 Jan 2021

Form: Symptom Log (4)

Generated On: 10 Jun 2021 07:56:44

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:25:37
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 19:46:06
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 22:12:02
User entered 'Mild (Mild)'	(b) (4) Brenda Anderson (b) (4) (b) (4)	27 Jan 2021 12:33:50

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Folder: Covid-19 Assessment 26 Jan 2021

Form: Symptom Log (4)

Generated On: 10 Jun 2021 07:56:44

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:25:37
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 19:46:06
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 22:12:02
User entered 'None (None)'	(b) (4) Brenda Anderson (b) (4) (b) (4)	27 Jan 2021 12:33:50

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Folder: Covid-19 Assessment 26 Jan 2021

Form: Symptom Log (4)

Generated On: 10 Jun 2021 07:56:44

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:25:37
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 19:46:06
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 22:12:02
User entered 'None (None)'	(b) (4) Brenda Anderson (b) (4)	27 Jan 2021 12:33:50



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Folder: Covid-19 Assessment 26 Jan 2021

Form: Symptom Log (4)

Generated On: 10 Jun 2021 07:56:44

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:25:37
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 19:46:06
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 22:12:02
User entered 'Mild (Mild)'	(b) (4) Brenda Anderson (b) (4) (b) (4)	27 Jan 2021 12:33:50

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Folder: Covid-19 Assessment 26 Jan 2021

Form: Symptom Log (4)

Generated On: 10 Jun 2021 07:56:44

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:25:37
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 19:46:06
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 22:12:02
User entered 'Mild (Mild)'	(b) (4) Brenda Anderson (b) (4) (b) (4)	27 Jan 2021 12:33:50

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Folder: Covid-19 Assessment 26 Jan 2021

Form: Symptom Log (4)

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[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:25:37
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 19:46:06
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 22:12:02
User entered 'None (None)'	(b) (4) Brenda Anderson (b) (4)	27 Jan 2021 12:33:50

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Folder: Covid-19 Assessment 26 Jan 2021

Form: Symptom Log (4)

Generated On: 10 Jun 2021 07:56:44

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:25:37
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 19:46:06
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 22:12:02
User entered 'None (None)'	(b) (4) Brenda Anderson (b) (4)	27 Jan 2021 12:33:50

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Folder: Covid-19 Assessment 26 Jan 2021

Form: Symptom Log (4)

Generated On: 10 Jun 2021 07:56:44

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:25:37
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 19:46:06
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 22:12:02
User entered 'None (None)'	(b) (4) Brenda Anderson (b) (4)	27 Jan 2021 12:33:50

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Folder: Covid-19 Assessment 26 Jan 2021

Form: Symptom Log (4)

Generated On: 10 Jun 2021 07:56:44

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:25:37
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 19:46:06
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 22:12:02
User entered 'Mild (Mild)'	(b) (4) Brenda Anderson (b) (4) (b) (4)	27 Jan 2021 12:33:50

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Folder: Covid-19 Assessment 26 Jan 2021

Form: Symptom Log (5)

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[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:25:37
User signature succeeded.	Michael Koren (b) (4)	26 Feb 2021 20:02:47
User entered 'Day 5 (Day 5)'	Brenda Anderson (b) (4)	24 Feb 2021 15:43:43

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Folder: Covid-19 Assessment 26 Jan 2021

Form: Symptom Log (5)

Generated On: 10 Jun 2021 07:56:44

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:25:37
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 19:46:06
User signature succeeded.	Michael Koren (b) (4)	26 Feb 2021 20:02:47
User entered '27 Jan 2021'	(b) (4) Brenda Anderson (b) (4)	24 Feb 2021 15:43:43



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Form: Symptom Log (5)

Generated On: 10 Jun 2021 07:56:44

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:25:37
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 19:46:06
User signature succeeded.	Michael Koren (b) (4)	26 Feb 2021 20:02:47
User entered '0'	(b) (4) Brenda Anderson (b) (4) (b) (4)	24 Feb 2021 15:43:43

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Folder: Covid-19 Assessment 26 Jan 2021

Form: Symptom Log (5)

Generated On: 10 Jun 2021 07:56:44

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:25:37
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 19:46:06
User signature succeeded.	Michael Koren (b) (4)	26 Feb 2021 20:02:47
User entered '94'	(b) (4) Brenda Anderson (b) (4)	24 Feb 2021 15:43:43

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Folder: Covid-19 Assessment 26 Jan 2021

Form: Symptom Log (5)

Generated On: 10 Jun 2021 07:56:44

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:25:37
User entered '%'	System	24 Feb 2021 15:43:43

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Folder: Covid-19 Assessment 26 Jan 2021

Form: Symptom Log (5)

Generated On: 10 Jun 2021 07:56:44

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:25:37
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 19:46:06
User signature succeeded.	Michael Koren (b) (4)	26 Feb 2021 20:02:47
User entered '97.5' F	(b) (4) Brenda Anderson (b) (4)	24 Feb 2021 15:43:43

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Folder: Covid-19 Assessment 26 Jan 2021

Form: Symptom Log (5)

Generated On: 10 Jun 2021 07:56:44

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:25:37
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 19:46:06
User signature succeeded.	Michael Koren (b) (4)	26 Feb 2021 20:02:47
User entered 'None (None)'	(b) (4) Brenda Anderson (b) (4)	24 Feb 2021 15:43:43

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Folder: Covid-19 Assessment 26 Jan 2021

Form: Symptom Log (5)

Generated On: 10 Jun 2021 07:56:44

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:25:37
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 19:46:06
User signature succeeded.	Michael Koren (b) (4)	26 Feb 2021 20:02:47
User entered 'Mild (Mild)'	(b) (4) Brenda Anderson (b) (4)	24 Feb 2021 15:43:43

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Folder: Covid-19 Assessment 26 Jan 2021

Form: Symptom Log (5)

Generated On: 10 Jun 2021 07:56:44

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:25:37
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 19:46:06
User signature succeeded.	Michael Koren (b) (4)	26 Feb 2021 20:02:47
User entered 'None (None)'	(b) (4) Brenda Anderson (b) (4)	24 Feb 2021 15:43:43

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Folder: Covid-19 Assessment 26 Jan 2021

Form: Symptom Log (5)

Generated On: 10 Jun 2021 07:56:44

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:25:37
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 19:46:06
User signature succeeded.	Michael Koren (b) (4)	26 Feb 2021 20:02:47
User entered 'None (None)'	(b) (4) Brenda Anderson (b) (4)	24 Feb 2021 15:43:43



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Folder: Covid-19 Assessment 26 Jan 2021

Form: Symptom Log (5)

Generated On: 10 Jun 2021 07:56:44

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:25:37
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 19:46:06
User signature succeeded.	Michael Koren (b) (4)	26 Feb 2021 20:02:47
User entered 'None (None)'	(b) (4) Brenda Anderson (b) (4) (b) (4)	24 Feb 2021 15:43:43

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Folder: Covid-19 Assessment 26 Jan 2021

Form: Symptom Log (5)

Generated On: 10 Jun 2021 07:56:44

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:25:37
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 19:46:06
User signature succeeded.	Michael Koren (b) (4)	26 Feb 2021 20:02:47
User entered 'None (None)'	(b) (4) Brenda Anderson (b) (4)	24 Feb 2021 15:43:43

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Folder: Covid-19 Assessment 26 Jan 2021

Form: Symptom Log (5)

Generated On: 10 Jun 2021 07:56:44

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:25:37
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 19:46:06
User signature succeeded.	Michael Koren (b) (4)	26 Feb 2021 20:02:47
User entered 'None (None)'	(b) (4) Brenda Anderson (b) (4)	24 Feb 2021 15:43:43

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Folder: Covid-19 Assessment 26 Jan 2021

Form: Symptom Log (5)

Generated On: 10 Jun 2021 07:56:44

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:25:37
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 19:46:06
User signature succeeded.	Michael Koren (b) (4)	26 Feb 2021 20:02:47
User entered 'None (None)'	(b) (4) Brenda Anderson (b) (4)	24 Feb 2021 15:43:43

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Folder: Covid-19 Assessment 26 Jan 2021

Form: Symptom Log (5)

Generated On: 10 Jun 2021 07:56:44

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:25:37
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 19:46:06
User signature succeeded.	Michael Koren (b) (4)	26 Feb 2021 20:02:47
User entered 'None (None)'	(b) (4) Brenda Anderson (b) (4)	24 Feb 2021 15:43:43

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Folder: Covid-19 Assessment 26 Jan 2021

Form: Symptom Log (5)

Generated On: 10 Jun 2021 07:56:44

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:25:37
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 19:46:06
User signature succeeded.	Michael Koren (b) (4)	26 Feb 2021 20:02:47
User entered 'None (None)'	(b) (4) Brenda Anderson (b) (4) (b) (4)	24 Feb 2021 15:43:43

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Folder: Covid-19 Assessment 26 Jan 2021

Form: Symptom Log (5)

Generated On: 10 Jun 2021 07:56:44

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:25:37
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 19:46:06
User signature succeeded.	Michael Koren (b) (4)	26 Feb 2021 20:02:47
User entered 'None (None)'	(b) (4) Brenda Anderson (b) (4)	24 Feb 2021 15:43:43

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Folder: Covid-19 Assessment 26 Jan 2021

Form: Symptom Log (5)

Generated On: 10 Jun 2021 07:56:44

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:25:37
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 19:46:06
User signature succeeded.	Michael Koren (b) (4)	26 Feb 2021 20:02:47
User entered 'None (None)'	(b) (4) Brenda Anderson (b) (4)	24 Feb 2021 15:43:43



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Folder: Covid-19 Assessment 26 Jan 2021

Form: Symptom Log (5)

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[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:25:37
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 19:46:06
User signature succeeded.	Michael Koren (b) (4)	26 Feb 2021 20:02:47
User entered 'None (None)'	(b) (4) Brenda Anderson (b) (4)	24 Feb 2021 15:43:43

US3512248

Folder: Covid-19 Assessment 26 Jan 2021

Form: Symptom Log (5)

Generated On: 10 Jun 2021 07:56:44

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:25:37
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 19:46:06
User signature succeeded.	Michael Koren (b) (4)	26 Feb 2021 20:02:47
User entered 'None (None)'	(b) (4) Brenda Anderson (b) (4)	24 Feb 2021 15:43:43

US3512248

Folder: Covid-19 Assessment 26 Jan 2021

Form: Symptom Log (5)

Generated On: 10 Jun 2021 07:56:44

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:25:37
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 19:46:06
User signature succeeded.	Michael Koren (b) (4)	26 Feb 2021 20:02:47
User entered 'None (None)'	(b) (4) Brenda Anderson (b) (4)	24 Feb 2021 15:43:43

US3512248

Folder: Covid-19 Assessment 26 Jan 2021

Form: Symptom Log (5)

Generated On: 10 Jun 2021 07:56:44

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:25:37
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 19:46:06
User signature succeeded.	Michael Koren (b) (4)	26 Feb 2021 20:02:47
User entered 'Mild (Mild)'	(b) (4) Brenda Anderson (b) (4)	24 Feb 2021 15:43:43

US3512248

Folder: Covid-19 Assessment 26 Jan 2021

Form: Symptom Log (6)

Generated On: 10 Jun 2021 07:56:44

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:25:37
User signature succeeded.	Michael Koren (b) (4)	26 Feb 2021 20:02:47
User entered 'Day 6 (Day 6)'	Brenda Anderson (b) (4)	24 Feb 2021 15:43:43

US3512248

Folder: Covid-19 Assessment 26 Jan 2021

Form: Symptom Log (6)

Generated On: 10 Jun 2021 07:56:44

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:25:37
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 19:46:06
User signature succeeded.	Michael Koren (b) (4)	26 Feb 2021 20:02:47
User entered '28 Jan 2021'	(b) (4) Brenda Anderson (b) (4)	24 Feb 2021 15:43:43

**US3512248**

**Folder: Covid-19 Assessment 26 Jan 2021**

**Form: Symptom Log (6)**

**Generated On: 10 Jun 2021 07:56:44**

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:25:37
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 19:46:06
User signature succeeded.	Michael Koren (b) (4)	26 Feb 2021 20:02:47
User entered '0'	(b) (4) Brenda Anderson (b) (4)	24 Feb 2021 15:43:43

US3512248

Folder: Covid-19 Assessment 26 Jan 2021

Form: Symptom Log (6)

Generated On: 10 Jun 2021 07:56:44

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:25:37
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 19:46:06
User signature succeeded.	Michael Koren (b) (4)	26 Feb 2021 20:02:47
User entered '97'	(b) (4) Brenda Anderson (b) (4)	24 Feb 2021 15:43:43



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Folder: Covid-19 Assessment 26 Jan 2021

Form: Symptom Log (6)

Generated On: 10 Jun 2021 07:56:44

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:25:37
User entered '%'	System	24 Feb 2021 15:43:43

US3512248

Folder: Covid-19 Assessment 26 Jan 2021

Form: Symptom Log (6)

Generated On: 10 Jun 2021 07:56:44

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:25:37
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 19:46:06
User signature succeeded.	Michael Koren (b) (4)	26 Feb 2021 20:02:47
User entered '96.8' F	(b) (4) Brenda Anderson (b) (4) (b) (4)	24 Feb 2021 15:43:43

US3512248

Folder: Covid-19 Assessment 26 Jan 2021

Form: Symptom Log (6)

Generated On: 10 Jun 2021 07:56:44

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:25:37
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 19:46:06
User signature succeeded.	Michael Koren (b) (4)	26 Feb 2021 20:02:47
User entered 'None (None)'	(b) (4) Brenda Anderson (b) (4)	24 Feb 2021 15:43:43

US3512248

Folder: Covid-19 Assessment 26 Jan 2021

Form: Symptom Log (6)

Generated On: 10 Jun 2021 07:56:44

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:25:37
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 19:46:06
User signature succeeded.	Michael Koren (b) (4)	26 Feb 2021 20:02:47
User entered 'Mild (Mild)'	(b) (4) Brenda Anderson (b) (4)	24 Feb 2021 15:43:43

US3512248

Folder: Covid-19 Assessment 26 Jan 2021

Form: Symptom Log (6)

Generated On: 10 Jun 2021 07:56:44

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:25:37
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 19:46:06
User signature succeeded.	Michael Koren (b) (4)	26 Feb 2021 20:02:47
User entered 'None (None)'	(b) (4) Brenda Anderson (b) (4)	24 Feb 2021 15:43:43

US3512248

Folder: Covid-19 Assessment 26 Jan 2021

Form: Symptom Log (6)

Generated On: 10 Jun 2021 07:56:44

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:25:37
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 19:46:06
User signature succeeded.	Michael Koren (b) (4)	26 Feb 2021 20:02:47
User entered 'None (None)'	(b) (4) Brenda Anderson (b) (4)	24 Feb 2021 15:43:43

US3512248

Folder: Covid-19 Assessment 26 Jan 2021

Form: Symptom Log (6)

Generated On: 10 Jun 2021 07:56:44

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:25:37
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 19:46:06
User signature succeeded.	Michael Koren (b) (4)	26 Feb 2021 20:02:47
User entered 'None (None)'	(b) (4) Brenda Anderson (b) (4)	24 Feb 2021 15:43:43

US3512248

Folder: Covid-19 Assessment 26 Jan 2021

Form: Symptom Log (6)

Generated On: 10 Jun 2021 07:56:44

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:25:37
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 19:46:06
User signature succeeded.	Michael Koren (b) (4)	26 Feb 2021 20:02:47
User entered 'None (None)'	(b) (4) Brenda Anderson (b) (4)	24 Feb 2021 15:43:43



US3512248

Folder: Covid-19 Assessment 26 Jan 2021

Form: Symptom Log (6)

Generated On: 10 Jun 2021 07:56:44

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:25:37
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 19:46:06
User signature succeeded.	Michael Koren (b) (4)	26 Feb 2021 20:02:47
User entered 'None (None)'	(b) (4) Brenda Anderson (b) (4)	24 Feb 2021 15:43:43

US3512248

Folder: Covid-19 Assessment 26 Jan 2021

Form: Symptom Log (6)

Generated On: 10 Jun 2021 07:56:44

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:25:37
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 19:46:06
User signature succeeded.	Michael Koren (b) (4)	26 Feb 2021 20:02:47
User entered 'None (None)'	(b) (4) Brenda Anderson (b) (4)	24 Feb 2021 15:43:43

US3512248

Folder: Covid-19 Assessment 26 Jan 2021

Form: Symptom Log (6)

Generated On: 10 Jun 2021 07:56:44

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:25:37
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 19:46:06
User signature succeeded.	Michael Koren (b) (4)	26 Feb 2021 20:02:47
User entered 'None (None)'	(b) (4) Brenda Anderson (b) (4)	24 Feb 2021 15:43:43

US3512248

Folder: Covid-19 Assessment 26 Jan 2021

Form: Symptom Log (6)

Generated On: 10 Jun 2021 07:56:44

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:25:37
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 19:46:06
User signature succeeded.	Michael Koren (b) (4)	26 Feb 2021 20:02:47
User entered 'None (None)'	(b) (4) Brenda Anderson (b) (4) (b) (4)	24 Feb 2021 15:43:43

US3512248

Folder: Covid-19 Assessment 26 Jan 2021

Form: Symptom Log (6)

Generated On: 10 Jun 2021 07:56:44

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:25:37
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 19:46:06
User signature succeeded.	Michael Koren (b) (4)	26 Feb 2021 20:02:47
User entered 'None (None)'	(b) (4) Brenda Anderson (b) (4)	24 Feb 2021 15:43:43

US3512248

Folder: Covid-19 Assessment 26 Jan 2021

Form: Symptom Log (6)

Generated On: 10 Jun 2021 07:56:44

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:25:37
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 19:46:06
User signature succeeded.	Michael Koren (b) (4)	26 Feb 2021 20:02:47
User entered 'None (None)'	(b) (4) Brenda Anderson (b) (4)	24 Feb 2021 15:43:43

US3512248

Folder: Covid-19 Assessment 26 Jan 2021

Form: Symptom Log (6)

Generated On: 10 Jun 2021 07:56:44

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:25:37
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 19:46:06
User signature succeeded.	Michael Koren (b) (4)	26 Feb 2021 20:02:47
User entered 'None (None)'	(b) (4) Brenda Anderson (b) (4)	24 Feb 2021 15:43:43

US3512248

Folder: Covid-19 Assessment 26 Jan 2021

Form: Symptom Log (6)

Generated On: 10 Jun 2021 07:56:44

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:25:37
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 19:46:06
User signature succeeded.	Michael Koren (b) (4)	26 Feb 2021 20:02:47
User entered 'None (None)'	(b) (4) Brenda Anderson (b) (4)	24 Feb 2021 15:43:43



US3512248

Folder: Covid-19 Assessment 26 Jan 2021

Form: Symptom Log (6)

Generated On: 10 Jun 2021 07:56:44

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:25:37
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 19:46:06
User signature succeeded.	Michael Koren (b) (4)	26 Feb 2021 20:02:47
User entered 'None (None)'	(b) (4) Brenda Anderson (b) (4)	24 Feb 2021 15:43:43

US3512248

Folder: Covid-19 Assessment 26 Jan 2021

Form: Symptom Log (6)

Generated On: 10 Jun 2021 07:56:44

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:25:37
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 19:46:06
User signature succeeded.	Michael Koren (b) (4)	26 Feb 2021 20:02:47
User entered 'None (None)'	(b) (4) Brenda Anderson (b) (4) (b) (4)	24 Feb 2021 15:43:43

US3512248

Folder: Covid-19 Assessment 26 Jan 2021

Form: Symptom Log (7)

Generated On: 10 Jun 2021 07:56:44

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:25:37
User signature succeeded.	Michael Koren (b) (4)	26 Feb 2021 20:02:47
User entered 'Day 7 (Day 7)'	Brenda Anderson (b) (4)	24 Feb 2021 15:43:43

US3512248

Folder: Covid-19 Assessment 26 Jan 2021

Form: Symptom Log (7)

Generated On: 10 Jun 2021 07:56:44

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:25:37
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 19:46:06
User signature succeeded.	Michael Koren (b) (4)	26 Feb 2021 20:02:47
User entered '29 Jan 2021'	(b) (4) Brenda Anderson (b) (4)	24 Feb 2021 15:43:43

US3512248

Folder: Covid-19 Assessment 26 Jan 2021

Form: Symptom Log (7)

Generated On: 10 Jun 2021 07:56:44

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:25:37
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 19:46:06
User signature succeeded.	Michael Koren (b) (4)	26 Feb 2021 20:02:47
User entered '0'	(b) (4) Brenda Anderson (b) (4)	24 Feb 2021 15:43:43

US3512248

Folder: Covid-19 Assessment 26 Jan 2021

Form: Symptom Log (7)

Generated On: 10 Jun 2021 07:56:44

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:25:37
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 19:46:06
User signature succeeded.	Michael Koren (b) (4)	26 Feb 2021 20:02:47
User entered '98'	(b) (4) Brenda Anderson (b) (4)	24 Feb 2021 15:43:43

**US3512248**

**Folder: Covid-19 Assessment 26 Jan 2021**

**Form: Symptom Log (7)**

**Generated On: 10 Jun 2021 07:56:44**

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:25:37
User entered '%'	System	24 Feb 2021 15:43:43

US3512248

Folder: Covid-19 Assessment 26 Jan 2021

Form: Symptom Log (7)

Generated On: 10 Jun 2021 07:56:44

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:25:37
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 19:46:06
User signature succeeded.	Michael Koren (b) (4)	26 Feb 2021 20:02:47
User entered '96.2' F	(b) (4) Brenda Anderson (b) (4)	24 Feb 2021 15:43:43



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Folder: Covid-19 Assessment 26 Jan 2021

Form: Symptom Log (7)

Generated On: 10 Jun 2021 07:56:44

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:25:37
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 19:46:06
User signature succeeded.	Michael Koren (b) (4)	26 Feb 2021 20:02:47
User entered 'None (None)'	(b) (4) Brenda Anderson (b) (4)	24 Feb 2021 15:43:43

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Folder: Covid-19 Assessment 26 Jan 2021

Form: Symptom Log (7)

Generated On: 10 Jun 2021 07:56:44

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:25:37
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 19:46:06
User signature succeeded.	Michael Koren (b) (4)	26 Feb 2021 20:02:47
User entered 'Mild (Mild)'	(b) (4) Brenda Anderson (b) (4)	24 Feb 2021 15:43:43

US3512248

Folder: Covid-19 Assessment 26 Jan 2021

Form: Symptom Log (7)

Generated On: 10 Jun 2021 07:56:44

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:25:37
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 19:46:06
User signature succeeded.	Michael Koren (b) (4)	26 Feb 2021 20:02:47
User entered 'None (None)'	(b) (4) Brenda Anderson (b) (4) (b) (4)	24 Feb 2021 15:43:43

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Folder: Covid-19 Assessment 26 Jan 2021

Form: Symptom Log (7)

Generated On: 10 Jun 2021 07:56:44

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:25:37
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 19:46:06
User signature succeeded.	Michael Koren (b) (4)	26 Feb 2021 20:02:47
User entered 'None (None)'	(b) (4) Brenda Anderson (b) (4)	24 Feb 2021 15:43:43

US3512248

Folder: Covid-19 Assessment 26 Jan 2021

Form: Symptom Log (7)

Generated On: 10 Jun 2021 07:56:44

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:25:37
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 19:46:06
User signature succeeded.	Michael Koren (b) (4)	26 Feb 2021 20:02:47
User entered 'None (None)'	(b) (4) Brenda Anderson (b) (4)	24 Feb 2021 15:43:43

US3512248

Folder: Covid-19 Assessment 26 Jan 2021

Form: Symptom Log (7)

Generated On: 10 Jun 2021 07:56:44

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:25:37
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 19:46:06
User signature succeeded.	Michael Koren (b) (4)	26 Feb 2021 20:02:47
User entered 'None (None)'	(b) (4) Brenda Anderson (b) (4)	24 Feb 2021 15:43:43

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Folder: Covid-19 Assessment 26 Jan 2021

Form: Symptom Log (7)

Generated On: 10 Jun 2021 07:56:44

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:25:37
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 19:46:06
User signature succeeded.	Michael Koren (b) (4)	26 Feb 2021 20:02:47
User entered 'None (None)'	(b) (4) Brenda Anderson (b) (4)	24 Feb 2021 15:43:43

US3512248

Folder: Covid-19 Assessment 26 Jan 2021

Form: Symptom Log (7)

Generated On: 10 Jun 2021 07:56:44

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:25:37
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 19:46:06
User signature succeeded.	Michael Koren (b) (4)	26 Feb 2021 20:02:47
User entered 'None (None)'	(b) (4) Brenda Anderson (b) (4)	24 Feb 2021 15:43:43



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Folder: Covid-19 Assessment 26 Jan 2021

Form: Symptom Log (7)

Generated On: 10 Jun 2021 07:56:44

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:25:37
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 19:46:06
User signature succeeded.	Michael Koren (b) (4)	26 Feb 2021 20:02:47
User entered 'None (None)'	(b) (4) Brenda Anderson (b) (4)	24 Feb 2021 15:43:43

US3512248

Folder: Covid-19 Assessment 26 Jan 2021

Form: Symptom Log (7)

Generated On: 10 Jun 2021 07:56:44

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:25:37
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 19:46:06
User signature succeeded.	Michael Koren (b) (4)	26 Feb 2021 20:02:47
User entered 'None (None)'	(b) (4) Brenda Anderson (b) (4)	24 Feb 2021 15:43:43

US3512248

Folder: Covid-19 Assessment 26 Jan 2021

Form: Symptom Log (7)

Generated On: 10 Jun 2021 07:56:44

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:25:37
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 19:46:06
User signature succeeded.	Michael Koren (b) (4)	26 Feb 2021 20:02:47
User entered 'None (None)'	(b) (4) Brenda Anderson (b) (4)	24 Feb 2021 15:43:43

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Folder: Covid-19 Assessment 26 Jan 2021

Form: Symptom Log (7)

Generated On: 10 Jun 2021 07:56:44

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:25:37
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 19:46:06
User signature succeeded.	Michael Koren (b) (4)	26 Feb 2021 20:02:47
User entered 'None (None)'	(b) (4) Brenda Anderson (b) (4)	24 Feb 2021 15:43:43

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Folder: Covid-19 Assessment 26 Jan 2021

Form: Symptom Log (7)

Generated On: 10 Jun 2021 07:56:44

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:25:37
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 19:46:06
User signature succeeded.	Michael Koren (b) (4)	26 Feb 2021 20:02:47
User entered 'None (None)'	(b) (4) Brenda Anderson (b) (4)	24 Feb 2021 15:43:43

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Folder: Covid-19 Assessment 26 Jan 2021

Form: Symptom Log (7)

Generated On: 10 Jun 2021 07:56:44

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:25:37
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 19:46:06
User signature succeeded.	Michael Koren (b) (4)	26 Feb 2021 20:02:47
User entered 'None (None)'	(b) (4) Brenda Anderson (b) (4)	24 Feb 2021 15:43:43

US3512248

Folder: Covid-19 Assessment 26 Jan 2021

Form: Symptom Log (7)

Generated On: 10 Jun 2021 07:56:44

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:25:37
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 19:46:06
User signature succeeded.	Michael Koren (b) (4)	26 Feb 2021 20:02:47
User entered 'None (None)'	(b) (4) Brenda Anderson (b) (4)	24 Feb 2021 15:43:43

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Folder: Covid-19 Assessment 26 Jan 2021

Form: Symptom Log (7)

Generated On: 10 Jun 2021 07:56:44

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:25:37
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 19:46:06
User signature succeeded.	Michael Koren (b) (4)	26 Feb 2021 20:02:47
User entered 'None (None)'	(b) (4) Brenda Anderson (b) (4) (b) (4)	24 Feb 2021 15:43:43



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Folder: Covid-19 Assessment 26 Jan 2021

Form: Symptom Log (8)

Generated On: 10 Jun 2021 07:56:44

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:25:37
User signature succeeded.	Michael Koren (b) (4)	26 Feb 2021 20:02:47
User entered 'Day 8 (Day 8)'	Brenda Anderson (b) (4)	24 Feb 2021 15:43:43

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Folder: Covid-19 Assessment 26 Jan 2021

Form: Symptom Log (8)

Generated On: 10 Jun 2021 07:56:44

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:25:37
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 19:46:06
User signature succeeded.	Michael Koren (b) (4)	26 Feb 2021 20:02:47
User entered '30 Jan 2021'	(b) (4) Brenda Anderson (b) (4)	24 Feb 2021 15:43:43

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Folder: Covid-19 Assessment 26 Jan 2021

Form: Symptom Log (8)

Generated On: 10 Jun 2021 07:56:44

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:25:37
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 19:46:06
User signature succeeded.	Michael Koren (b) (4)	26 Feb 2021 20:02:47
User entered '0'	(b) (4) Brenda Anderson (b) (4)	24 Feb 2021 15:43:43

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Folder: Covid-19 Assessment 26 Jan 2021

Form: Symptom Log (8)

Generated On: 10 Jun 2021 07:56:44

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:25:37
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 19:46:06
User signature succeeded.	Michael Koren (b) (4)	26 Feb 2021 20:02:47
User entered '98' reason for change: Data Entry Error	(b) (4)	
	Brenda Anderson (b) (4)	24 Feb 2021 15:46:41
User entered empty.	(b) (4)	
	Brenda Anderson (b) (4)	24 Feb 2021 15:43:43
	(b) (4)	

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Folder: Covid-19 Assessment 26 Jan 2021

Form: Symptom Log (8)

Generated On: 10 Jun 2021 07:56:44

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:25:37
User entered '%'	System	24 Feb 2021 15:46:41
User entered empty.	System	24 Feb 2021 15:43:43

US3512248

Folder: Covid-19 Assessment 26 Jan 2021

Form: Symptom Log (8)

Generated On: 10 Jun 2021 07:56:44

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:25:37
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 19:46:06
User signature succeeded.	Michael Koren (b) (4)	26 Feb 2021 20:02:47
User entered '96.2' F reason for change: Data Entry Error	(b) (4)	
	Brenda Anderson (b) (4)	24 Feb 2021 15:46:41
User entered empty.	(b) (4)	
	Brenda Anderson (b) (4)	24 Feb 2021 15:43:43
	(b) (4)	

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Folder: Covid-19 Assessment 26 Jan 2021

Form: Symptom Log (8)

Generated On: 10 Jun 2021 07:56:44

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:25:37
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 19:46:06
User signature succeeded.	Michael Koren (b) (4)	26 Feb 2021 20:02:47
User entered 'None (None)'	(b) (4) Brenda Anderson (b) (4)	24 Feb 2021 15:43:43

US3512248

Folder: Covid-19 Assessment 26 Jan 2021

Form: Symptom Log (8)

Generated On: 10 Jun 2021 07:56:44

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:25:37
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 19:46:06
User signature succeeded.	Michael Koren (b) (4)	26 Feb 2021 20:02:47
User entered 'Mild (Mild)'	(b) (4) Brenda Anderson (b) (4)	24 Feb 2021 15:43:43



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Folder: Covid-19 Assessment 26 Jan 2021

Form: Symptom Log (8)

Generated On: 10 Jun 2021 07:56:44

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:25:37
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 19:46:06
User signature succeeded.	Michael Koren (b) (4)	26 Feb 2021 20:02:47
User entered 'None (None)'	(b) (4) Brenda Anderson (b) (4)	24 Feb 2021 15:43:43

US3512248

Folder: Covid-19 Assessment 26 Jan 2021

Form: Symptom Log (8)

Generated On: 10 Jun 2021 07:56:44

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:25:37
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 19:46:06
User signature succeeded.	Michael Koren (b) (4)	26 Feb 2021 20:02:47
User entered 'None (None)'	(b) (4) Brenda Anderson (b) (4) (b) (4)	24 Feb 2021 15:43:43

US3512248

Folder: Covid-19 Assessment 26 Jan 2021

Form: Symptom Log (8)

Generated On: 10 Jun 2021 07:56:44

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:25:37
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 19:46:06
User signature succeeded.	Michael Koren (b) (4)	26 Feb 2021 20:02:47
User entered 'None (None)'	(b) (4) Brenda Anderson (b) (4)	24 Feb 2021 15:43:43

US3512248

Folder: Covid-19 Assessment 26 Jan 2021

Form: Symptom Log (8)

Generated On: 10 Jun 2021 07:56:44

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:25:37
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 19:46:06
User signature succeeded.	Michael Koren (b) (4)	26 Feb 2021 20:02:47
User entered 'None (None)'	(b) (4) Brenda Anderson (b) (4)	24 Feb 2021 15:43:43

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Folder: Covid-19 Assessment 26 Jan 2021

Form: Symptom Log (8)

Generated On: 10 Jun 2021 07:56:44

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:25:37
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 19:46:06
User signature succeeded.	Michael Koren (b) (4)	26 Feb 2021 20:02:47
User entered 'None (None)'	(b) (4) Brenda Anderson (b) (4)	24 Feb 2021 15:43:43

US3512248

Folder: Covid-19 Assessment 26 Jan 2021

Form: Symptom Log (8)

Generated On: 10 Jun 2021 07:56:44

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:25:37
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 19:46:06
User signature succeeded.	Michael Koren (b) (4)	26 Feb 2021 20:02:47
User entered 'None (None)'	(b) (4) Brenda Anderson (b) (4)	24 Feb 2021 15:43:43

US3512248

Folder: Covid-19 Assessment 26 Jan 2021

Form: Symptom Log (8)

Generated On: 10 Jun 2021 07:56:44

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:25:37
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 19:46:06
User signature succeeded.	Michael Koren (b) (4)	26 Feb 2021 20:02:47
User entered 'None (None)'	(b) (4) Brenda Anderson (b) (4)	24 Feb 2021 15:43:43

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Folder: Covid-19 Assessment 26 Jan 2021

Form: Symptom Log (8)

Generated On: 10 Jun 2021 07:56:44

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:25:37
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 19:46:06
User signature succeeded.	Michael Koren (b) (4)	26 Feb 2021 20:02:47
User entered 'None (None)'	(b) (4) Brenda Anderson (b) (4) (b) (4)	24 Feb 2021 15:43:43



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Folder: Covid-19 Assessment 26 Jan 2021

Form: Symptom Log (8)

Generated On: 10 Jun 2021 07:56:44

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:25:37
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 19:46:06
User signature succeeded.	Michael Koren (b) (4)	26 Feb 2021 20:02:47
User entered 'None (None)'	(b) (4) Brenda Anderson (b) (4)	24 Feb 2021 15:43:43

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Folder: Covid-19 Assessment 26 Jan 2021

Form: Symptom Log (8)

Generated On: 10 Jun 2021 07:56:44

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:25:37
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 19:46:06
User signature succeeded.	Michael Koren (b) (4)	26 Feb 2021 20:02:47
User entered 'None (None)'	(b) (4) Brenda Anderson (b) (4)	24 Feb 2021 15:43:43

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Folder: Covid-19 Assessment 26 Jan 2021

Form: Symptom Log (8)

Generated On: 10 Jun 2021 07:56:44

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:25:37
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 19:46:06
User signature succeeded.	Michael Koren (b) (4)	26 Feb 2021 20:02:47
User entered 'None (None)'	(b) (4) Brenda Anderson (b) (4)	24 Feb 2021 15:43:43

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Folder: Covid-19 Assessment 26 Jan 2021

Form: Symptom Log (8)

Generated On: 10 Jun 2021 07:56:44

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:25:37
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 19:46:06
User signature succeeded.	Michael Koren (b) (4)	26 Feb 2021 20:02:47
User entered 'None (None)'	(b) (4) Brenda Anderson (b) (4)	24 Feb 2021 15:43:43

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Folder: Covid-19 Assessment 26 Jan 2021

Form: Symptom Log (8)

Generated On: 10 Jun 2021 07:56:44

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:25:37
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 19:46:06
User signature succeeded.	Michael Koren (b) (4)	26 Feb 2021 20:02:47
User entered 'None (None)'	(b) (4) Brenda Anderson (b) (4)	24 Feb 2021 15:43:43

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Folder: Covid-19 Assessment 26 Jan 2021

Form: Symptom Log (8)

Generated On: 10 Jun 2021 07:56:44

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:25:37
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 19:46:06
User signature succeeded.	Michael Koren (b) (4)	26 Feb 2021 20:02:47
User entered 'None (None)'	(b) (4) Brenda Anderson (b) (4)	24 Feb 2021 15:43:43

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Folder: Covid-19 Assessment 26 Jan 2021

Form: Symptom Log (9)

Generated On: 10 Jun 2021 07:56:44

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:25:37
User signature succeeded.	Michael Koren (b) (4)	26 Feb 2021 20:02:47
User entered 'Day 9 (Day 9)'	Brenda Anderson (b) (4)	24 Feb 2021 15:43:43

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Folder: Covid-19 Assessment 26 Jan 2021

Form: Symptom Log (9)

Generated On: 10 Jun 2021 07:56:44

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:25:37
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 19:46:06
User signature succeeded.	Michael Koren (b) (4)	26 Feb 2021 20:02:47
User entered '31 Jan 2021'	(b) (4) Brenda Anderson (b) (4)	24 Feb 2021 15:43:43



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Folder: Covid-19 Assessment 26 Jan 2021

Form: Symptom Log (9)

Generated On: 10 Jun 2021 07:56:44

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:25:37
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 19:46:06
User signature succeeded.	Michael Koren (b) (4)	26 Feb 2021 20:02:47
User entered '0'	(b) (4) Brenda Anderson (b) (4) (b) (4)	24 Feb 2021 15:43:43

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Folder: Covid-19 Assessment 26 Jan 2021

Form: Symptom Log (9)

Generated On: 10 Jun 2021 07:56:44

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:25:37
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 19:46:06
User signature succeeded.	Michael Koren (b) (4)	26 Feb 2021 20:02:47
User entered '97' reason for change: Data Entry Error	(b) (4)	
	Brenda Anderson (b) (4)	24 Feb 2021 15:46:41
User entered empty.	(b) (4)	
	Brenda Anderson (b) (4)	24 Feb 2021 15:43:43
	(b) (4)	

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Folder: Covid-19 Assessment 26 Jan 2021

Form: Symptom Log (9)

Generated On: 10 Jun 2021 07:56:44

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:25:37
User entered '%'	System	24 Feb 2021 15:46:41
User entered empty.	System	24 Feb 2021 15:43:43

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Folder: Covid-19 Assessment 26 Jan 2021

Form: Symptom Log (9)

Generated On: 10 Jun 2021 07:56:44

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:25:37
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 19:46:06
User signature succeeded.	Michael Koren (b) (4)	26 Feb 2021 20:02:47
User entered '97.0' F reason for change: Data Entry Error	(b) (4)	
	Brenda Anderson (b) (4)	24 Feb 2021 15:46:41
User entered empty.	(b) (4)	
	Brenda Anderson (b) (4)	24 Feb 2021 15:43:43
	(b) (4)	

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Folder: Covid-19 Assessment 26 Jan 2021

Form: Symptom Log (9)

Generated On: 10 Jun 2021 07:56:44

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:25:37
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 19:46:06
User signature succeeded.	Michael Koren (b) (4)	26 Feb 2021 20:02:47
User entered 'None (None)'	(b) (4) Brenda Anderson (b) (4)	24 Feb 2021 15:43:43

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Folder: Covid-19 Assessment 26 Jan 2021

Form: Symptom Log (9)

Generated On: 10 Jun 2021 07:56:44

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:25:37
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 19:46:06
User signature succeeded.	Michael Koren (b) (4)	26 Feb 2021 20:02:47
User entered 'Mild (Mild)'	(b) (4) Brenda Anderson (b) (4)	24 Feb 2021 15:43:43

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Folder: Covid-19 Assessment 26 Jan 2021

Form: Symptom Log (9)

Generated On: 10 Jun 2021 07:56:44

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:25:37
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 19:46:06
User signature succeeded.	Michael Koren (b) (4)	26 Feb 2021 20:02:47
User entered 'None (None)'	(b) (4) Brenda Anderson (b) (4)	24 Feb 2021 15:43:43

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Folder: Covid-19 Assessment 26 Jan 2021

Form: Symptom Log (9)

Generated On: 10 Jun 2021 07:56:44

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:25:37
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 19:46:06
User signature succeeded.	Michael Koren (b) (4)	26 Feb 2021 20:02:47
User entered 'None (None)'	(b) (4) Brenda Anderson (b) (4)	24 Feb 2021 15:43:43



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Folder: Covid-19 Assessment 26 Jan 2021

Form: Symptom Log (9)

Generated On: 10 Jun 2021 07:56:44

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:25:37
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 19:46:06
User signature succeeded.	Michael Koren (b) (4)	26 Feb 2021 20:02:47
User entered 'None (None)'	(b) (4) Brenda Anderson (b) (4)	24 Feb 2021 15:43:43

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Folder: Covid-19 Assessment 26 Jan 2021

Form: Symptom Log (9)

Generated On: 10 Jun 2021 07:56:44

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:25:37
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 19:46:06
User signature succeeded.	Michael Koren (b) (4)	26 Feb 2021 20:02:47
User entered 'None (None)'	(b) (4) Brenda Anderson (b) (4)	24 Feb 2021 15:43:43

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Folder: Covid-19 Assessment 26 Jan 2021

Form: Symptom Log (9)

Generated On: 10 Jun 2021 07:56:44

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:25:37
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 19:46:06
User signature succeeded.	Michael Koren (b) (4)	26 Feb 2021 20:02:47
User entered 'None (None)'	(b) (4) Brenda Anderson (b) (4)	24 Feb 2021 15:43:43

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Folder: Covid-19 Assessment 26 Jan 2021

Form: Symptom Log (9)

Generated On: 10 Jun 2021 07:56:44

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:25:37
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 19:46:06
User signature succeeded.	Michael Koren (b) (4)	26 Feb 2021 20:02:47
User entered 'None (None)'	(b) (4) Brenda Anderson (b) (4)	24 Feb 2021 15:43:43

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Folder: Covid-19 Assessment 26 Jan 2021

Form: Symptom Log (9)

Generated On: 10 Jun 2021 07:56:44

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:25:37
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 19:46:06
User signature succeeded.	Michael Koren (b) (4)	26 Feb 2021 20:02:47
User entered 'None (None)'	(b) (4) Brenda Anderson (b) (4) (b) (4)	24 Feb 2021 15:43:43

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Folder: Covid-19 Assessment 26 Jan 2021

Form: Symptom Log (9)

Generated On: 10 Jun 2021 07:56:44

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:25:37
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 19:46:06
User signature succeeded.	Michael Koren (b) (4)	26 Feb 2021 20:02:47
User entered 'None (None)'	(b) (4) Brenda Anderson (b) (4) (b) (4)	24 Feb 2021 15:43:43

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Folder: Covid-19 Assessment 26 Jan 2021

Form: Symptom Log (9)

Generated On: 10 Jun 2021 07:56:44

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:25:37
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 19:46:06
User signature succeeded.	Michael Koren (b) (4)	26 Feb 2021 20:02:47
User entered 'None (None)'	(b) (4) Brenda Anderson (b) (4)	24 Feb 2021 15:43:43

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Folder: Covid-19 Assessment 26 Jan 2021

Form: Symptom Log (9)

Generated On: 10 Jun 2021 07:56:44

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:25:37
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 19:46:06
User signature succeeded.	Michael Koren (b) (4)	26 Feb 2021 20:02:47
User entered 'None (None)'	(b) (4) Brenda Anderson (b) (4)	24 Feb 2021 15:43:43



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Form: Symptom Log (9)

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[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:25:37
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 19:46:06
User signature succeeded.	Michael Koren (b) (4)	26 Feb 2021 20:02:47
User entered 'None (None)'	(b) (4) Brenda Anderson (b) (4)	24 Feb 2021 15:43:43

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Folder: Covid-19 Assessment 26 Jan 2021

Form: Symptom Log (9)

Generated On: 10 Jun 2021 07:56:44

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:25:37
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 19:46:06
User signature succeeded.	Michael Koren (b) (4)	26 Feb 2021 20:02:47
User entered 'None (None)'	(b) (4) Brenda Anderson (b) (4)	24 Feb 2021 15:43:43

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Folder: Covid-19 Assessment 26 Jan 2021

Form: Symptom Log (9)

Generated On: 10 Jun 2021 07:56:44

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:25:37
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 19:46:06
User signature succeeded.	Michael Koren (b) (4)	26 Feb 2021 20:02:47
User entered 'None (None)'	(b) (4) Brenda Anderson (b) (4)	24 Feb 2021 15:43:43

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Folder: Covid-19 Assessment 26 Jan 2021

Form: Symptom Log (9)

Generated On: 10 Jun 2021 07:56:44

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:25:37
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 19:46:06
User signature succeeded.	Michael Koren (b) (4)	26 Feb 2021 20:02:47
User entered 'None (None)'	(b) (4) Brenda Anderson (b) (4)	24 Feb 2021 15:43:43

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Folder: Covid-19 Assessment 26 Jan 2021

Form: Symptom Log (10)

Generated On: 10 Jun 2021 07:56:44

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:25:37
User signature succeeded.	Michael Koren (b) (4)	26 Feb 2021 20:02:47
User entered 'Day 10 (Day 10)'	Brenda Anderson (b) (4)	24 Feb 2021 15:43:43

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Folder: Covid-19 Assessment 26 Jan 2021

Form: Symptom Log (10)

Generated On: 10 Jun 2021 07:56:44

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:25:37
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 19:46:06
User signature succeeded.	Michael Koren (b) (4)	26 Feb 2021 20:02:47
User entered '1 Feb 2021'	(b) (4) Brenda Anderson (b) (4)	24 Feb 2021 15:43:43

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Folder: Covid-19 Assessment 26 Jan 2021

Form: Symptom Log (10)

Generated On: 10 Jun 2021 07:56:44

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:25:37
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 19:46:06
User signature succeeded.	Michael Koren (b) (4)	26 Feb 2021 20:02:47
User entered '0'	(b) (4) Brenda Anderson (b) (4)	24 Feb 2021 15:43:43

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Folder: Covid-19 Assessment 26 Jan 2021

Form: Symptom Log (10)

Generated On: 10 Jun 2021 07:56:44

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:25:37
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 19:46:06
User signature succeeded.	Michael Koren (b) (4)	26 Feb 2021 20:02:47
User entered '97' reason for change: Data Entry Error	(b) (4)	
	Brenda Anderson (b) (4)	24 Feb 2021 15:46:41
User entered empty.	(b) (4)	
	Brenda Anderson (b) (4)	24 Feb 2021 15:43:43
	(b) (4)	



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Form: Symptom Log (10)

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[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:25:37
User entered '%'	System	24 Feb 2021 15:46:41
User entered empty.	System	24 Feb 2021 15:43:43

US3512248

Folder: Covid-19 Assessment 26 Jan 2021

Form: Symptom Log (10)

Generated On: 10 Jun 2021 07:56:44

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:25:37
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 19:46:06
User signature succeeded.	Michael Koren (b) (4)	26 Feb 2021 20:02:47
User entered '98.1' F reason for change: Data Entry Error	(b) (4)	
	Brenda Anderson (b) (4)	24 Feb 2021 15:46:41
User entered empty.	(b) (4)	
	Brenda Anderson (b) (4)	24 Feb 2021 15:43:43
	(b) (4)	

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Folder: Covid-19 Assessment 26 Jan 2021

Form: Symptom Log (10)

Generated On: 10 Jun 2021 07:56:44

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:25:37
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 19:46:06
User signature succeeded.	Michael Koren (b) (4)	26 Feb 2021 20:02:47
User entered 'None (None)'	(b) (4) Brenda Anderson (b) (4)	24 Feb 2021 15:43:43

US3512248

Folder: Covid-19 Assessment 26 Jan 2021

Form: Symptom Log (10)

Generated On: 10 Jun 2021 07:56:44

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:25:37
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 19:46:06
User signature succeeded.	Michael Koren (b) (4)	26 Feb 2021 20:02:47
User entered 'Mild (Mild)'	(b) (4) Brenda Anderson (b) (4)	24 Feb 2021 15:43:43

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Folder: Covid-19 Assessment 26 Jan 2021

Form: Symptom Log (10)

Generated On: 10 Jun 2021 07:56:44

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:25:37
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 19:46:06
User signature succeeded.	Michael Koren (b) (4)	26 Feb 2021 20:02:47
User entered 'None (None)'	(b) (4) Brenda Anderson (b) (4)	24 Feb 2021 15:43:43

US3512248

Folder: Covid-19 Assessment 26 Jan 2021

Form: Symptom Log (10)

Generated On: 10 Jun 2021 07:56:44

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:25:37
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 19:46:06
User signature succeeded.	Michael Koren (b) (4)	26 Feb 2021 20:02:47
User entered 'None (None)'	(b) (4) Brenda Anderson (b) (4)	24 Feb 2021 15:43:43

US3512248

Folder: Covid-19 Assessment 26 Jan 2021

Form: Symptom Log (10)

Generated On: 10 Jun 2021 07:56:44

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:25:37
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 19:46:06
User signature succeeded.	Michael Koren (b) (4)	26 Feb 2021 20:02:47
User entered 'None (None)'	(b) (4) Brenda Anderson (b) (4)	24 Feb 2021 15:43:43

US3512248

Folder: Covid-19 Assessment 26 Jan 2021

Form: Symptom Log (10)

Generated On: 10 Jun 2021 07:56:44

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:25:37
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 19:46:06
User signature succeeded.	Michael Koren (b) (4)	26 Feb 2021 20:02:47
User entered 'None (None)'	(b) (4) Brenda Anderson (b) (4)	24 Feb 2021 15:43:43



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Folder: Covid-19 Assessment 26 Jan 2021

Form: Symptom Log (10)

Generated On: 10 Jun 2021 07:56:44

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:25:37
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 19:46:06
User signature succeeded.	Michael Koren (b) (4)	26 Feb 2021 20:02:47
User entered 'None (None)'	(b) (4) Brenda Anderson (b) (4)	24 Feb 2021 15:43:43

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Folder: Covid-19 Assessment 26 Jan 2021

Form: Symptom Log (10)

Generated On: 10 Jun 2021 07:56:44

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:25:37
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 19:46:06
User signature succeeded.	Michael Koren (b) (4)	26 Feb 2021 20:02:47
User entered 'None (None)'	(b) (4) Brenda Anderson (b) (4)	24 Feb 2021 15:43:43

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Folder: Covid-19 Assessment 26 Jan 2021

Form: Symptom Log (10)

Generated On: 10 Jun 2021 07:56:44

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:25:37
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 19:46:06
User signature succeeded.	Michael Koren (b) (4)	26 Feb 2021 20:02:47
User entered 'None (None)'	(b) (4) Brenda Anderson (b) (4) (b) (4)	24 Feb 2021 15:43:43

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Folder: Covid-19 Assessment 26 Jan 2021

Form: Symptom Log (10)

Generated On: 10 Jun 2021 07:56:44

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:25:37
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 19:46:06
User signature succeeded.	Michael Koren (b) (4)	26 Feb 2021 20:02:47
User entered 'None (None)'	(b) (4) Brenda Anderson (b) (4)	24 Feb 2021 15:43:43

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Folder: Covid-19 Assessment 26 Jan 2021

Form: Symptom Log (10)

Generated On: 10 Jun 2021 07:56:44

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:25:37
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 19:46:06
User signature succeeded.	Michael Koren (b) (4)	26 Feb 2021 20:02:47
User entered 'None (None)'	(b) (4) Brenda Anderson (b) (4)	24 Feb 2021 15:43:43

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Folder: Covid-19 Assessment 26 Jan 2021

Form: Symptom Log (10)

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[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:25:37
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 19:46:06
User signature succeeded.	Michael Koren (b) (4)	26 Feb 2021 20:02:47
User entered 'None (None)'	(b) (4) Brenda Anderson (b) (4)	24 Feb 2021 15:43:43

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Folder: Covid-19 Assessment 26 Jan 2021

Form: Symptom Log (10)

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[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:25:37
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 19:46:06
User signature succeeded.	Michael Koren (b) (4)	26 Feb 2021 20:02:47
User entered 'None (None)'	(b) (4) Brenda Anderson (b) (4)	24 Feb 2021 15:43:43

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Folder: Covid-19 Assessment 26 Jan 2021

Form: Symptom Log (10)

Generated On: 10 Jun 2021 07:56:44

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:25:37
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 19:46:06
User signature succeeded.	Michael Koren (b) (4)	26 Feb 2021 20:02:47
User entered 'None (None)'	(b) (4) Brenda Anderson (b) (4)	24 Feb 2021 15:43:43



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Folder: Covid-19 Assessment 26 Jan 2021

Form: Symptom Log (10)

Generated On: 10 Jun 2021 07:56:44

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:25:37
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 19:46:06
User signature succeeded.	Michael Koren (b) (4)	26 Feb 2021 20:02:47
User entered 'None (None)'	(b) (4) Brenda Anderson (b) (4)	24 Feb 2021 15:43:43

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Folder: Covid-19 Assessment 26 Jan 2021

Form: Symptom Log (10)

Generated On: 10 Jun 2021 07:56:44

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:25:37
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 19:46:06
User signature succeeded.	Michael Koren (b) (4)	26 Feb 2021 20:02:47
User entered 'None (None)'	(b) (4) Brenda Anderson (b) (4)	24 Feb 2021 15:43:43

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Folder: Covid-19 Assessment 26 Jan 2021

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[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:25:37
User signature succeeded.	Michael Koren (b) (4)	26 Feb 2021 20:02:47
User entered 'Day 11 (Day 11)'	Brenda Anderson (b) (4)	24 Feb 2021 15:43:43

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Folder: Covid-19 Assessment 26 Jan 2021

Form: Symptom Log (11)

Generated On: 10 Jun 2021 07:56:44

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:25:37
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 19:46:06
User signature succeeded.	Michael Koren (b) (4)	26 Feb 2021 20:02:47
User entered '2 Feb 2021'	(b) (4) Brenda Anderson (b) (4)	24 Feb 2021 15:43:43

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Folder: Covid-19 Assessment 26 Jan 2021

Form: Symptom Log (11)

Generated On: 10 Jun 2021 07:56:44

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:25:37
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 19:46:06
User signature succeeded.	Michael Koren (b) (4)	26 Feb 2021 20:02:47
User entered '0'	(b) (4) Brenda Anderson (b) (4)	24 Feb 2021 15:43:43

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Folder: Covid-19 Assessment 26 Jan 2021

Form: Symptom Log (11)

Generated On: 10 Jun 2021 07:56:44

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:25:37
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 19:46:06
User signature succeeded.	Michael Koren (b) (4)	26 Feb 2021 20:02:47
User entered '97' reason for change: Data Entry Error	(b) (4)	
	Brenda Anderson (b) (4)	24 Feb 2021 15:46:41
User entered empty.	(b) (4)	
	Brenda Anderson (b) (4)	24 Feb 2021 15:43:43
	(b) (4)	

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Folder: Covid-19 Assessment 26 Jan 2021

Form: Symptom Log (11)

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[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:25:37
User entered '%'	System	24 Feb 2021 15:46:41
User entered empty.	System	24 Feb 2021 15:43:43

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Folder: Covid-19 Assessment 26 Jan 2021

Form: Symptom Log (11)

Generated On: 10 Jun 2021 07:56:44

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:25:37
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 19:46:06
User signature succeeded.	Michael Koren (b) (4)	26 Feb 2021 20:02:47
User entered '98.2' F reason for change: Data Entry Error	(b) (4)	
	Brenda Anderson (b) (4)	24 Feb 2021 15:46:41
User entered empty.	(b) (4)	
	Brenda Anderson (b) (4)	24 Feb 2021 15:43:43
	(b) (4)	



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Folder: Covid-19 Assessment 26 Jan 2021

Form: Symptom Log (11)

Generated On: 10 Jun 2021 07:56:44

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:25:37
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 19:46:06
User signature succeeded.	Michael Koren (b) (4)	26 Feb 2021 20:02:47
User entered 'None (None)'	(b) (4) Brenda Anderson (b) (4)	24 Feb 2021 15:43:43

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Folder: Covid-19 Assessment 26 Jan 2021

Form: Symptom Log (11)

Generated On: 10 Jun 2021 07:56:44

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:25:37
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 19:46:06
User signature succeeded.	Michael Koren (b) (4)	26 Feb 2021 20:02:47
User entered 'Mild (Mild)'	(b) (4) Brenda Anderson (b) (4) (b) (4)	24 Feb 2021 15:43:43

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Folder: Covid-19 Assessment 26 Jan 2021

Form: Symptom Log (11)

Generated On: 10 Jun 2021 07:56:44

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:25:37
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 19:46:06
User signature succeeded.	Michael Koren (b) (4)	26 Feb 2021 20:02:47
User entered 'None (None)'	(b) (4) Brenda Anderson (b) (4)	24 Feb 2021 15:43:43

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Folder: Covid-19 Assessment 26 Jan 2021

Form: Symptom Log (11)

Generated On: 10 Jun 2021 07:56:44

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:25:37
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 19:46:06
User signature succeeded.	Michael Koren (b) (4)	26 Feb 2021 20:02:47
User entered 'None (None)'	(b) (4) Brenda Anderson (b) (4) (b) (4)	24 Feb 2021 15:43:43

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Folder: Covid-19 Assessment 26 Jan 2021

Form: Symptom Log (11)

Generated On: 10 Jun 2021 07:56:44

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:25:37
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 19:46:06
User signature succeeded.	Michael Koren (b) (4)	26 Feb 2021 20:02:47
User entered 'None (None)'	(b) (4) Brenda Anderson (b) (4)	24 Feb 2021 15:43:43

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Folder: Covid-19 Assessment 26 Jan 2021

Form: Symptom Log (11)

Generated On: 10 Jun 2021 07:56:44

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:25:37
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 19:46:06
User signature succeeded.	Michael Koren (b) (4)	26 Feb 2021 20:02:47
User entered 'None (None)'	(b) (4) Brenda Anderson (b) (4)	24 Feb 2021 15:43:43

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Folder: Covid-19 Assessment 26 Jan 2021

Form: Symptom Log (11)

Generated On: 10 Jun 2021 07:56:44

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:25:37
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 19:46:06
User signature succeeded.	Michael Koren (b) (4)	26 Feb 2021 20:02:47
User entered 'None (None)'	(b) (4) Brenda Anderson (b) (4)	24 Feb 2021 15:43:43

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Folder: Covid-19 Assessment 26 Jan 2021

Form: Symptom Log (11)

Generated On: 10 Jun 2021 07:56:44

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:25:37
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 19:46:06
User signature succeeded.	Michael Koren (b) (4)	26 Feb 2021 20:02:47
User entered 'Not Done (Not Done)'	(b) (4) Brenda Anderson (b) (4) (b) (4)	24 Feb 2021 15:43:43



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Folder: Covid-19 Assessment 26 Jan 2021

Form: Symptom Log (11)

Generated On: 10 Jun 2021 07:56:44

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:25:37
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 19:46:06
User signature succeeded.	Michael Koren (b) (4)	26 Feb 2021 20:02:47
User entered 'None (None)'	(b) (4) Brenda Anderson (b) (4) (b) (4)	24 Feb 2021 15:43:43

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Folder: Covid-19 Assessment 26 Jan 2021

Form: Symptom Log (11)

Generated On: 10 Jun 2021 07:56:44

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:25:37
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 19:46:06
User signature succeeded.	Michael Koren (b) (4)	26 Feb 2021 20:02:47
User entered 'None (None)'	(b) (4) Brenda Anderson (b) (4)	24 Feb 2021 15:43:43

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**Folder: Covid-19 Assessment 26 Jan 2021**

**Form: Symptom Log (11)**

**Generated On: 10 Jun 2021 07:56:44**

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:25:37
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 19:46:06
User signature succeeded.	Michael Koren (b) (4)	26 Feb 2021 20:02:47
User entered 'None (None)'	(b) (4) Brenda Anderson (b) (4)	24 Feb 2021 15:43:43

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Folder: Covid-19 Assessment 26 Jan 2021

Form: Symptom Log (11)

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[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:25:37
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 19:46:06
User signature succeeded.	Michael Koren (b) (4)	26 Feb 2021 20:02:47
User entered 'None (None)'	(b) (4) Brenda Anderson (b) (4)	24 Feb 2021 15:43:43

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[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:25:37
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 19:46:06
User signature succeeded.	Michael Koren (b) (4)	26 Feb 2021 20:02:47
User entered 'None (None)'	(b) (4) Brenda Anderson (b) (4)	24 Feb 2021 15:43:43

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Folder: Covid-19 Assessment 26 Jan 2021

Form: Symptom Log (11)

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[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:25:37
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 19:46:06
User signature succeeded.	Michael Koren (b) (4)	26 Feb 2021 20:02:47
User entered 'None (None)'	(b) (4) Brenda Anderson (b) (4)	24 Feb 2021 15:43:43

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Folder: Covid-19 Assessment 26 Jan 2021

Form: Symptom Log (11)

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[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:25:37
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 19:46:06
User signature succeeded.	Michael Koren (b) (4)	26 Feb 2021 20:02:47
User entered 'None (None)'	(b) (4) Brenda Anderson (b) (4)	24 Feb 2021 15:43:43

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Folder: Covid-19 Assessment 26 Jan 2021

Form: Symptom Log (11)

Generated On: 10 Jun 2021 07:56:44

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:25:37
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 19:46:06
User signature succeeded.	Michael Koren (b) (4)	26 Feb 2021 20:02:47
User entered 'None (None)'	(b) (4) Brenda Anderson (b) (4) (b) (4)	24 Feb 2021 15:43:43



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Folder: Covid-19 Assessment 26 Jan 2021

Form: Symptom Log (12)

Generated On: 10 Jun 2021 07:56:44

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:25:37
User signature succeeded.	Michael Koren (b) (4)	26 Feb 2021 20:02:47
User entered 'Day 12 (Day 12)'	Brenda Anderson (b) (4)	24 Feb 2021 15:43:43

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Folder: Covid-19 Assessment 26 Jan 2021

Form: Symptom Log (12)

Generated On: 10 Jun 2021 07:56:44

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:25:37
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 19:46:06
User signature succeeded.	Michael Koren (b) (4)	26 Feb 2021 20:02:47
User entered '3 Feb 2021'	(b) (4) Brenda Anderson (b) (4)	24 Feb 2021 15:43:43

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Folder: Covid-19 Assessment 26 Jan 2021

Form: Symptom Log (12)

Generated On: 10 Jun 2021 07:56:44

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:25:37
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 19:46:06
User signature succeeded.	Michael Koren (b) (4)	26 Feb 2021 20:02:47
User entered '0'	(b) (4) Brenda Anderson (b) (4)	24 Feb 2021 15:43:43

US3512248

Folder: Covid-19 Assessment 26 Jan 2021

Form: Symptom Log (12)

Generated On: 10 Jun 2021 07:56:44

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:25:37
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 19:46:06
User signature succeeded.	Michael Koren (b) (4)	26 Feb 2021 20:02:47
User entered '94' reason for change: Data Entry Error	(b) (4)	
	Brenda Anderson (b) (4)	24 Feb 2021 15:46:41
User entered empty.	(b) (4)	
	Brenda Anderson (b) (4)	24 Feb 2021 15:43:43
	(b) (4)	

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Folder: Covid-19 Assessment 26 Jan 2021

Form: Symptom Log (12)

Generated On: 10 Jun 2021 07:56:44

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:25:37
User entered '%'	System	24 Feb 2021 15:46:41
User entered empty.	System	24 Feb 2021 15:43:43

US3512248

Folder: Covid-19 Assessment 26 Jan 2021

Form: Symptom Log (12)

Generated On: 10 Jun 2021 07:56:44

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:25:37
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 19:46:06
User signature succeeded.	Michael Koren (b) (4)	26 Feb 2021 20:02:47
User entered '97.3' F reason for change: Data Entry Error	(b) (4)	
	Brenda Anderson (b) (4)	24 Feb 2021 15:46:41
User entered empty.	(b) (4)	
	Brenda Anderson (b) (4)	24 Feb 2021 15:43:43
	(b) (4)	

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Folder: Covid-19 Assessment 26 Jan 2021

Form: Symptom Log (12)

Generated On: 10 Jun 2021 07:56:44

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:25:37
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 19:46:06
User signature succeeded.	Michael Koren (b) (4)	26 Feb 2021 20:02:47
User entered 'None (None)'	(b) (4) Brenda Anderson (b) (4)	24 Feb 2021 15:43:43

US3512248

Folder: Covid-19 Assessment 26 Jan 2021

Form: Symptom Log (12)

Generated On: 10 Jun 2021 07:56:44

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:25:37
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 19:46:06
User signature succeeded.	Michael Koren (b) (4)	26 Feb 2021 20:02:47
User entered 'Mild (Mild)'	(b) (4) Brenda Anderson (b) (4)	24 Feb 2021 15:43:43



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Folder: Covid-19 Assessment 26 Jan 2021

Form: Symptom Log (12)

Generated On: 10 Jun 2021 07:56:44

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:25:37
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 19:46:06
User signature succeeded.	Michael Koren (b) (4)	26 Feb 2021 20:02:47
User entered 'None (None)'	(b) (4) Brenda Anderson (b) (4)	24 Feb 2021 15:43:43

US3512248

Folder: Covid-19 Assessment 26 Jan 2021

Form: Symptom Log (12)

Generated On: 10 Jun 2021 07:56:44

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:25:37
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 19:46:06
User signature succeeded.	Michael Koren (b) (4)	26 Feb 2021 20:02:47
User entered 'None (None)'	(b) (4) Brenda Anderson (b) (4) (b) (4)	24 Feb 2021 15:43:43

US3512248

Folder: Covid-19 Assessment 26 Jan 2021

Form: Symptom Log (12)

Generated On: 10 Jun 2021 07:56:44

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:25:37
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 19:46:06
User signature succeeded.	Michael Koren (b) (4)	26 Feb 2021 20:02:47
User entered 'None (None)'	(b) (4) Brenda Anderson (b) (4)	24 Feb 2021 15:43:43

US3512248

Folder: Covid-19 Assessment 26 Jan 2021

Form: Symptom Log (12)

Generated On: 10 Jun 2021 07:56:44

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:25:37
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 19:46:06
User signature succeeded.	Michael Koren (b) (4)	26 Feb 2021 20:02:47
User entered 'None (None)'	(b) (4) Brenda Anderson (b) (4)	24 Feb 2021 15:43:43

US3512248

Folder: Covid-19 Assessment 26 Jan 2021

Form: Symptom Log (12)

Generated On: 10 Jun 2021 07:56:44

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:25:37
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 19:46:06
User signature succeeded.	Michael Koren (b) (4)	26 Feb 2021 20:02:47
User entered 'None (None)'	(b) (4) Brenda Anderson (b) (4)	24 Feb 2021 15:43:43

US3512248

Folder: Covid-19 Assessment 26 Jan 2021

Form: Symptom Log (12)

Generated On: 10 Jun 2021 07:56:44

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:25:37
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 19:46:06
User signature succeeded.	Michael Koren (b) (4)	26 Feb 2021 20:02:47
User entered 'None (None)'	(b) (4) Brenda Anderson (b) (4)	24 Feb 2021 15:43:43

US3512248

Folder: Covid-19 Assessment 26 Jan 2021

Form: Symptom Log (12)

Generated On: 10 Jun 2021 07:56:44

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:25:37
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 19:46:06
User signature succeeded.	Michael Koren (b) (4)	26 Feb 2021 20:02:47
User entered 'None (None)'	(b) (4) Brenda Anderson (b) (4)	24 Feb 2021 15:43:43

US3512248

Folder: Covid-19 Assessment 26 Jan 2021

Form: Symptom Log (12)

Generated On: 10 Jun 2021 07:56:44

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:25:37
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 19:46:06
User signature succeeded.	Michael Koren (b) (4)	26 Feb 2021 20:02:47
User entered 'None (None)'	(b) (4) Brenda Anderson (b) (4)	24 Feb 2021 15:43:43



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Folder: Covid-19 Assessment 26 Jan 2021

Form: Symptom Log (12)

Generated On: 10 Jun 2021 07:56:44

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:25:37
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 19:46:06
User signature succeeded.	Michael Koren (b) (4)	26 Feb 2021 20:02:47
User entered 'None (None)'	(b) (4) Brenda Anderson (b) (4)	24 Feb 2021 15:43:43

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Folder: Covid-19 Assessment 26 Jan 2021

Form: Symptom Log (12)

Generated On: 10 Jun 2021 07:56:44

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:25:37
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 19:46:06
User signature succeeded.	Michael Koren (b) (4)	26 Feb 2021 20:02:47
User entered 'None (None)'	(b) (4) Brenda Anderson (b) (4)	24 Feb 2021 15:43:43

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Folder: Covid-19 Assessment 26 Jan 2021

Form: Symptom Log (12)

Generated On: 10 Jun 2021 07:56:44

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:25:37
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 19:46:06
User signature succeeded.	Michael Koren (b) (4)	26 Feb 2021 20:02:47
User entered 'None (None)'	(b) (4) Brenda Anderson (b) (4)	24 Feb 2021 15:43:43

US3512248

Folder: Covid-19 Assessment 26 Jan 2021

Form: Symptom Log (12)

Generated On: 10 Jun 2021 07:56:44

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:25:37
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 19:46:06
User signature succeeded.	Michael Koren (b) (4)	26 Feb 2021 20:02:47
User entered 'None (None)'	(b) (4) Brenda Anderson (b) (4)	24 Feb 2021 15:43:43

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Folder: Covid-19 Assessment 26 Jan 2021

Form: Symptom Log (12)

Generated On: 10 Jun 2021 07:56:44

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:25:37
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 19:46:06
User signature succeeded.	Michael Koren (b) (4)	26 Feb 2021 20:02:47
User entered 'None (None)'	(b) (4) Brenda Anderson (b) (4)	24 Feb 2021 15:43:43

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Folder: Covid-19 Assessment 26 Jan 2021

Form: Symptom Log (12)

Generated On: 10 Jun 2021 07:56:44

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:25:37
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 19:46:06
User signature succeeded.	Michael Koren (b) (4)	26 Feb 2021 20:02:47
User entered 'None (None)'	(b) (4) Brenda Anderson (b) (4)	24 Feb 2021 15:43:43

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Folder: Covid-19 Assessment 26 Jan 2021

Form: Symptom Log (13)

Generated On: 10 Jun 2021 07:56:44

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:25:37
User signature succeeded.	Michael Koren (b) (4)	26 Feb 2021 20:02:47
User entered 'Day 13 (Day 13)'	Brenda Anderson (b) (4)	24 Feb 2021 15:43:43

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Folder: Covid-19 Assessment 26 Jan 2021

Form: Symptom Log (13)

Generated On: 10 Jun 2021 07:56:44

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:25:37
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 19:46:06
User signature succeeded.	Michael Koren (b) (4)	26 Feb 2021 20:02:47
User entered '4 Feb 2021'	(b) (4) Brenda Anderson (b) (4)	24 Feb 2021 15:43:43



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Folder: Covid-19 Assessment 26 Jan 2021

Form: Symptom Log (13)

Generated On: 10 Jun 2021 07:56:44

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:25:37
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 19:46:06
User signature succeeded.	Michael Koren (b) (4)	26 Feb 2021 20:02:47
User entered '0'	(b) (4) Brenda Anderson (b) (4)	24 Feb 2021 15:43:43

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Folder: Covid-19 Assessment 26 Jan 2021

Form: Symptom Log (13)

Generated On: 10 Jun 2021 07:56:44

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:25:37
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 19:46:06
User signature succeeded.	Michael Koren (b) (4)	26 Feb 2021 20:02:47
User entered '97' reason for change: Data Entry Error	(b) (4)	
	Brenda Anderson (b) (4)	24 Feb 2021 15:46:47
User entered '97.' (non-conformant).	(b) (4)	
	Brenda Anderson (b) (4)	24 Feb 2021 15:46:41
User entered empty.	(b) (4)	
	Brenda Anderson (b) (4)	24 Feb 2021 15:43:43
	(b) (4)	

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Folder: Covid-19 Assessment 26 Jan 2021

Form: Symptom Log (13)

Generated On: 10 Jun 2021 07:56:44

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:25:37
User entered '%'	System	24 Feb 2021 15:46:47
User entered empty.	System	24 Feb 2021 15:43:43

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Folder: Covid-19 Assessment 26 Jan 2021

Form: Symptom Log (13)

Generated On: 10 Jun 2021 07:56:44

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:25:37
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 19:46:06
User signature succeeded.	Michael Koren (b) (4)	26 Feb 2021 20:02:47
User entered '95.7' F reason for change: Data Entry Error	(b) (4)	
	Brenda Anderson (b) (4)	24 Feb 2021 15:46:41
User entered empty.	(b) (4)	
	Brenda Anderson (b) (4)	24 Feb 2021 15:43:43
	(b) (4)	

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Folder: Covid-19 Assessment 26 Jan 2021

Form: Symptom Log (13)

Generated On: 10 Jun 2021 07:56:44

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:25:37
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 19:46:06
User signature succeeded.	Michael Koren (b) (4)	26 Feb 2021 20:02:47
User entered 'None (None)'	(b) (4) Brenda Anderson (b) (4)	24 Feb 2021 15:43:43

US3512248

Folder: Covid-19 Assessment 26 Jan 2021

Form: Symptom Log (13)

Generated On: 10 Jun 2021 07:56:44

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:25:37
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 19:46:06
User signature succeeded.	Michael Koren (b) (4)	26 Feb 2021 20:02:47
User entered 'Mild (Mild)'	(b) (4) Brenda Anderson (b) (4)	24 Feb 2021 15:43:43

US3512248

Folder: Covid-19 Assessment 26 Jan 2021

Form: Symptom Log (13)

Generated On: 10 Jun 2021 07:56:44

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:25:37
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 19:46:06
User signature succeeded.	Michael Koren (b) (4)	26 Feb 2021 20:02:47
User entered 'None (None)'	(b) (4) Brenda Anderson (b) (4) (b) (4)	24 Feb 2021 15:43:43

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Folder: Covid-19 Assessment 26 Jan 2021

Form: Symptom Log (13)

Generated On: 10 Jun 2021 07:56:44

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:25:37
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 19:46:06
User signature succeeded.	Michael Koren (b) (4)	26 Feb 2021 20:02:47
User entered 'None (None)'	(b) (4) Brenda Anderson (b) (4)	24 Feb 2021 15:43:43



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Folder: Covid-19 Assessment 26 Jan 2021

Form: Symptom Log (13)

Generated On: 10 Jun 2021 07:56:44

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:25:37
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 19:46:06
User signature succeeded.	Michael Koren (b) (4)	26 Feb 2021 20:02:47
User entered 'None (None)'	(b) (4) Brenda Anderson (b) (4)	24 Feb 2021 15:43:43

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Folder: Covid-19 Assessment 26 Jan 2021

Form: Symptom Log (13)

Generated On: 10 Jun 2021 07:56:44

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:25:37
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 19:46:06
User signature succeeded.	Michael Koren (b) (4)	26 Feb 2021 20:02:47
User entered 'None (None)'	(b) (4) Brenda Anderson (b) (4)	24 Feb 2021 15:43:43

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Folder: Covid-19 Assessment 26 Jan 2021

Form: Symptom Log (13)

Generated On: 10 Jun 2021 07:56:44

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:25:37
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 19:46:06
User signature succeeded.	Michael Koren (b) (4)	26 Feb 2021 20:02:47
User entered 'None (None)'	(b) (4) Brenda Anderson (b) (4)	24 Feb 2021 15:43:43

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Folder: Covid-19 Assessment 26 Jan 2021

Form: Symptom Log (13)

Generated On: 10 Jun 2021 07:56:44

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:25:37
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 19:46:06
User signature succeeded.	Michael Koren (b) (4)	26 Feb 2021 20:02:47
User entered 'None (None)'	(b) (4) Brenda Anderson (b) (4)	24 Feb 2021 15:43:43

US3512248

Folder: Covid-19 Assessment 26 Jan 2021

Form: Symptom Log (13)

Generated On: 10 Jun 2021 07:56:44

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:25:37
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 19:46:06
User signature succeeded.	Michael Koren (b) (4)	26 Feb 2021 20:02:47
User entered 'None (None)'	(b) (4) Brenda Anderson (b) (4) (b) (4)	24 Feb 2021 15:43:43

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Folder: Covid-19 Assessment 26 Jan 2021

Form: Symptom Log (13)

Generated On: 10 Jun 2021 07:56:44

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:25:37
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 19:46:06
User signature succeeded.	Michael Koren (b) (4)	26 Feb 2021 20:02:47
User entered 'None (None)'	(b) (4) Brenda Anderson (b) (4) (b) (4)	24 Feb 2021 15:43:43

US3512248

Folder: Covid-19 Assessment 26 Jan 2021

Form: Symptom Log (13)

Generated On: 10 Jun 2021 07:56:44

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:25:37
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 19:46:06
User signature succeeded.	Michael Koren (b) (4)	26 Feb 2021 20:02:47
User entered 'None (None)'	(b) (4) Brenda Anderson (b) (4)	24 Feb 2021 15:43:43

US3512248

Folder: Covid-19 Assessment 26 Jan 2021

Form: Symptom Log (13)

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[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:25:37
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 19:46:06
User signature succeeded.	Michael Koren (b) (4)	26 Feb 2021 20:02:47
User entered 'None (None)'	(b) (4) Brenda Anderson (b) (4)	24 Feb 2021 15:43:43



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Form: Symptom Log (13)

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[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:25:37
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 19:46:06
User signature succeeded.	Michael Koren (b) (4)	26 Feb 2021 20:02:47
User entered 'None (None)'	(b) (4) Brenda Anderson (b) (4)	24 Feb 2021 15:43:43

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Folder: Covid-19 Assessment 26 Jan 2021

Form: Symptom Log (13)

Generated On: 10 Jun 2021 07:56:44

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:25:37
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 19:46:06
User signature succeeded.	Michael Koren (b) (4)	26 Feb 2021 20:02:47
User entered 'None (None)'	(b) (4) Brenda Anderson (b) (4)	24 Feb 2021 15:43:43

US3512248

Folder: Covid-19 Assessment 26 Jan 2021

Form: Symptom Log (13)

Generated On: 10 Jun 2021 07:56:44

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:25:37
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 19:46:06
User signature succeeded.	Michael Koren (b) (4)	26 Feb 2021 20:02:47
User entered 'None (None)'	(b) (4) Brenda Anderson (b) (4)	24 Feb 2021 15:43:43

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Folder: Covid-19 Assessment 26 Jan 2021

Form: Symptom Log (13)

Generated On: 10 Jun 2021 07:56:44

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:25:37
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 19:46:06
User signature succeeded.	Michael Koren (b) (4)	26 Feb 2021 20:02:47
User entered 'None (None)'	(b) (4) Brenda Anderson (b) (4)	24 Feb 2021 15:43:43

US3512248

Folder: Covid-19 Assessment 26 Jan 2021

Form: Symptom Log (14)

Generated On: 10 Jun 2021 07:56:44

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:25:37
User signature succeeded.	Michael Koren (b) (4)	26 Feb 2021 20:02:47
User entered 'Day 14 (Day 14)'	Brenda Anderson (b) (4)	24 Feb 2021 15:43:43

US3512248

Folder: Covid-19 Assessment 26 Jan 2021

Form: Symptom Log (14)

Generated On: 10 Jun 2021 07:56:44

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:25:37
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 19:46:06
User signature succeeded.	Michael Koren (b) (4)	26 Feb 2021 20:02:47
User entered '5 Feb 2021'	(b) (4) Brenda Anderson (b) (4)	24 Feb 2021 15:43:43

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Folder: Covid-19 Assessment 26 Jan 2021

Form: Symptom Log (14)

Generated On: 10 Jun 2021 07:56:44

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:25:37
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 19:46:06
User signature succeeded.	Michael Koren (b) (4)	26 Feb 2021 20:02:47
User entered '0'	(b) (4) Brenda Anderson (b) (4) (b) (4)	24 Feb 2021 15:43:43

US3512248

Folder: Covid-19 Assessment 26 Jan 2021

Form: Symptom Log (14)

Generated On: 10 Jun 2021 07:56:44

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:25:37
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 19:46:06
User signature succeeded.	Michael Koren (b) (4)	26 Feb 2021 20:02:47
User entered '97' reason for change: Data Entry Error	(b) (4)	
	Brenda Anderson (b) (4)	24 Feb 2021 15:46:41
User entered empty.	(b) (4)	
	Brenda Anderson (b) (4)	24 Feb 2021 15:43:43
	(b) (4)	



US3512248

Folder: Covid-19 Assessment 26 Jan 2021

Form: Symptom Log (14)

Generated On: 10 Jun 2021 07:56:44

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:25:37
User entered '%'	System	24 Feb 2021 15:46:41
User entered empty.	System	24 Feb 2021 15:43:43

US3512248

Folder: Covid-19 Assessment 26 Jan 2021

Form: Symptom Log (14)

Generated On: 10 Jun 2021 07:56:44

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:25:37
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 19:46:06
User signature succeeded.	Michael Koren (b) (4)	26 Feb 2021 20:02:47
User entered '97.3' F reason for change: Data Entry Error	(b) (4)	
	Brenda Anderson (b) (4)	24 Feb 2021 15:46:41
User entered empty.	(b) (4)	
	Brenda Anderson (b) (4)	24 Feb 2021 15:43:43
	(b) (4)	

US3512248

Folder: Covid-19 Assessment 26 Jan 2021

Form: Symptom Log (14)

Generated On: 10 Jun 2021 07:56:44

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:25:37
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 19:46:06
User signature succeeded.	Michael Koren (b) (4)	26 Feb 2021 20:02:47
User entered 'None (None)'	(b) (4) Brenda Anderson (b) (4)	24 Feb 2021 15:43:43

US3512248

Folder: Covid-19 Assessment 26 Jan 2021

Form: Symptom Log (14)

Generated On: 10 Jun 2021 07:56:44

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:25:37
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 19:46:06
User signature succeeded.	Michael Koren (b) (4)	26 Feb 2021 20:02:47
User entered 'Mild (Mild)'	(b) (4) Brenda Anderson (b) (4) (b) (4)	24 Feb 2021 15:43:43

US3512248

Folder: Covid-19 Assessment 26 Jan 2021

Form: Symptom Log (14)

Generated On: 10 Jun 2021 07:56:44

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:25:37
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 19:46:06
User signature succeeded.	Michael Koren (b) (4)	26 Feb 2021 20:02:47
User entered 'None (None)'	(b) (4) Brenda Anderson (b) (4) (b) (4)	24 Feb 2021 15:43:43

US3512248

Folder: Covid-19 Assessment 26 Jan 2021

Form: Symptom Log (14)

Generated On: 10 Jun 2021 07:56:44

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:25:37
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 19:46:06
User signature succeeded.	Michael Koren (b) (4)	26 Feb 2021 20:02:47
User entered 'None (None)'	(b) (4) Brenda Anderson (b) (4)	24 Feb 2021 15:43:43

US3512248

Folder: Covid-19 Assessment 26 Jan 2021

Form: Symptom Log (14)

Generated On: 10 Jun 2021 07:56:44

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:25:37
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 19:46:06
User signature succeeded.	Michael Koren (b) (4)	26 Feb 2021 20:02:47
User entered 'None (None)'	(b) (4) Brenda Anderson (b) (4)	24 Feb 2021 15:43:43

US3512248

Folder: Covid-19 Assessment 26 Jan 2021

Form: Symptom Log (14)

Generated On: 10 Jun 2021 07:56:44

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:25:37
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 19:46:06
User signature succeeded.	Michael Koren (b) (4)	26 Feb 2021 20:02:47
User entered 'None (None)'	(b) (4) Brenda Anderson (b) (4)	24 Feb 2021 15:43:43



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Folder: Covid-19 Assessment 26 Jan 2021

Form: Symptom Log (14)

Generated On: 10 Jun 2021 07:56:44

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:25:37
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 19:46:06
User signature succeeded.	Michael Koren (b) (4)	26 Feb 2021 20:02:47
User entered 'None (None)'	(b) (4) Brenda Anderson (b) (4)	24 Feb 2021 15:43:43

US3512248

Folder: Covid-19 Assessment 26 Jan 2021

Form: Symptom Log (14)

Generated On: 10 Jun 2021 07:56:44

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:25:37
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 19:46:06
User signature succeeded.	Michael Koren (b) (4)	26 Feb 2021 20:02:47
User entered 'None (None)'	(b) (4) Brenda Anderson (b) (4)	24 Feb 2021 15:43:43

US3512248

Folder: Covid-19 Assessment 26 Jan 2021

Form: Symptom Log (14)

Generated On: 10 Jun 2021 07:56:44

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:25:37
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 19:46:06
User signature succeeded.	Michael Koren (b) (4)	26 Feb 2021 20:02:47
User entered 'None (None)'	(b) (4) Brenda Anderson (b) (4) (b) (4)	24 Feb 2021 15:43:43

US3512248

Folder: Covid-19 Assessment 26 Jan 2021

Form: Symptom Log (14)

Generated On: 10 Jun 2021 07:56:44

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:25:37
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 19:46:06
User signature succeeded.	Michael Koren (b) (4)	26 Feb 2021 20:02:47
User entered 'None (None)'	(b) (4) Brenda Anderson (b) (4)	24 Feb 2021 15:43:43

US3512248

Folder: Covid-19 Assessment 26 Jan 2021

Form: Symptom Log (14)

Generated On: 10 Jun 2021 07:56:44

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:25:37
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 19:46:06
User signature succeeded.	Michael Koren (b) (4)	26 Feb 2021 20:02:47
User entered 'None (None)'	(b) (4) Brenda Anderson (b) (4)	24 Feb 2021 15:43:43

US3512248

Folder: Covid-19 Assessment 26 Jan 2021

Form: Symptom Log (14)

Generated On: 10 Jun 2021 07:56:44

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:25:37
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 19:46:06
User signature succeeded.	Michael Koren (b) (4)	26 Feb 2021 20:02:47
User entered 'None (None)'	(b) (4) Brenda Anderson (b) (4)	24 Feb 2021 15:43:43

US3512248

Folder: Covid-19 Assessment 26 Jan 2021

Form: Symptom Log (14)

Generated On: 10 Jun 2021 07:56:44

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:25:37
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 19:46:06
User signature succeeded.	Michael Koren (b) (4)	26 Feb 2021 20:02:47
User entered 'None (None)'	(b) (4) Brenda Anderson (b) (4)	24 Feb 2021 15:43:43

US3512248

Folder: Covid-19 Assessment 26 Jan 2021

Form: Symptom Log (14)

Generated On: 10 Jun 2021 07:56:44

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:25:37
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 19:46:06
User signature succeeded.	Michael Koren (b) (4)	26 Feb 2021 20:02:47
User entered 'None (None)'	(b) (4) Brenda Anderson (b) (4)	24 Feb 2021 15:43:43



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Folder: Covid-19 Assessment 26 Jan 2021

Form: Symptom Log (14)

Generated On: 10 Jun 2021 07:56:44

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:25:37
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 19:46:06
User signature succeeded.	Michael Koren (b) (4)	26 Feb 2021 20:02:47
User entered 'None (None)'	(b) (4) Brenda Anderson (b) (4)	24 Feb 2021 15:43:43

US3512248

Folder: Covid-19 Assessment 26 Jan 2021

Form: Symptom Log (14)

Generated On: 10 Jun 2021 07:56:44

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:25:37
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 19:46:06
User signature succeeded.	Michael Koren (b) (4)	26 Feb 2021 20:02:47
User entered 'Mild (Mild)'	(b) (4) Brenda Anderson (b) (4) (b) (4)	24 Feb 2021 15:43:43

US3512248

Folder: Covid-19 Assessment 26 Jan 2021

Form: COVID Diagnostic Test

Generated On: 10 Jun 2021 07:56:44

[Date of Visit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:25:40
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 19:46:13
User signature succeeded.	Michael Koren (b) (4)	26 Feb 2021 20:02:47
User entered '26 Jan 2021'	(b) (4) Brenda Anderson (b) (4)	27 Jan 2021 12:34:49

**US3512248**

**Folder: Covid-19 Assessment 26 Jan 2021**

**Form: COVID Diagnostic Test**

**Generated On: 10 Jun 2021 07:56:44**

[Was the Subject Tested For SARS-CoV-2 by RT-PCR?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:25:40
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 19:46:13
User signature succeeded.	Michael Koren (b) (4)	26 Feb 2021 20:02:47
User entered 'Yes (Y)'	Brenda Anderson (b) (4)	27 Jan 2021 12:34:49

US3512248

Folder: Covid-19 Assessment 26 Jan 2021

Form: COVID Diagnostic Test

Generated On: 10 Jun 2021 07:56:44

Did Subject Test Positive For SARS-CoV-2 by RT-PCR?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:25:40
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 19:46:13
User signature succeeded.	Michael Koren (b) (4)	26 Feb 2021 20:02:47
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4)	24 Feb 2021 15:50:36
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	24 Feb 2021 15:50:36
User entered 'No (N)' reason for change: Data Entry Error	Brenda Anderson (b) (4)	24 Feb 2021 15:50:36
User opened query 'Data is required. Please complete.' (Site from System).	(b) (4)	27 Jan 2021 12:34:49
User entered empty.	System	27 Jan 2021 12:34:49
	Brenda Anderson (b) (4)	27 Jan 2021 12:34:49
	(b) (4)	

US3512248

Folder: Covid-19 Assessment 26 Jan 2021

Form: COVID Diagnostic Test

Generated On: 10 Jun 2021 07:56:44

[Date of Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:25:40
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 19:46:13
User signature succeeded.	Michael Koren (b) (4)	26 Feb 2021 20:02:47
User entered '26 Jan 2021'	(b) (4) Brenda Anderson (b) (4)	27 Jan 2021 12:34:49

**US3512248**

**Folder: Covid-19 Assessment 26 Jan 2021**

**Form: COVID Diagnostic Test**

**Generated On: 10 Jun 2021 07:56:44**

[Type of Test Performed](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:25:40
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 19:46:13
User signature succeeded.	Michael Koren (b) (4)	26 Feb 2021 20:02:47
User entered 'Nasopharyngeal Swab (Nasopharyngeal Swab)'	(b) (4) Brenda Anderson (b) (4)	27 Jan 2021 12:34:49

US3512248

Folder: Covid-19 Assessment 26 Jan 2021

Form: COVID Diagnostic Test

Generated On: 10 Jun 2021 07:56:44

[Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:25:40
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 19:46:13
User signature succeeded.	Michael Koren (b) (4)	26 Feb 2021 20:02:47
User entered empty.	(b) (4) Brenda Anderson (b) (4)	27 Jan 2021 12:34:49



US3512248

Folder: Covid-19 Assessment 26 Jan 2021

Form: COVID Diagnostic Test

Generated On: 10 Jun 2021 07:56:44

[Was this diagnostic test performed at a lab other than the Study Central Lab?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:25:40
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 19:46:13
User signature succeeded.	Michael Koren (b) (4)	26 Feb 2021 20:02:47
User entered 'No (N)'	(b) (4) Brenda Anderson (b) (4) (b) (4)	27 Jan 2021 12:34:49

US3512248

Folder: Covid-19 Assessment 26 Jan 2021

Form: COVID Diagnostic Test

Generated On: 10 Jun 2021 07:56:44

[Lab/ Institution Test Performed](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:25:40
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 19:46:13
User signature succeeded.	Michael Koren (b) (4)	26 Feb 2021 20:02:47
User entered empty.	(b) (4) Brenda Anderson (b) (4)	27 Jan 2021 12:34:49

US3512248

Folder: Covid-19 Assessment 26 Jan 2021

Form: COVID Diagnostic Test

Generated On: 10 Jun 2021 07:56:44

[CLIA Certified?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:25:40
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 19:46:13
User signature succeeded.	Michael Koren (b) (4)	26 Feb 2021 20:02:47
User entered empty.	(b) (4) Brenda Anderson (b) (4)	27 Jan 2021 12:34:49

**US3512248**

**Folder: Covid-19 Assessment 26 Jan 2021**

**Form: COVID Diagnostic Test**

**Generated On: 10 Jun 2021 07:56:44**

[COVID-19 Positive \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:25:40
User entered '0'	System	24 Feb 2021 15:50:36

US3512248

Folder: Illness Visit (1)

Form: Saliva Collection (1)

Generated On: 10 Jun 2021 07:56:44

[Visit](#)

Audit	User	Time (GMT)
User accepted default value 'Day 3 (Day 3)'	Taylor Johnson (b) (4) (b) (4)	14 Feb 2021 17:36:16

**US3512248**

**Folder: Illness Visit (1)**

**Form: Saliva Collection (1)**

**Generated On: 10 Jun 2021 07:56:44**

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 19:46:40
User signature succeeded.	Michael Koren (b) (4)	19 Feb 2021 21:27:20
User entered 'Yes (Y)'	(b) (4) Taylor Johnson (b) (4)	14 Feb 2021 17:36:16

**US3512248**

**Folder: Illness Visit (1)**

**Form: Saliva Collection (1)**

**Generated On: 10 Jun 2021 07:56:44**

[Date of Collection](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 19:46:40
User signature succeeded.	Michael Koren (b) (4)	19 Feb 2021 21:27:20
User entered '28 Jan 2021'	(b) (4) Taylor Johnson (b) (4)	14 Feb 2021 17:36:16

US3512248

Folder: Illness Visit (1)

Form: Saliva Collection (2)

Generated On: 10 Jun 2021 07:56:44

[Visit](#)

Audit	User	Time (GMT)
User accepted default value 'Day 5 (Day 5)'	Taylor Johnson (b) (4) (b) (4)	14 Feb 2021 17:36:16



**US3512248**

**Folder: Illness Visit (1)**

**Form: Saliva Collection (2)**

**Generated On: 10 Jun 2021 07:56:44**

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 19:46:40
User signature succeeded.	Michael Koren (b) (4)	19 Feb 2021 21:27:20
User entered 'Yes (Y)'	(b) (4) Taylor Johnson (b) (4)	14 Feb 2021 17:36:16

**US3512248**

**Folder: Illness Visit (1)**

**Form: Saliva Collection (2)**

**Generated On: 10 Jun 2021 07:56:44**

[Date of Collection](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 19:46:40
User signature succeeded.	Michael Koren (b) (4)	19 Feb 2021 21:27:20
User entered '30 Jan 2021'	(b) (4) Taylor Johnson (b) (4)	14 Feb 2021 17:36:16

**US3512248**

**Folder: Illness Visit (1)**

**Form: Saliva Collection (3)**

**Generated On: 10 Jun 2021 07:56:44**

[Visit](#)

Audit	User	Time (GMT)
User accepted default value 'Day 7 (Day 7)'	Taylor Johnson (b) (4) (b) (4)	14 Feb 2021 17:36:16

**US3512248**

**Folder: Illness Visit (1)**

**Form: Saliva Collection (3)**

**Generated On: 10 Jun 2021 07:56:44**

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 19:46:40
User signature succeeded.	Michael Koren (b) (4)	19 Feb 2021 21:27:20
User entered 'Yes (Y)'	Taylor Johnson (b) (4)	14 Feb 2021 17:36:16

**US3512248**

**Folder: Illness Visit (1)**

**Form: Saliva Collection (3)**

**Generated On: 10 Jun 2021 07:56:44**

[Date of Collection](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 19:46:40
User signature succeeded.	Michael Koren (b) (4)	19 Feb 2021 21:27:20
User entered '01 Feb 2021'	(b) (4) Taylor Johnson (b) (4)	14 Feb 2021 17:36:16

**US3512248**

**Folder: Illness Visit (1)**

**Form: Saliva Collection (4)**

**Generated On: 10 Jun 2021 07:56:44**

[Visit](#)

Audit	User	Time (GMT)
User accepted default value 'Day 9 (Day 9)'	Taylor Johnson (b) (4) (b) (4)	14 Feb 2021 17:36:16

**US3512248**

**Folder: Illness Visit (1)**

**Form: Saliva Collection (4)**

**Generated On: 10 Jun 2021 07:56:44**

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 19:46:40
User signature succeeded.	Michael Koren (b) (4)	19 Feb 2021 21:27:20
User entered 'Yes (Y)'	Taylor Johnson (b) (4)	14 Feb 2021 17:36:16

**US3512248**

**Folder: Illness Visit (1)**

**Form: Saliva Collection (4)**

**Generated On: 10 Jun 2021 07:56:44**

[Date of Collection](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 19:46:40
User signature succeeded.	Michael Koren (b) (4)	19 Feb 2021 21:27:20
User entered '03 Feb 2021'	Taylor Johnson (b) (4)	14 Feb 2021 17:36:16



**US3512248**

**Folder: Illness Visit (1)**

**Form: Saliva Collection (5)**

**Generated On: 10 Jun 2021 07:56:44**

[Visit](#)

Audit	User	Time (GMT)
User accepted default value 'Day 14 (Day 14)'	Taylor Johnson (b) (4) (b) (4)	14 Feb 2021 17:36:16

**US3512248**

**Folder: Illness Visit (1)**

**Form: Saliva Collection (5)**

**Generated On: 10 Jun 2021 07:56:44**

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 19:46:40
User signature succeeded.	Michael Koren (b) (4)	19 Feb 2021 21:27:20
User entered 'NA (COVID-19 Negative) (NA)'	Taylor Johnson (b) (4)	14 Feb 2021 17:36:16

**US3512248**

**Folder: Illness Visit (1)**

**Form: Saliva Collection (5)**

**Generated On: 10 Jun 2021 07:56:44**

[Date of Collection](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 19:46:40
User signature succeeded.	Michael Koren (b) (4)	19 Feb 2021 21:27:20
User entered empty.	Taylor Johnson (b) (4)	14 Feb 2021 17:36:16

**US3512248**

**Folder: Illness Visit (1)**

**Form: Saliva Collection (6)**

**Generated On: 10 Jun 2021 07:56:44**

[Visit](#)

Audit	User	Time (GMT)
User accepted default value 'Day 21 (Day 21)'	Taylor Johnson (b) (4) (b) (4)	14 Feb 2021 17:36:16

**US3512248**

**Folder: Illness Visit (1)**

**Form: Saliva Collection (6)**

**Generated On: 10 Jun 2021 07:56:44**

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 19:46:40
User signature succeeded.	Michael Koren (b) (4)	19 Feb 2021 21:27:20
User entered 'NA (COVID-19 Negative) (NA)'	Taylor Johnson (b) (4)	14 Feb 2021 17:36:16

**US3512248**

**Folder: Illness Visit (1)**

**Form: Saliva Collection (6)**

**Generated On: 10 Jun 2021 07:56:44**

[Date of Collection](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 19:46:40
User signature succeeded.	Michael Koren (b) (4)	19 Feb 2021 21:27:20
User entered empty.	Taylor Johnson (b) (4)	14 Feb 2021 17:36:16

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Folder: Illness Visit (1)

Form: Saliva Collection (7)

Generated On: 10 Jun 2021 07:56:44

[Visit](#)

Audit	User	Time (GMT)
User accepted default value 'Day 28 (Day 28)'	Taylor Johnson (b) (4) (b) (4)	14 Feb 2021 17:36:16

**US3512248**

**Folder: Illness Visit (1)**

**Form: Saliva Collection (7)**

**Generated On: 10 Jun 2021 07:56:44**

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 19:46:40
User signature succeeded.	Michael Koren (b) (4)	19 Feb 2021 21:27:20
User entered 'NA (COVID-19 Negative) (NA)'	Taylor Johnson (b) (4)	14 Feb 2021 17:36:16



**US3512248**

**Folder: Illness Visit (1)**

**Form: Saliva Collection (7)**

**Generated On: 10 Jun 2021 07:56:44**

[Date of Collection](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 19:46:40
User signature succeeded.	Michael Koren (b) (4)	19 Feb 2021 21:27:20
User entered empty.	(b) (4) Taylor Johnson (b) (4)	14 Feb 2021 17:36:16

**US3512248**

**Folder: Illness Visit (2)**

**Form: Saliva Collection (1)**

**Generated On: 10 Jun 2021 07:56:44**

[Visit](#)

Audit	User	Time (GMT)
User accepted default value 'Day 3 (Day 3)'	Sheldon Warren (b) (4) (b) (4)	23 Apr 2021 19:16:57

**US3512248**

**Folder: Illness Visit (2)**

**Form: Saliva Collection (1)**

**Generated On: 10 Jun 2021 07:56:44**

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 19:25:44
User signature succeeded.	Michael Koren (b) (4)	26 Apr 2021 15:25:40
User entered 'Yes (Y)'	Sheldon Warren (b) (4)	23 Apr 2021 19:16:57

**US3512248**

**Folder: Illness Visit (2)**

**Form: Saliva Collection (1)**

**Generated On: 10 Jun 2021 07:56:44**

[Date of Collection](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 19:25:44
User signature succeeded.	Michael Koren (b) (4)	26 Apr 2021 15:25:40
User entered '22 Apr 2021'	Sheldon Warren (b) (4)	23 Apr 2021 19:16:57

**US3512248**

**Folder: Illness Visit (2)**

**Form: Saliva Collection (2)**

**Generated On: 10 Jun 2021 07:56:44**

[Visit](#)

Audit	User	Time (GMT)
User accepted default value 'Day 5 (Day 5)'	Sheldon Warren (b) (4) (b) (4)	26 Apr 2021 21:33:07

**US3512248**

**Folder: Illness Visit (2)**

**Form: Saliva Collection (2)**

**Generated On: 10 Jun 2021 07:56:44**

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	28 Apr 2021 21:04:50
	(b) (4)	
User entered 'Yes (Y)'	Sheldon Warren (b) (4)	26 Apr 2021 21:33:07
	(b) (4)	

**US3512248**

**Folder: Illness Visit (2)**

**Form: Saliva Collection (2)**

**Generated On: 10 Jun 2021 07:56:44**

[Date of Collection](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	28 Apr 2021 21:04:50
	(b) (4)	
User entered '24 Apr 2021'	Sheldon Warren (b) (4)	26 Apr 2021 21:33:07
	(b) (4)	

**US3512248**

**Folder: Illness Visit (2)**

**Form: Saliva Collection (3)**

**Generated On: 10 Jun 2021 07:56:44**

[Visit](#)

Audit	User	Time (GMT)
User accepted default value 'Day 7 (Day 7)'	Sheldon Warren (b) (4) (b) (4)	26 Apr 2021 21:33:07



**US3512248**

**Folder: Illness Visit (2)**

**Form: Saliva Collection (3)**

**Generated On: 10 Jun 2021 07:56:44**

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	28 Apr 2021 21:04:50
	(b) (4)	
User entered 'Yes (Y)'	Sheldon Warren (b) (4)	26 Apr 2021 21:33:07
	(b) (4)	

**US3512248**

**Folder: Illness Visit (2)**

**Form: Saliva Collection (3)**

**Generated On: 10 Jun 2021 07:56:44**

[Date of Collection](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	28 Apr 2021 21:04:50
	(b) (4)	
User entered '26 Apr 2021'	Sheldon Warren (b) (4)	26 Apr 2021 21:33:07
	(b) (4)	

**US3512248**

**Folder: Illness Visit (2)**

**Form: Saliva Collection (4)**

**Generated On: 10 Jun 2021 07:56:44**

[Visit](#)

Audit	User	Time (GMT)
User accepted default value 'Day 9 (Day 9)'	Sheldon Warren (b) (4) (b) (4)	26 Apr 2021 21:33:07

US3512248

Folder: Illness Visit (2)

Form: Saliva Collection (4)

Generated On: 10 Jun 2021 07:56:44

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	28 Apr 2021 21:04:50
	(b) (4)	
User closed query 'Data is required. Please complete.' (Site from System).	System	27 Apr 2021 16:39:52
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	27 Apr 2021 16:39:52
User entered 'NA (COVID-19 Negative) (NA)' reason for change: New Information	Sheldon Warren (b) (4)	27 Apr 2021 16:39:52
	(b) (4)	
User opened query 'Data is required. Please complete.' (Site from System).	System	26 Apr 2021 21:33:07
User entered empty.	Sheldon Warren (b) (4)	26 Apr 2021 21:33:07
	(b) (4)	

**US3512248**

**Folder: Illness Visit (2)**

**Form: Saliva Collection (4)**

**Generated On: 10 Jun 2021 07:56:44**

[Date of Collection](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4) (b) (4)	28 Apr 2021 21:04:50
User entered empty.	Sheldon Warren (b) (4) (b) (4)	26 Apr 2021 21:33:07

**US3512248**

**Folder: Illness Visit (2)**

**Form: Saliva Collection (5)**

**Generated On: 10 Jun 2021 07:56:44**

[Visit](#)

Audit	User	Time (GMT)
User accepted default value 'Day 14 (Day 14)'	Sheldon Warren (b) (4) (b) (4)	26 Apr 2021 21:33:07

US3512248

Folder: Illness Visit (2)

Form: Saliva Collection (5)

Generated On: 10 Jun 2021 07:56:44

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	28 Apr 2021 21:04:50
	(b) (4)	
User closed query 'Data is required. Please complete.' (Site from System).	System	27 Apr 2021 16:39:52
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	27 Apr 2021 16:39:52
User entered 'NA (COVID-19 Negative) (NA)' reason for change: New Information	Sheldon Warren (b) (4)	27 Apr 2021 16:39:52
	(b) (4)	
User opened query 'Data is required. Please complete.' (Site from System).	System	26 Apr 2021 21:33:07
User entered empty.	Sheldon Warren (b) (4)	26 Apr 2021 21:33:07
	(b) (4)	

**US3512248**

**Folder: Illness Visit (2)**

**Form: Saliva Collection (5)**

**Generated On: 10 Jun 2021 07:56:44**

[Date of Collection](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	28 Apr 2021 21:04:50
	(b) (4)	
User entered empty.	Sheldon Warren (b) (4)	26 Apr 2021 21:33:07
	(b) (4)	



**US3512248**

**Folder: Illness Visit (2)**

**Form: Saliva Collection (6)**

**Generated On: 10 Jun 2021 07:56:44**

[Visit](#)

Audit	User	Time (GMT)
User accepted default value 'Day 21 (Day 21)'	Sheldon Warren (b) (4) (b) (4)	26 Apr 2021 21:33:07

US3512248

Folder: Illness Visit (2)

Form: Saliva Collection (6)

Generated On: 10 Jun 2021 07:56:44

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	28 Apr 2021 21:04:50
	(b) (4)	
User closed query 'Data is required. Please complete.' (Site from System).	System	27 Apr 2021 16:39:52
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	27 Apr 2021 16:39:52
User entered 'NA (COVID-19 Negative) (NA)' reason for change: New Information	Sheldon Warren (b) (4)	27 Apr 2021 16:39:52
	(b) (4)	
User opened query 'Data is required. Please complete.' (Site from System).	System	26 Apr 2021 21:33:07
User entered empty.	Sheldon Warren (b) (4)	26 Apr 2021 21:33:07
	(b) (4)	

**US3512248**

**Folder: Illness Visit (2)**

**Form: Saliva Collection (6)**

**Generated On: 10 Jun 2021 07:56:44**

[Date of Collection](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	28 Apr 2021 21:04:50
	(b) (4)	
User entered empty.	Sheldon Warren (b) (4)	26 Apr 2021 21:33:07
	(b) (4)	

US3512248

Folder: Illness Visit (2)

Form: Saliva Collection (7)

Generated On: 10 Jun 2021 07:56:44

[Visit](#)

Audit	User	Time (GMT)
User accepted default value 'Day 28 (Day 28)'	Sheldon Warren (b) (4) (b) (4)	26 Apr 2021 21:33:07

US3512248

Folder: Illness Visit (2)

Form: Saliva Collection (7)

Generated On: 10 Jun 2021 07:56:44

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	28 Apr 2021 21:04:50
	(b) (4)	
User closed query 'Data is required. Please complete.' (Site from System).	System	27 Apr 2021 16:39:52
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	27 Apr 2021 16:39:52
User entered 'NA (COVID-19 Negative) (NA)' reason for change: New Information	Sheldon Warren (b) (4)	27 Apr 2021 16:39:52
	(b) (4)	
User opened query 'Data is required. Please complete.' (Site from System).	System	26 Apr 2021 21:33:07
User entered empty.	Sheldon Warren (b) (4)	26 Apr 2021 21:33:07
	(b) (4)	

**US3512248**

**Folder: Illness Visit (2)**

**Form: Saliva Collection (7)**

**Generated On: 10 Jun 2021 07:56:44**

[Date of Collection](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	28 Apr 2021 21:04:50
	(b) (4)	
User entered empty.	Sheldon Warren (b) (4)	26 Apr 2021 21:33:07
	(b) (4)	

US3512248

Folder: Illness Visit Day 1 (1)

Form: Visit Date

Generated On: 10 Jun 2021 07:56:44

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 18:07:39
DataPoint Verified.	(b) (4), (b) (6)	10 Mar 2021 19:27:03
User closed query 'Per GCL Lab Reconciliation: Saliva: Sample dated 28JAN2021 is reported under Illness visit in PPD Central lab, however the data is missing in EDC. Please review if the sample has been collected then update the details under appropriate visit. Else clarify, thank you. ' (Site from DM).	(b) (4), (b) (6)	22 Feb 2021 07:36:51
User signature succeeded.	Michael Koren (b) (4)	19 Feb 2021 21:27:20
Query 'Per GCL Lab Reconciliation: Saliva: Sample dated 28JAN2021 is reported under Illness visit in PPD Central lab, however the data is missing in EDC. Please review if the sample has been collected then update the details under appropriate visit. Else clarify, thank you. ' answered with 'DATA UPDATED' (Site from DM).	(b) (4) Taylor Johnson (b) (4)	14 Feb 2021 17:48:12
User opened query 'Per GCL Lab Reconciliation: Saliva: Sample dated 28JAN2021 is reported under Illness visit in PPD Central lab, however the data is missing in EDC. Please review if the sample has been collected then update the details under appropriate visit. Else clarify, thank you. ' (Site from DM).	(b) (4), (b) (6)	10 Feb 2021 10:36:07
Query 'Per GCL Lab Reconciliation: Saliva: Sample dated 28JAN2021 is reported under Illness visit in PPD Central lab, however the same is missing in EDC. Please review if the sample has been collected then update the details under appropriate visit. Else clarify, thank you. ' canceled (Site from DM).	(b) (4), (b) (6)	10 Feb 2021 10:35:51
User opened query 'Per GCL Lab Reconciliation: Saliva: Sample dated 28JAN2021 is reported under Illness visit in PPD Central lab, however the same is missing in EDC. Please review if the sample has been collected then update the details under appropriate visit. Else clarify, thank you. ' (Site from DM).	(b) (4), (b) (6)	10 Feb 2021 10:35:44

US3512248

Folder: Illness Visit Day 1 (1)

Form: Visit Date

Generated On: 10 Jun 2021 07:56:44

[Was this visit performed?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Brenda Anderson (b) (4) (b) (4)	27 Jan 2021 12:35:06



**US3512248**

**Folder: Illness Visit Day 1 (1)**

**Form: Visit Date**

**Generated On: 10 Jun 2021 07:56:44**

[Visit date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 18:07:39
DataPoint Verified.	(b) (4), (b) (6)	10 Mar 2021 19:27:03
User signature succeeded.	Michael Koren (b) (4)	19 Feb 2021 21:27:20
User entered '26 Jan 2021'	(b) (4) Brenda Anderson (b) (4)	27 Jan 2021 12:35:06

**US3512248**

**Folder: Illness Visit Day 1 (1)**

**Form: Visit Date**

**Generated On: 10 Jun 2021 07:56:44**

[Was visit performed at the participant's home or at the clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 18:07:39
DataPoint Verified.	(b) (4), (b) (6)	10 Mar 2021 19:27:03
User signature succeeded.	Michael Koren (b) (4)	19 Feb 2021 21:27:20
User entered 'Clinic (Clinic)'	Brenda Anderson (b) (4)	27 Jan 2021 12:35:06

**US3512248**

**Folder: Illness Visit Day 1 (1)**

**Form: Visit Date**

**Generated On: 10 Jun 2021 07:56:44**

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 18:07:39
User entered 'SICKD1'	System	27 Jan 2021 12:35:06

US3512248

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 07:56:44

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 18:07:39
DataPoint Verified.	(b) (4), (b) (6)	10 Mar 2021 19:27:09
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 22:12:02
User entered 'Yes (Y)'	(b) (4) Brenda Anderson (b) (4) (b) (4)	27 Jan 2021 12:36:04

US3512248

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 07:56:44

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 18:07:39
DataPoint Verified.	(b) (4), (b) (6)	10 Mar 2021 19:27:09
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 22:12:02
User entered '26 Jan 2021'	(b) (4) Brenda Anderson (b) (4) (b) (4)	27 Jan 2021 12:36:04

**US3512248**

**Folder: Illness Visit Day 1 (1)**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 07:56:44**

**Time of assessment (00:00-23:59)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 18:07:39
DataPoint Verified.	(b) (4), (b) (6)	10 Mar 2021 19:27:09
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 22:12:02
User entered '10:31'	(b) (4) Brenda Anderson (b) (4) (b) (4)	27 Jan 2021 12:36:04

**US3512248**

**Folder: Illness Visit Day 1 (1)**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 07:56:44**

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 18:07:39
User entered '26 Jan 2021 10:31'	System	27 Jan 2021 12:36:04

US3512248

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 07:56:44

Height (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 18:07:39
DataPoint Verified.	(b) (4), (b) (6)	10 Mar 2021 19:27:09
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 22:12:02
User entered '71' in	(b) (4) Brenda Anderson (b) (4)	27 Jan 2021 12:36:04
DataPoint set to visible.	(b) (4) System	27 Jan 2021 12:35:06



US3512248

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 07:56:44

Weight (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 18:07:39
DataPoint Verified.	(b) (4), (b) (6)	10 Mar 2021 19:27:09
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 22:12:02
User entered '231.4' lb	(b) (4) Brenda Anderson (b) (4)	27 Jan 2021 12:36:04
DataPoint set to visible.	(b) (4) System	27 Jan 2021 12:35:06

**US3512248**

**Folder: Illness Visit Day 1 (1)**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 07:56:44**

[Temperature \(xxx.x\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 18:07:39
DataPoint Verified.	(b) (4), (b) (6)	10 Mar 2021 19:27:09
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 22:12:02
User entered '97.5' F	(b) (4) Brenda Anderson (b) (4)	27 Jan 2021 12:36:04

US3512248

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 07:56:44

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 18:07:39
DataPoint Verified.	(b) (4), (b) (6)	10 Mar 2021 19:27:09
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 22:12:02
User entered 'Oral (Oral)'	(b) (4) Brenda Anderson (b) (4) (b) (4)	27 Jan 2021 12:36:04

**US3512248**

**Folder: Illness Visit Day 1 (1)**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 07:56:44**

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 18:07:39
DataPoint Verified.	(b) (4), (b) (6)	10 Mar 2021 19:27:09
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 22:12:02
User entered empty.	(b) (4) Brenda Anderson (b) (4)	27 Jan 2021 12:36:04

**US3512248**

**Folder: Illness Visit Day 1 (1)**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 07:56:44**

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 18:07:39
DataPoint Verified.	(b) (4), (b) (6)	10 Mar 2021 19:27:09
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 22:12:02
User entered '65'	(b) (4) Brenda Anderson (b) (4) (b) (4)	27 Jan 2021 12:36:04

**US3512248**

**Folder: Illness Visit Day 1 (1)**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 07:56:44**

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 18:07:39
User entered 'bpm'	System	27 Jan 2021 12:36:04

US3512248

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 07:56:44

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 18:07:39
DataPoint Verified.	(b) (4), (b) (6)	10 Mar 2021 19:27:09
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 22:12:02
User entered '16'	(b) (4) Brenda Anderson (b) (4) (b) (4)	27 Jan 2021 12:36:04

US3512248

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 07:56:44

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 18:07:39
User entered 'breaths/min'	System	27 Jan 2021 12:36:04



**US3512248**

**Folder: Illness Visit Day 1 (1)**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 07:56:44**

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 18:07:39
DataPoint Verified.	(b) (4), (b) (6)	10 Mar 2021 19:27:09
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 22:12:02
User entered '132'	(b) (4) Brenda Anderson (b) (4) (b) (4)	27 Jan 2021 12:36:04

**US3512248**

**Folder: Illness Visit Day 1 (1)**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 07:56:44**

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 18:07:39
User entered 'mmHg'	System	27 Jan 2021 12:36:04

**US3512248**

**Folder: Illness Visit Day 1 (1)**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 07:56:44**

[Diastolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 18:07:39
DataPoint Verified.	(b) (4), (b) (6)	10 Mar 2021 19:27:09
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 22:12:02
User entered '66'	(b) (4) Brenda Anderson (b) (4)	27 Jan 2021 12:36:04

**US3512248**

**Folder: Illness Visit Day 1 (1)**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 07:56:44**

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 18:07:39
User entered 'mmHg'	System	27 Jan 2021 12:36:04

**US3512248**

**Folder: Illness Visit Day 1 (1)**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 07:56:44**

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 18:07:39

US3512248

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 07:56:44

Weight (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 18:07:39

US3512248

Folder: Illness Visit Day 1 (1)

Form: Physical Examination

Generated On: 10 Jun 2021 07:56:44

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 18:07:39
DataPoint Verified.	(b) (4), (b) (6)	10 Mar 2021 19:27:14
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 22:12:02
User entered 'Yes (Y)'	(b) (4) Brenda Anderson (b) (4) (b) (4)	27 Jan 2021 12:50:19

**US3512248**

**Folder: Illness Visit Day 1 (1)**

**Form: Physical Examination**

**Generated On: 10 Jun 2021 07:56:44**

**Date of examination (dd MMM yyyy)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 18:07:39
DataPoint Verified.	(b) (4), (b) (6)	10 Mar 2021 19:27:14
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 22:12:02
User entered '26 Jan 2021'	(b) (4) Brenda Anderson (b) (4)	27 Jan 2021 12:50:19



US3512248

Folder: Illness Visit Day 1 (1)

Form: Blood Sample Collection for Immunologic Assessment of SARS-CoV-2 Infection

Generated On: 10 Jun 2021 07:56:44

[Was Blood Sample Taken for Immunologic Assessment of SARS\\_COV-2 Infection?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 18:07:39
DataPoint Verified.	(b) (4), (b) (6)	10 Mar 2021 19:27:21
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 22:12:02
User entered 'Yes (Y)'	(b) (4) Brenda Anderson (b) (4)	27 Jan 2021 12:50:25

**US3512248**

**Folder: Illness Visit Day 1 (1)**

**Form: Blood Sample Collection for Immunologic Assessment of SARS-CoV-2 Infection**

**Generated On: 10 Jun 2021 07:56:44**

[Date of Collection](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 18:07:39
DataPoint Verified.	(b) (4), (b) (6)	10 Mar 2021 19:27:21
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 22:12:02
User entered '26 Jan 2021'	(b) (4) Brenda Anderson (b) (4)	27 Jan 2021 12:50:25

**US3512248**

**Folder: Illness Visit Day 1 (1)**

**Form: Visit Date**

**Generated On: 10 Jun 2021 07:56:44**

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 18:07:39
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 19:24:12
User signature succeeded.	Michael Koren (b) (4)	26 Apr 2021 15:25:40
User entered 'Yes (Y)'	(b) (4) Sheldon Warren (b) (4)	23 Apr 2021 19:03:10
	(b) (4)	

**US3512248**

**Folder: Illness Visit Day 1 (1)**

**Form: Visit Date**

**Generated On: 10 Jun 2021 07:56:44**

[Visit date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 18:07:39
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 19:24:12
User signature succeeded.	Michael Koren (b) (4)	26 Apr 2021 15:25:40
User entered '20 Apr 2021'	(b) (4) Sheldon Warren (b) (4)	23 Apr 2021 19:03:10
	(b) (4)	

**US3512248**

**Folder: Illness Visit Day 1 (1)**

**Form: Visit Date**

**Generated On: 10 Jun 2021 07:56:44**

[Was visit performed at the participant's home or at the clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 18:07:39
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 19:24:12
User signature succeeded.	Michael Koren (b) (4)	26 Apr 2021 15:25:40
User entered 'Clinic (Clinic)'	(b) (4) Sheldon Warren (b) (4) (b) (4)	23 Apr 2021 19:03:10

**US3512248**

**Folder: Illness Visit Day 1 (1)**

**Form: Visit Date**

**Generated On: 10 Jun 2021 07:56:44**

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 18:07:39
User entered 'SICKD1'	System	23 Apr 2021 19:03:10

**US3512248**

**Folder: Illness Visit Day 1 (1)**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 07:56:44**

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 18:07:39
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 19:25:27
User signature succeeded.	Michael Koren (b) (4)	26 Apr 2021 15:25:40
User entered 'Yes (Y)'	(b) (4) Sheldon Warren (b) (4)	23 Apr 2021 19:15:41
	(b) (4)	

**US3512248**

**Folder: Illness Visit Day 1 (1)**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 07:56:44**

**Date of assessment** (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 18:07:39
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 19:25:27
User signature succeeded.	Michael Koren (b) (4)	26 Apr 2021 15:25:40
User entered '20 Apr 2021'	(b) (4) Sheldon Warren (b) (4) (b) (4)	23 Apr 2021 19:15:41



**US3512248**

**Folder: Illness Visit Day 1 (1)**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 07:56:44**

**Time of assessment (00:00-23:59)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 18:07:39
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 19:25:27
User signature succeeded.	Michael Koren (b) (4)	26 Apr 2021 15:25:40
User entered '9:45'	(b) (4) Sheldon Warren (b) (4) (b) (4)	23 Apr 2021 19:15:41

**US3512248**

**Folder: Illness Visit Day 1 (1)**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 07:56:44**

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 18:07:39
User entered '20 Apr 2021 9:45'	System	23 Apr 2021 19:15:41

US3512248

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 07:56:44

[Height \(xxx.x\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 18:07:39
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 19:25:27
User signature succeeded.	Michael Koren (b) (4)	26 Apr 2021 15:25:40
User entered '71' in	(b) (4) Sheldon Warren (b) (4)	23 Apr 2021 19:15:41
DataPoint set to visible.	(b) (4) System	23 Apr 2021 19:03:10

**US3512248**

**Folder: Illness Visit Day 1 (1)**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 07:56:44**

[Weight \(xxx.x\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 18:07:39
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 19:25:27
User signature succeeded.	Michael Koren (b) (4)	26 Apr 2021 15:25:40
User entered '231.4' lb	(b) (4) Sheldon Warren (b) (4)	23 Apr 2021 19:15:41
DataPoint set to visible.	(b) (4) System	23 Apr 2021 19:03:10

US3512248

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 07:56:44

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 18:07:39
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 19:25:27
User signature succeeded.	Michael Koren (b) (4)	26 Apr 2021 15:25:40
User entered '98.3' F	(b) (4) Sheldon Warren (b) (4) (b) (4)	23 Apr 2021 19:15:41

**US3512248**

**Folder: Illness Visit Day 1 (1)**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 07:56:44**

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 18:07:39
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 19:25:27
User signature succeeded.	Michael Koren (b) (4)	26 Apr 2021 15:25:40
User entered 'Oral (Oral)'	(b) (4) Sheldon Warren (b) (4) (b) (4)	23 Apr 2021 19:15:41

**US3512248**

**Folder: Illness Visit Day 1 (1)**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 07:56:44**

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 18:07:39
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 19:25:27
User signature succeeded.	Michael Koren (b) (4)	26 Apr 2021 15:25:40
User entered empty.	(b) (4) Sheldon Warren (b) (4) (b) (4)	23 Apr 2021 19:15:41

**US3512248**

**Folder: Illness Visit Day 1 (1)**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 07:56:44**

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 18:07:39
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 19:25:27
User signature succeeded.	Michael Koren (b) (4)	26 Apr 2021 15:25:40
User entered '86'	(b) (4) Sheldon Warren (b) (4) (b) (4)	23 Apr 2021 19:15:41



**US3512248**

**Folder: Illness Visit Day 1 (1)**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 07:56:44**

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 18:07:39
User entered 'bpm'	System	23 Apr 2021 19:15:41

US3512248

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 07:56:44

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 18:07:39
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 19:25:27
User signature succeeded.	Michael Koren (b) (4)	26 Apr 2021 15:25:40
User entered '16'	(b) (4) Sheldon Warren (b) (4) (b) (4)	23 Apr 2021 19:15:41

US3512248

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 07:56:44

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 18:07:39
User entered 'breaths/min'	System	23 Apr 2021 19:15:41

US3512248

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 07:56:44

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 18:07:39
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 19:25:27
User signature succeeded.	Michael Koren (b) (4)	26 Apr 2021 15:25:40
User entered '137'	(b) (4) Sheldon Warren (b) (4) (b) (4)	23 Apr 2021 19:15:41

**US3512248**

**Folder: Illness Visit Day 1 (1)**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 07:56:44**

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 18:07:39
User entered 'mmHg'	System	23 Apr 2021 19:15:41

**US3512248**

**Folder: Illness Visit Day 1 (1)**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 07:56:44**

[Diastolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 18:07:39
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 19:25:27
User signature succeeded.	Michael Koren (b) (4)	26 Apr 2021 15:25:40
User entered '66'	(b) (4) Sheldon Warren (b) (4) (b) (4)	23 Apr 2021 19:15:41

US3512248

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 07:56:44

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 18:07:39
User entered 'mmHg'	System	23 Apr 2021 19:15:41

**US3512248**

**Folder: Illness Visit Day 1 (1)**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 07:56:44**

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 18:07:39



US3512248

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 07:56:44

Weight (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 18:07:39

US3512248

Folder: Illness Visit Day 1 (1)

Form: Physical Examination

Generated On: 10 Jun 2021 07:56:44

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 18:07:39
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 19:25:32
User signature succeeded.	Michael Koren (b) (4)	26 Apr 2021 15:25:40
User entered 'Yes (Y)'	(b) (4) Sheldon Warren (b) (4) (b) (4)	23 Apr 2021 19:16:17

US3512248

Folder: Illness Visit Day 1 (1)

Form: Physical Examination

Generated On: 10 Jun 2021 07:56:44

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 18:07:39
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 19:25:32
User signature succeeded.	Michael Koren (b) (4)	26 Apr 2021 15:25:40
User entered '20 Apr 2021'	(b) (4) Sheldon Warren (b) (4) (b) (4)	23 Apr 2021 19:16:17

US3512248

Folder: Illness Visit Day 1 (1)

Form: Blood Sample Collection for Immunologic Assessment of SARS-CoV-2 Infection

Generated On: 10 Jun 2021 07:56:44

[Was Blood Sample Taken for Immunologic Assessment of SARS\\_COV-2 Infection?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 18:07:39
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 19:25:37
User signature succeeded.	Michael Koren (b) (4)	26 Apr 2021 15:25:40
User entered 'Yes (Y)'	(b) (4) Sheldon Warren (b) (4) (b) (4)	23 Apr 2021 19:16:29

**US3512248**

**Folder: Illness Visit Day 1 (1)**

**Form: Blood Sample Collection for Immunologic Assessment of SARS-CoV-2 Infection**

**Generated On: 10 Jun 2021 07:56:44**

[Date of Collection](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 18:07:39
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 19:25:37
User signature succeeded.	Michael Koren (b) (4)	26 Apr 2021 15:25:40
User entered '20 Apr 2021'	(b) (4) Sheldon Warren (b) (4) (b) (4)	23 Apr 2021 19:16:29

**US3512248**

**Folder: Convalescence Visit Day 28 (1)**

**Form: Visit Date**

**Generated On: 10 Jun 2021 07:56:44**

[Was this visit performed?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 19:46:33
User signature succeeded.	Michael Koren (b) (4)	26 Feb 2021 20:02:47
User entered 'No (N)'	Brenda Anderson (b) (4)	24 Feb 2021 15:48:20

US3512248

Folder: Convalescence Visit Day 28 (1)

Form: Visit Date

Generated On: 10 Jun 2021 07:56:44

[Visit date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 19:46:33
User signature succeeded.	Michael Koren (b) (4)	26 Feb 2021 20:02:47
User entered empty.	Brenda Anderson (b) (4)	24 Feb 2021 15:48:20

US3512248

Folder: Convalescence Visit Day 28 (1)

Form: Visit Date

Generated On: 10 Jun 2021 07:56:44

[Was visit performed at the participant's home or at the clinic?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 19:46:33
User signature succeeded.	Michael Koren (b) (4)	26 Feb 2021 20:02:47
User entered empty.	Brenda Anderson (b) (4)	24 Feb 2021 15:48:20



**US3512248**

**Folder: Convalescence Visit Day 28 (1)**

**Form: Visit Date**

**Generated On: 10 Jun 2021 07:56:44**

[Folder OID](#)

Audit	User	Time (GMT)
User entered 'SICKD28'	System	24 Feb 2021 15:48:20

**US3512248**

**Folder: Convalescence Visit Day 28 (1)**

**Form: Visit Date**

**Generated On: 10 Jun 2021 07:56:44**

[Was this visit performed?](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	28 Apr 2021 21:04:50
	(b) (4)	
User entered 'No (N)'	Sheldon Warren (b) (4)	27 Apr 2021 16:36:06
	(b) (4)	

**US3512248**

**Folder: Convalescence Visit Day 28 (1)**

**Form: Visit Date**

**Generated On: 10 Jun 2021 07:56:44**

[Visit date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4) (b) (4)	28 Apr 2021 21:04:50
User entered empty.	Sheldon Warren (b) (4) (b) (4)	27 Apr 2021 16:36:06

**US3512248**

**Folder: Convalescence Visit Day 28 (1)**

**Form: Visit Date**

**Generated On: 10 Jun 2021 07:56:44**

[Was visit performed at the participant's home or at the clinic?](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	28 Apr 2021 21:04:50
	(b) (4)	
User entered empty.	Sheldon Warren (b) (4)	27 Apr 2021 16:36:06
	(b) (4)	

**US3512248**

**Folder: Convalescence Visit Day 28 (1)**

**Form: Visit Date**

**Generated On: 10 Jun 2021 07:56:44**

[Folder OID](#)

Audit	User	Time (GMT)
User entered 'SICKD28'	System	27 Apr 2021 16:36:06

US3512248

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 07:56:44

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	28 Apr 2021 21:04:50
	(b) (4)	
User entered 'No (N)'	Sheldon Warren (b) (4)	27 Apr 2021 16:36:14
	(b) (4)	

US3512248

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 07:56:44

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4) (b) (4)	28 Apr 2021 21:04:50
User entered empty.	Sheldon Warren (b) (4) (b) (4)	27 Apr 2021 16:36:14

**US3512248**

**Folder: Convalescence Visit Day 28 (1)**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 07:56:44**

**Time of assessment (00:00-23:59)**

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	28 Apr 2021 21:04:50
	(b) (4)	
User entered empty.	Sheldon Warren (b) (4)	27 Apr 2021 16:36:14
	(b) (4)	



**US3512248**

**Folder: Convalescence Visit Day 28 (1)**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 07:56:44**

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	27 Apr 2021 16:36:14

US3512248

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 07:56:44

Temperature (xxx.x)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4) (b) (4)	28 Apr 2021 21:04:50
User entered empty.	Sheldon Warren (b) (4) (b) (4)	27 Apr 2021 16:36:14

US3512248

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 07:56:44

[Route of measurement](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	28 Apr 2021 21:04:50
	(b) (4)	
User entered empty.	Sheldon Warren (b) (4)	27 Apr 2021 16:36:14
	(b) (4)	

US3512248

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 07:56:44

[If Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	28 Apr 2021 21:04:50
	(b) (4)	
User entered empty.	Sheldon Warren (b) (4)	27 Apr 2021 16:36:14
	(b) (4)	

US3512248

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 07:56:44

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	28 Apr 2021 21:04:50
	(b) (4)	
User entered empty.	Sheldon Warren (b) (4)	27 Apr 2021 16:36:14
	(b) (4)	

**US3512248**

**Folder: Convalescence Visit Day 28 (1)**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 07:56:44**

[Pulse units](#)

Audit	User	Time (GMT)
User entered empty.	System	27 Apr 2021 16:36:14

US3512248

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 07:56:44

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	28 Apr 2021 21:04:50
	(b) (4)	
User entered empty.	Sheldon Warren (b) (4)	27 Apr 2021 16:36:14
	(b) (4)	

**US3512248**

**Folder: Convalescence Visit Day 28 (1)**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 07:56:44**

[Respiratory Rate units](#)

Audit	User	Time (GMT)
User entered empty.	System	27 Apr 2021 16:36:14



US3512248

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 07:56:44

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	28 Apr 2021 21:04:50
	(b) (4)	
User entered empty.	Sheldon Warren (b) (4)	27 Apr 2021 16:36:14
	(b) (4)	

**US3512248**

**Folder: Convalescence Visit Day 28 (1)**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 07:56:44**

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered empty.	System	27 Apr 2021 16:36:14

US3512248

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 07:56:44

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	28 Apr 2021 21:04:50
	(b) (4)	
User entered empty.	Sheldon Warren (b) (4)	27 Apr 2021 16:36:14
	(b) (4)	

**US3512248**

**Folder: Convalescence Visit Day 28 (1)**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 07:56:44**

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered empty.	System	27 Apr 2021 16:36:14

**US3512248**

**Folder: Convalescence Visit Day 28 (1)**

**Form: Physical Examination**

**Generated On: 10 Jun 2021 07:56:44**

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	28 Apr 2021 21:04:50
	(b) (4)	
User entered 'No (N)'	Sheldon Warren (b) (4)	27 Apr 2021 16:36:20
	(b) (4)	

US3512248

Folder: Convalescence Visit Day 28 (1)

Form: Physical Examination

Generated On: 10 Jun 2021 07:56:44

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	28 Apr 2021 21:04:50
	(b) (4)	
User entered empty.	Sheldon Warren (b) (4)	27 Apr 2021 16:36:20
	(b) (4)	

US3512248

**Folder: Convalescence Visit Day 28 (1)**

**Form: Blood Sample Collection for Immunologic Assessment of SARS-CoV-2 Infection**

**Generated On: 10 Jun 2021 07:56:44**

[Was Blood Sample Taken for Immunologic Assessment of SARS\\_COV-2 Infection?](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	28 Apr 2021 21:04:50
	(b) (4)	
User entered 'NA (COVID-19 Negative) (NA)'	Sheldon Warren (b) (4)	27 Apr 2021 16:36:26
	(b) (4)	

US3512248

Folder: Convalescence Visit Day 28 (1)

Form: Blood Sample Collection for Immunologic Assessment of SARS-CoV-2 Infection

Generated On: 10 Jun 2021 07:56:44

[Date of Collection](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	28 Apr 2021 21:04:50
	(b) (4)	
User entered empty.	Sheldon Warren (b) (4)	27 Apr 2021 16:36:26
	(b) (4)	



**US3512248**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Visit Date**

**Generated On: 10 Jun 2021 07:56:44**

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:34:02
DataPoint Verified.	(b) (4), (b) (6)	10 Mar 2021 19:27:53
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 22:12:02
User entered 'Yes (Y)'	Brenda Anderson (b) (4)	20 Jan 2021 20:55:11

**US3512248**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Visit Date**

**Generated On: 10 Jun 2021 07:56:44**

[Visit date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:34:02
DataPoint Verified.	(b) (4), (b) (6)	10 Mar 2021 19:27:53
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 22:12:02
User entered '20 Jan 2021'	(b) (4) Brenda Anderson (b) (4)	20 Jan 2021 20:55:11

**US3512248**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Visit Date**

**Generated On: 10 Jun 2021 07:56:44**

[Was visit performed at the participant's home or at the clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:34:02
DataPoint Verified.	(b) (4), (b) (6)	10 Mar 2021 19:27:53
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 22:12:02
User entered 'Clinic (Clinic)'	Brenda Anderson (b) (4)	20 Jan 2021 20:55:11

**US3512248**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Visit Date**

**Generated On: 10 Jun 2021 07:56:44**

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:34:02
User entered 'UNBLND_DECIDE'	System	20 Jan 2021 20:55:11

US3512248

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 10 Jun 2021 07:56:44

Date of updated informed consent (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:34:02
DataPoint Verified.	(b) (4), (b) (6)	10 Mar 2021 19:28:28
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 22:12:02
User entered '20 Jan 2021'	(b) (4) Brenda Anderson (b) (4) (b) (4)	20 Jan 2021 20:55:40

**US3512248**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Unblinding**

**Generated On: 10 Jun 2021 07:56:44**

[N/A - Subject Unblinded under Amendment 5 and Discontinued from Study](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:34:02
User signature succeeded.	Michael Koren (b) (4)	19 Mar 2021 20:45:28
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Mar 2021 23:12:26
User entered '0'	Allison Crain (b) (4)	16 Mar 2021 15:07:23
Amendment Manager inserted this DataPoint.	(b) (4) System	06 Mar 2021 14:56:45

**US3512248**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Unblinding**

**Generated On: 10 Jun 2021 07:56:44**

[Was the participant unblinded?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:34:02
DataPoint Verified.	(b) (4), (b) (6)	10 Mar 2021 19:28:28
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 22:12:02
User entered 'Yes (Y)'	Brenda Anderson (b) (4)	20 Jan 2021 20:55:40

US3512248

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 10 Jun 2021 07:56:44

[Under what version of the Protocol was the Participant unblinded?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:34:02
User signature succeeded.	Michael Koren (b) (4)	19 Mar 2021 20:45:28
DataPoint Verified.	(b) (4)	16 Mar 2021 23:12:22
User closed query 'Data Required ' (Site from CRA).	(b) (4), (b) (6)	16 Mar 2021 23:12:20
Query 'Data Required ' answered with 'updated' (Site from CRA).	Allison Crain (b) (4)	16 Mar 2021 15:07:31
User entered 'Amendment 6 or later (Amendment 6 or later)'	(b) (4)	16 Mar 2021 15:07:23
User opened query 'Data Required ' (Site from CRA).	(b) (4), (b) (6)	10 Mar 2021 19:28:25
Amendment Manager inserted this DataPoint.	System	06 Mar 2021 14:56:45



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Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 10 Jun 2021 07:56:44

Date of unblinding (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:34:02
DataPoint Verified.	(b) (4), (b) (6)	10 Mar 2021 19:28:28
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 22:12:02
User entered '20 Jan 2021'	(b) (4) Brenda Anderson (b) (4) (b) (4)	20 Jan 2021 20:55:40

US3512248

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 10 Jun 2021 07:56:44

[Participant randomization assignment](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:34:02
DataPoint Verified.	(b) (4), (b) (6)	10 Mar 2021 19:28:28
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 22:12:02
User entered 'Placebo (Placebo)'	Brenda Anderson (b) (4)	20 Jan 2021 20:55:40

**US3512248**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Unblinding**

**Generated On: 10 Jun 2021 07:56:44**

[Actual Dose 1](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:34:02
DataPoint Verified.	(b) (4), (b) (6)	10 Mar 2021 19:28:28
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 22:12:02
User entered 'Placebo (Placebo)'	Brenda Anderson (b) (4)	20 Jan 2021 20:55:40

**US3512248**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Unblinding**

**Generated On: 10 Jun 2021 07:56:44**

[Actual Dose 2](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:34:02
DataPoint Verified.	(b) (4), (b) (6)	10 Mar 2021 19:28:28
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 22:12:02
User entered 'Placebo (Placebo)'	Brenda Anderson (b) (4)	20 Jan 2021 20:55:40

US3512248

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 10 Jun 2021 07:56:44

[Will participant receive mRNA-1273?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:34:02
DataPoint Verified.	(b) (4), (b) (6)	10 Mar 2021 19:28:28
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 22:12:02
User entered 'Yes (Y)'	Brenda Anderson (b) (4)	20 Jan 2021 20:55:40

**US3512248**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Unblinding**

**Generated On: 10 Jun 2021 07:56:44**

[Placebo Only Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:34:02
User entered '1'	System	20 Jan 2021 20:55:40

**US3512248**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Unblinding**

**Generated On: 10 Jun 2021 07:56:44**

[Continuing with mRNA-1273](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:34:02
User entered 'I'	System	20 Jan 2021 20:55:40

US3512248

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 07:56:44

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:34:02
DataPoint Verified.	(b) (4), (b) (6)	10 Mar 2021 19:28:59
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 22:12:02
User entered '71.0' in	(b) (4) Brenda Anderson (b) (4)	20 Jan 2021 21:00:23



US3512248

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 07:56:44

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:34:02
DataPoint Verified.	(b) (4), (b) (6)	10 Mar 2021 19:28:59
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 22:12:02
User entered '232.0' lb	(b) (4) Brenda Anderson (b) (4)	20 Jan 2021 21:00:23

US3512248

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 07:56:44

BMI (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:34:02
User entered '32.42509'	System	20 Jan 2021 21:00:23
DataPoint set to visible.	System	20 Jan 2021 20:55:40

**US3512248**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Vital Signs - Dosing**

**Generated On: 10 Jun 2021 07:56:44**

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:34:02
DataPoint Verified.	(b) (4), (b) (6)	10 Mar 2021 19:28:59
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 22:12:02
User entered '71.0' in	(b) (4) Brenda Anderson (b) (4)	20 Jan 2021 21:00:23

**US3512248**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Vital Signs - Dosing**

**Generated On: 10 Jun 2021 07:56:44**

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:34:02
DataPoint Verified.	(b) (4), (b) (6)	10 Mar 2021 19:28:59
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 22:12:02
User entered '232.0' lb	Brenda Anderson (b) (4)	20 Jan 2021 21:00:23

US3512248

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 07:56:44

BMI (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:34:02
User entered '32.42509'	System	20 Jan 2021 21:00:23
DataPoint set to visible.	System	20 Jan 2021 20:55:40

US3512248

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 07:56:44

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:34:02
User accepted default value 'Pre-Dose (PREDOSE)'	Brenda Anderson (b) (4)	20 Jan 2021 21:00:23
	(b) (4)	

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Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 07:56:44

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:34:02
DataPoint Verified.	(b) (4), (b) (6)	10 Mar 2021 19:28:59
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 22:12:02
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	20 Jan 2021 21:00:30
User entered 'Yes (Y)' reason for change: Data Entry Error	System	20 Jan 2021 21:00:30
User opened query 'Data is required. Please complete.' (Site from System).	Brenda Anderson (b) (4)	20 Jan 2021 21:00:30
User entered empty.	(b) (4)	
	System	20 Jan 2021 21:00:23
	Brenda Anderson (b) (4)	20 Jan 2021 21:00:23
	(b) (4)	

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Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 07:56:44

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:34:02
DataPoint Verified.	(b) (4), (b) (6)	10 Mar 2021 19:28:59
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 22:12:02
User entered '20 Jan 2021'	(b) (4) Brenda Anderson (b) (4) (b) (4)	20 Jan 2021 21:00:23



**US3512248**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 10 Jun 2021 07:56:44**

[Time of assessment \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:34:02
DataPoint Verified.	(b) (4), (b) (6)	10 Mar 2021 19:28:59
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 22:12:02
User entered '13:06'	(b) (4) Brenda Anderson (b) (4)	20 Jan 2021 21:00:23

**US3512248**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 10 Jun 2021 07:56:44**

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:34:02
User entered '20 Jan 2021 13:06'	System	20 Jan 2021 21:00:23

**US3512248**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 10 Jun 2021 07:56:44**

[Temperature \(xxx.x\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:34:02
DataPoint Verified.	(b) (4), (b) (6)	10 Mar 2021 19:28:59
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 22:12:02
User entered '97.5' F	(b) (4) Brenda Anderson (b) (4)	20 Jan 2021 21:00:23

**US3512248**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 10 Jun 2021 07:56:44**

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:34:02
DataPoint Verified.	(b) (4), (b) (6)	10 Mar 2021 19:28:59
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 22:12:02
User entered 'Oral (Oral)'	Brenda Anderson (b) (4)	20 Jan 2021 21:00:23

**US3512248**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 10 Jun 2021 07:56:44**

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:34:02
DataPoint Verified.	(b) (4), (b) (6)	10 Mar 2021 19:28:59
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 22:12:02
User entered empty.	(b) (4) Brenda Anderson (b) (4)	20 Jan 2021 21:00:23

**US3512248**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 10 Jun 2021 07:56:44**

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:34:02
DataPoint Verified.	(b) (4), (b) (6)	10 Mar 2021 19:28:59
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 22:12:02
User entered '64'	Brenda Anderson (b) (4)	20 Jan 2021 21:00:23

**US3512248**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 10 Jun 2021 07:56:44**

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:34:02
User entered 'bpm'	System	20 Jan 2021 21:00:23

US3512248

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 07:56:44

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:34:02
DataPoint Verified.	(b) (4), (b) (6)	10 Mar 2021 19:28:59
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 22:12:02
User entered '12'	(b) (4) Brenda Anderson (b) (4) (b) (4)	20 Jan 2021 21:00:23



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Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 07:56:44

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:34:02
User entered 'breaths/min'	System	20 Jan 2021 21:00:23

US3512248

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 07:56:44

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:34:02
DataPoint Verified.	(b) (4), (b) (6)	10 Mar 2021 19:28:59
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 22:12:02
User entered '126'	(b) (4) Brenda Anderson (b) (4)	20 Jan 2021 21:00:23

**US3512248**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 10 Jun 2021 07:56:44**

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:34:02
User entered 'mmHg'	System	20 Jan 2021 21:00:23

**US3512248**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 10 Jun 2021 07:56:44**

[Diastolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:34:02
DataPoint Verified.	(b) (4), (b) (6)	10 Mar 2021 19:28:59
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 22:12:02
User entered '71'	(b) (4) Brenda Anderson (b) (4)	20 Jan 2021 21:00:23

**US3512248**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 10 Jun 2021 07:56:44**

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:34:02
User entered 'mmHg'	System	20 Jan 2021 21:00:23

**US3512248**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Vital Signs - Dosing**

**Generated On: 10 Jun 2021 07:56:44**

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:34:02
DataPoint Verified.	(b) (4), (b) (6)	10 Mar 2021 19:28:59
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 22:12:02
User entered '71.0' in	(b) (4) Brenda Anderson (b) (4) (b) (4)	20 Jan 2021 21:00:23

**US3512248**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Vital Signs - Dosing**

**Generated On: 10 Jun 2021 07:56:44**

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:34:02
DataPoint Verified.	(b) (4), (b) (6)	10 Mar 2021 19:28:59
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 22:12:02
User entered '232.0' lb	Brenda Anderson (b) (4)	20 Jan 2021 21:00:23

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Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 07:56:44

BMI (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:34:02
User entered '32.42509'	System	20 Jan 2021 21:00:23
DataPoint set to visible.	System	20 Jan 2021 20:55:40



US3512248

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 07:56:44

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:34:02
User accepted default value 'Post-Dose (POSTDOSE)'	Brenda Anderson (b) (4) (b) (4)	20 Jan 2021 21:00:23

**US3512248**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 10 Jun 2021 07:56:44**

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:34:02
DataPoint Verified.	(b) (4), (b) (6)	10 Mar 2021 19:28:59
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 22:12:02
User entered 'Yes (Y)'	(b) (4) Brenda Anderson (b) (4)	20 Jan 2021 21:00:23

**US3512248**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 10 Jun 2021 07:56:44**

[Date of assessment \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:34:02
DataPoint Verified.	(b) (4), (b) (6)	10 Mar 2021 19:28:59
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 22:12:02
User entered '20 Jan 2021'	(b) (4) Brenda Anderson (b) (4)	20 Jan 2021 21:00:23

**US3512248**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 10 Jun 2021 07:56:44**

[Time of assessment \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:34:02
DataPoint Verified.	(b) (4), (b) (6)	10 Mar 2021 19:28:59
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 22:12:02
User entered '14:37'	(b) (4) Brenda Anderson (b) (4) (b) (4)	20 Jan 2021 21:00:23

**US3512248**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 10 Jun 2021 07:56:44**

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:34:02
User entered '20 Jan 2021 14:37'	System	20 Jan 2021 21:00:23

**US3512248**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 10 Jun 2021 07:56:44**

[Temperature \(xxx.x\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:34:02
DataPoint Verified.	(b) (4), (b) (6)	10 Mar 2021 19:28:59
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 22:12:02
User entered '97.4' F	(b) (4) Brenda Anderson (b) (4)	20 Jan 2021 21:00:23

**US3512248**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 10 Jun 2021 07:56:44**

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:34:02
DataPoint Verified.	(b) (4), (b) (6)	10 Mar 2021 19:28:59
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 22:12:02
User entered 'Oral (Oral)'	Brenda Anderson (b) (4)	20 Jan 2021 21:00:23

**US3512248**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 10 Jun 2021 07:56:44**

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:34:02
DataPoint Verified.	(b) (4), (b) (6)	10 Mar 2021 19:28:59
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 22:12:02
User entered empty.	(b) (4) Brenda Anderson (b) (4)	20 Jan 2021 21:00:23



**US3512248**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 10 Jun 2021 07:56:44**

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:34:02
DataPoint Verified.	(b) (4), (b) (6)	10 Mar 2021 19:28:59
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 22:12:02
User entered '65'	(b) (4) Brenda Anderson (b) (4)	20 Jan 2021 21:00:23

**US3512248**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 10 Jun 2021 07:56:44**

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:34:02
User entered 'bpm'	System	20 Jan 2021 21:00:23

US3512248

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 07:56:44

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:34:02
DataPoint Verified.	(b) (4), (b) (6)	10 Mar 2021 19:28:59
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 22:12:02
User entered '14'	(b) (4) Brenda Anderson (b) (4) (b) (4)	20 Jan 2021 21:00:23

**US3512248**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 10 Jun 2021 07:56:44**

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:34:02
User entered 'breaths/min'	System	20 Jan 2021 21:00:23

**US3512248**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 10 Jun 2021 07:56:44**

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:34:02
DataPoint Verified.	(b) (4), (b) (6)	10 Mar 2021 19:28:59
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 22:12:02
User entered '113'	Brenda Anderson (b) (4)	20 Jan 2021 21:00:23

**US3512248**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 10 Jun 2021 07:56:44**

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:34:02
User entered 'mmHg'	System	20 Jan 2021 21:00:23

US3512248

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 07:56:44

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:34:02
DataPoint Verified.	(b) (4), (b) (6)	10 Mar 2021 19:28:59
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 22:12:02
User closed query 'Diastolic Blood Pressure reported is out of range < 60 or > 110 per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' (Site from System).	(b) (4) (b) (4), (b) (6)	22 Jan 2021 06:50:49
Query 'Diastolic Blood Pressure reported is out of range < 60 or > 110 per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' answered with 'ncs per PI' (Site from System).	Brenda Anderson (b) (4) (b) (4)	20 Jan 2021 21:03:51
User opened query 'Diastolic Blood Pressure reported System is out of range < 60 or > 110 per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' (Site from System).		20 Jan 2021 21:00:23
User entered '59'	Brenda Anderson (b) (4) (b) (4)	20 Jan 2021 21:00:23

**US3512248**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 10 Jun 2021 07:56:44**

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:34:02
User entered 'mmHg'	System	20 Jan 2021 21:00:23



**US3512248**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Physical Examination**

**Generated On: 10 Jun 2021 07:56:44**

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:34:02
DataPoint Verified.	(b) (4), (b) (6)	10 Mar 2021 19:29:04
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 22:12:02
User entered 'Yes (Y)'	Brenda Anderson (b) (4)	20 Jan 2021 20:57:45

**US3512248**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Physical Examination**

**Generated On: 10 Jun 2021 07:56:44**

**Date of examination (dd MMM yyyy)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:34:02
DataPoint Verified.	(b) (4), (b) (6)	10 Mar 2021 19:29:04
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 22:12:02
User entered '20 Jan 2021'	Brenda Anderson (b) (4)	20 Jan 2021 20:57:45

**US3512248**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Exposure**

**Generated On: 10 Jun 2021 07:56:44**

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:34:02
DataPoint Verified.	(b) (4), (b) (6)	10 Mar 2021 19:29:08
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 22:12:02
User entered 'Yes (Y)'	Brenda Anderson (b) (4)	20 Jan 2021 20:57:39

**US3512248**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Exposure**

**Generated On: 10 Jun 2021 07:56:44**

[If No, reason not given](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:34:02
DataPoint Verified.	(b) (4), (b) (6)	10 Mar 2021 19:29:08
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 22:12:02
User entered empty.	Brenda Anderson (b) (4)	20 Jan 2021 20:57:39

US3512248

Folder: Participant Decision Visit / OL-D1 (1)

Form: Exposure

Generated On: 10 Jun 2021 07:56:44

If reason is Physician Decision, Withdrawal of Consent by Participant, Protocol Deviation, or Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:34:02
DataPoint Verified.	(b) (4), (b) (6)	10 Mar 2021 19:29:08
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 22:12:02
User entered empty.	Brenda Anderson (b) (4)	20 Jan 2021 20:57:39

US3512248

Folder: Participant Decision Visit / OL-D1 (1)

Form: Exposure

Generated On: 10 Jun 2021 07:56:44

[What was the study treatment? \(Unblinded\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:34:02
User entered 'mRNA-1273'	System	20 Jan 2021 20:57:39
DataPoint set to visible.	System	20 Jan 2021 20:55:40

US3512248

Folder: Participant Decision Visit / OL-D1 (1)

Form: Exposure

Generated On: 10 Jun 2021 07:56:44

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:34:02
DataPoint Verified.	(b) (4), (b) (6)	10 Mar 2021 19:29:08
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 22:12:02
User entered '20 Jan 2021'	(b) (4) Brenda Anderson (b) (4) (b) (4)	20 Jan 2021 20:57:39

US3512248

Folder: Participant Decision Visit / OL-D1 (1)

Form: Exposure

Generated On: 10 Jun 2021 07:56:44

[What was the treatment time? \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:34:02
DataPoint Verified.	(b) (4), (b) (6)	10 Mar 2021 19:29:08
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 22:12:02
User entered '13:53'	(b) (4) Brenda Anderson (b) (4) (b) (4)	20 Jan 2021 20:57:39



**US3512248**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Exposure**

**Generated On: 10 Jun 2021 07:56:44**

[Treatment Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:34:02
User entered '20 Jan 2021 13:53'	System	20 Jan 2021 20:57:39

US3512248

Folder: Participant Decision Visit / OL-D1 (1)

Form: Exposure

Generated On: 10 Jun 2021 07:56:44

[Which arm was used to give treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:34:02
DataPoint Verified.	(b) (4), (b) (6)	10 Mar 2021 19:29:08
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 22:12:02
User entered 'Left Arm (LEFT ARM)'	Brenda Anderson (b) (4)	20 Jan 2021 20:57:39

US3512248

Folder: Participant Decision Visit / OL-D1 (1)

Form: Exposure

Generated On: 10 Jun 2021 07:56:44

[What was the frequency of the study treatment dosing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:34:02
DataPoint Verified.	(b) (4), (b) (6)	10 Mar 2021 19:29:08
User entered 'ONCE'	System	20 Jan 2021 20:57:39

US3512248

Folder: Participant Decision Visit / OL-D1 (1)

Form: Exposure

Generated On: 10 Jun 2021 07:56:44

What was the route of administration for the study treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:34:02
User entered 'INTRAMUSCULAR'	System	20 Jan 2021 20:57:39

**US3512248**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Immunogenicity Assessment**

**Generated On: 10 Jun 2021 07:56:44**

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:34:02
DataPoint Verified.	(b) (4), (b) (6)	10 Mar 2021 19:30:03
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 22:12:02
User entered 'Yes (Y)'	Brenda Anderson (b) (4)	20 Jan 2021 20:55:52

**US3512248**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Immunogenicity Assessment**

**Generated On: 10 Jun 2021 07:56:44**

[Collection date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:34:02
DataPoint Verified.	(b) (4), (b) (6)	10 Mar 2021 19:30:03
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 22:12:02
User entered '20 Jan 2021'	(b) (4) Brenda Anderson (b) (4)	20 Jan 2021 20:55:52

**US3512248**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Immunogenicity Assessment**

**Generated On: 10 Jun 2021 07:56:44**

[Collection time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:34:02
DataPoint Verified.	(b) (4), (b) (6)	10 Mar 2021 19:30:03
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 22:12:02
User entered '12:53'	(b) (4) Brenda Anderson (b) (4)	20 Jan 2021 20:55:52

**US3512248**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Immunogenicity Assessment**

**Generated On: 10 Jun 2021 07:56:44**

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:34:02
User entered '20 Jan 2021 12:53'	System	20 Jan 2021 20:55:52



**US3512248**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Central Laboratory - Nasopharyngeal Swab (Single)**

**Generated On: 10 Jun 2021 07:56:44**

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:34:02
DataPoint Verified.	(b) (4), (b) (6)	10 Mar 2021 19:30:12
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 22:12:02
User entered 'Yes (Y)'	Brenda Anderson (b) (4)	20 Jan 2021 20:56:03

**US3512248**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Central Laboratory - Nasopharyngeal Swab (Single)**

**Generated On: 10 Jun 2021 07:56:44**

[Collection date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:34:02
DataPoint Verified.	(b) (4), (b) (6)	10 Mar 2021 19:30:12
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 22:12:02
User entered '20 Jan 2021'	(b) (4) Brenda Anderson (b) (4)	20 Jan 2021 20:56:03

**US3512248**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Central Laboratory - Nasopharyngeal Swab (Single)**

**Generated On: 10 Jun 2021 07:56:44**

[Collection time \(00:00 - 23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:34:02
DataPoint Verified.	(b) (4), (b) (6)	10 Mar 2021 19:30:12
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 22:12:02
User entered '12:41'	Brenda Anderson (b) (4)	20 Jan 2021 20:56:03

**US3512248**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Central Laboratory - Nasopharyngeal Swab (Single)**

**Generated On: 10 Jun 2021 07:56:44**

[Collection Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:34:02
User entered '20 Jan 2021 12:41'	System	20 Jan 2021 20:56:03

US3512248

Folder: Participant Decision Visit / OL-D1 (1)

Form: Continuing

Generated On: 10 Jun 2021 07:56:44

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:34:02
DataPoint Verified.	(b) (4), (b) (6)	10 Mar 2021 19:30:18
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 22:12:02
User entered 'Yes (Y)'	Brenda Anderson (b) (4)	20 Jan 2021 20:56:11

**US3512248**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Continuing**

**Generated On: 10 Jun 2021 07:56:44**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:34:02
User entered 'I'	System	20 Jan 2021 20:56:11

**US3512248**

**Folder: Safety Call OL-D8 (1)**

**Form: Safety Call**

**Generated On: 10 Jun 2021 07:56:44**

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 05:58:39
DataPoint Verified.	(b) (4), (b) (6)	10 Mar 2021 19:30:27
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 22:12:02
User entered 'Yes (Y)'	(b) (4) Sheldon Warren (b) (4) (b) (4)	27 Jan 2021 17:54:28

**US3512248**

**Folder: Safety Call OL-D8 (1)**

**Form: Safety Call**

**Generated On: 10 Jun 2021 07:56:44**

[Date of Contact or Contact Attempt \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 05:58:39
DataPoint Verified.	(b) (4), (b) (6)	10 Mar 2021 19:30:27
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 22:12:02
User entered '27 Jan 2021'	(b) (4) Sheldon Warren (b) (4) (b) (4)	27 Jan 2021 17:54:28



**US3512248**

**Folder: Safety Call OL-D8 (1)**

**Form: Safety Call**

**Generated On: 10 Jun 2021 07:56:44**

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 05:58:39
DataPoint Verified.	(b) (4), (b) (6)	10 Mar 2021 19:30:27
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 22:12:02
User entered 'Contact Made (CONTACT MADE)'	(b) (4) Sheldon Warren (b) (4) (b) (4)	27 Jan 2021 17:54:28

US3512248

Folder: Safety Call OL-D8 (1)

Form: Safety Call

Generated On: 10 Jun 2021 07:56:44

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 05:58:39
DataPoint Verified.	(b) (4), (b) (6)	10 Mar 2021 19:30:27
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 22:12:02
User entered empty.	(b) (4) Sheldon Warren (b) (4) (b) (4)	27 Jan 2021 17:54:28

**US3512248**

**Folder: Safety Call OL-D8 (1)**

**Form: Continuing**

**Generated On: 10 Jun 2021 07:56:44**

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 05:58:39
DataPoint Verified.	(b) (4), (b) (6)	10 Mar 2021 19:30:35
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 22:12:02
User entered 'Yes (Y)'	(b) (4) Sheldon Warren (b) (4) (b) (4)	27 Jan 2021 17:54:32

**US3512248**

**Folder: Safety Call OL-D8 (1)**

**Form: Continuing**

**Generated On: 10 Jun 2021 07:56:44**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 05:58:39
User entered 'I'	System	27 Jan 2021 17:54:32

**US3512248**

**Folder: Safety Call OL-D8 (1)**

**Form: Continuing**

**Generated On: 10 Jun 2021 07:56:44**

[OLD29 Placebo Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 05:58:39
User entered '1'	System	27 Jan 2021 17:54:32
DataPoint set to visible.	System	27 Jan 2021 17:54:32

**US3512248**

**Folder: OL-D29 (1)**

**Form: Visit Date**

**Generated On: 10 Jun 2021 07:56:44**

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:56:56
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 16:03:04
User signature succeeded.	Michael Koren (b) (4)	31 Mar 2021 17:34:59
User entered 'Yes (Y)'	(b) (4) Brenda Anderson (b) (4)	29 Mar 2021 17:42:06

US3512248

Folder: OL-D29 (1)

Form: Visit Date

Generated On: 10 Jun 2021 07:56:44

Visit date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:56:56
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 16:03:04
User signature succeeded.	Michael Koren (b) (4)	31 Mar 2021 17:34:59
User closed query 'Per CDM Re-query: Site response noted. However, site reports Date of OL-Day 29 was completed on 25Mar2021, which is outside the Window Allowance for this visit. Please verify data and update Visit Date, else clarify why it has taken place outside the allowed window. Thank you.' (Site from DM).	(b) (4) (b) (4), (b) (6)	31 Mar 2021 10:58:38
Query 'Per CDM Re-query: Site response noted. However, site reports Date of OL-Day 29 was completed on 25Mar2021, which is outside the Window Allowance for this visit. Please verify data and update Visit Date, else clarify why it has taken place outside the allowed window. Thank you.' answered with 'Due to SAE septic join' (Site from DM).	Allison Crain (b) (4) (b) (4)	30 Mar 2021 15:30:24
User opened query 'Per CDM Re-query: Site response noted. However, site reports Date of OL-Day 29 was completed on 25Mar2021, which is outside the Window Allowance for this visit. Please verify data and update Visit Date, else clarify why it has taken place outside the allowed window. Thank you.' (Site from DM).	(b) (4), (b) (6)	30 Mar 2021 02:55:12
User closed query 'OL-D29 Visit Date is < 25 days or > 42 days after the Participant Decision visit vaccination. Please reconcile or confirm dates.' (Site from System).	(b) (4), (b) (6)	30 Mar 2021 02:54:13
Query 'OL-D29 Visit Date is < 25 days or > 42 days after the Participant Decision visit vaccination. Please reconcile or confirm dates.' answered with 'acknowledge' (Site from System).	Brenda Anderson (b) (4) (b) (4)	29 Mar 2021 17:43:06
User opened query 'OL-D29 Visit Date is < 25 days or > 42 days after the Participant Decision visit vaccination. Please reconcile or confirm dates.' (Site from System).	System	29 Mar 2021 17:42:06
User entered '25 Mar 2021'	Brenda Anderson (b) (4) (b) (4)	29 Mar 2021 17:42:06

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**US3512248**

**Folder: OL-D29 (1)**

**Form: Visit Date**

**Generated On: 10 Jun 2021 07:56:44**

[Was visit performed at the participant's home or at the clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:56:56
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 16:03:04
User signature succeeded.	Michael Koren (b) (4)	31 Mar 2021 17:34:59
User entered 'Clinic (Clinic)'	Brenda Anderson (b) (4)	29 Mar 2021 17:42:06



**US3512248**

**Folder: OL-D29 (1)**

**Form: Visit Date**

**Generated On: 10 Jun 2021 07:56:44**

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:56:56
User entered 'OLD29'	System	29 Mar 2021 17:42:06

**US3512248**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 10 Jun 2021 07:56:44**

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:56:56
User accepted default value 'Pre-Dose (PREDOSE)'	Brenda Anderson (b) (4)	29 Mar 2021 17:44:36

**US3512248**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 10 Jun 2021 07:56:44**

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:56:56
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 16:03:08
User signature succeeded.	Michael Koren (b) (4)	31 Mar 2021 17:34:59
User entered 'Yes (Y)'	(b) (4) Brenda Anderson (b) (4)	29 Mar 2021 17:44:36

**US3512248**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 10 Jun 2021 07:56:44**

**Date of assessment** (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:56:56
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 16:03:08
User signature succeeded.	Michael Koren (b) (4)	31 Mar 2021 17:34:59
User entered '25 Mar 2021'	(b) (4) Brenda Anderson (b) (4)	29 Mar 2021 17:44:36

**US3512248**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 10 Jun 2021 07:56:44**

**Time of assessment (00:00-23:59)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:56:56
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 16:03:08
User signature succeeded.	Michael Koren (b) (4)	31 Mar 2021 17:34:59
User entered '13:44'	(b) (4) Brenda Anderson (b) (4) (b) (4)	29 Mar 2021 17:44:36

**US3512248**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 10 Jun 2021 07:56:44**

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:56:56
User entered '25 Mar 2021 13:44'	System	29 Mar 2021 17:44:36

US3512248

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 07:56:44

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:56:56
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 16:03:08
User signature succeeded.	Michael Koren (b) (4)	31 Mar 2021 17:34:59
User entered '97.2' F	(b) (4) Brenda Anderson (b) (4)	29 Mar 2021 17:44:36

US3512248

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 07:56:44

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:56:56
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 16:03:08
User signature succeeded.	Michael Koren (b) (4)	31 Mar 2021 17:34:59
User entered 'Oral (Oral)'	(b) (4) Brenda Anderson (b) (4) (b) (4)	29 Mar 2021 17:44:36



**US3512248**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 10 Jun 2021 07:56:44**

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:56:56
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 16:03:08
User signature succeeded.	Michael Koren (b) (4)	31 Mar 2021 17:34:59
User entered empty.	(b) (4) Brenda Anderson (b) (4)	29 Mar 2021 17:44:36

**US3512248**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 10 Jun 2021 07:56:44**

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:56:56
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 16:03:08
User signature succeeded.	Michael Koren (b) (4)	31 Mar 2021 17:34:59
User entered '63'	(b) (4) Brenda Anderson (b) (4)	29 Mar 2021 17:44:36

**US3512248**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 10 Jun 2021 07:56:44**

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:56:56
User entered 'bpm'	System	29 Mar 2021 17:44:36

US3512248

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 07:56:44

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:56:56
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 16:03:08
User signature succeeded.	Michael Koren (b) (4)	31 Mar 2021 17:34:59
User entered '18'	(b) (4) Brenda Anderson (b) (4)	29 Mar 2021 17:44:36

**US3512248**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 10 Jun 2021 07:56:44**

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:56:56
User entered 'breaths/min'	System	29 Mar 2021 17:44:36

US3512248

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 07:56:44

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:56:56
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 16:03:08
User signature succeeded.	Michael Koren (b) (4)	31 Mar 2021 17:34:59
User entered '142'	(b) (4) Brenda Anderson (b) (4)	29 Mar 2021 17:44:36

**US3512248**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 10 Jun 2021 07:56:44**

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:56:56
User entered 'mmHg'	System	29 Mar 2021 17:44:36

US3512248

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 07:56:44

[Diastolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:56:56
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 16:03:08
User signature succeeded.	Michael Koren (b) (4)	31 Mar 2021 17:34:59
User entered '78'	(b) (4) Brenda Anderson (b) (4) (b) (4)	29 Mar 2021 17:44:36



**US3512248**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 10 Jun 2021 07:56:44**

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:56:56
User entered 'mmHg'	System	29 Mar 2021 17:44:36

US3512248

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 07:56:44

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:56:56
User accepted default value 'Post-Dose (POSTDOSE)'	Brenda Anderson (b) (4) (b) (4)	29 Mar 2021 17:44:36

**US3512248**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 10 Jun 2021 07:56:44**

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:56:56
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 16:03:08
User signature succeeded.	Michael Koren (b) (4)	31 Mar 2021 17:34:59
User entered 'No (N)'	(b) (4) Brenda Anderson (b) (4)	29 Mar 2021 17:44:36

US3512248

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 07:56:44

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:56:56
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 16:03:08
User signature succeeded.	Michael Koren (b) (4)	31 Mar 2021 17:34:59
User entered empty.	(b) (4) Brenda Anderson (b) (4) (b) (4)	29 Mar 2021 17:44:36

**US3512248**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 10 Jun 2021 07:56:44**

**Time of assessment (00:00-23:59)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:56:56
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 16:03:08
User signature succeeded.	Michael Koren (b) (4)	31 Mar 2021 17:34:59
User entered empty.	(b) (4) Brenda Anderson (b) (4)	29 Mar 2021 17:44:36

**US3512248**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 10 Jun 2021 07:56:44**

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:56:56
User entered empty.	System	29 Mar 2021 17:44:36

US3512248

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 07:56:44

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:56:56
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 16:03:08
User signature succeeded.	Michael Koren (b) (4)	31 Mar 2021 17:34:59
User entered empty.	(b) (4) Brenda Anderson (b) (4)	29 Mar 2021 17:44:36
	(b) (4)	

**US3512248**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 10 Jun 2021 07:56:44**

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:56:56
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 16:03:08
User signature succeeded.	Michael Koren (b) (4)	31 Mar 2021 17:34:59
User entered empty.	(b) (4) Brenda Anderson (b) (4)	29 Mar 2021 17:44:36



**US3512248**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 10 Jun 2021 07:56:44**

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:56:56
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 16:03:08
User signature succeeded.	Michael Koren (b) (4)	31 Mar 2021 17:34:59
User entered empty.	(b) (4) Brenda Anderson (b) (4)	29 Mar 2021 17:44:36

US3512248

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 07:56:44

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:56:56
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 16:03:08
User signature succeeded.	Michael Koren (b) (4)	31 Mar 2021 17:34:59
User entered empty.	(b) (4) Brenda Anderson (b) (4)	29 Mar 2021 17:44:36
	(b) (4)	

**US3512248**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 10 Jun 2021 07:56:44**

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:56:56
User entered empty.	System	29 Mar 2021 17:44:36

US3512248

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 07:56:44

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:56:56
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 16:03:08
User signature succeeded.	Michael Koren (b) (4)	31 Mar 2021 17:34:59
User entered empty.	Brenda Anderson (b) (4)	29 Mar 2021 17:44:36

**US3512248**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 10 Jun 2021 07:56:44**

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:56:56
User entered empty.	System	29 Mar 2021 17:44:36

US3512248

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 07:56:44

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:56:56
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 16:03:08
User signature succeeded.	Michael Koren (b) (4)	31 Mar 2021 17:34:59
User entered empty.	(b) (4) Brenda Anderson (b) (4)	29 Mar 2021 17:44:36
	(b) (4)	

**US3512248**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 10 Jun 2021 07:56:44**

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:56:56
User entered empty.	System	29 Mar 2021 17:44:36

US3512248

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 07:56:44

[Diastolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:56:56
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 16:03:08
User signature succeeded.	Michael Koren (b) (4)	31 Mar 2021 17:34:59
User entered empty.	(b) (4) Brenda Anderson (b) (4)	29 Mar 2021 17:44:36
	(b) (4)	



**US3512248**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 10 Jun 2021 07:56:44**

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:56:56
User entered empty.	System	29 Mar 2021 17:44:36

**US3512248**

**Folder: OL-D29 (1)**

**Form: Physical Examination**

**Generated On: 10 Jun 2021 07:56:44**

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:56:56
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 16:03:15
User signature succeeded.	Michael Koren (b) (4)	31 Mar 2021 17:34:59
User entered 'Yes (Y)'	(b) (4) Brenda Anderson (b) (4)	29 Mar 2021 17:44:53

**US3512248**

**Folder: OL-D29 (1)**

**Form: Physical Examination**

**Generated On: 10 Jun 2021 07:56:44**

**Date of examination (dd MMM yyyy)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:56:56
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 16:03:15
User signature succeeded.	Michael Koren (b) (4)	31 Mar 2021 17:34:59
User entered '25 Mar 2021'	(b) (4) Brenda Anderson (b) (4) (b) (4)	29 Mar 2021 17:44:53

US3512248

Folder: OL-D29 (1)

Form: Exposure

Generated On: 10 Jun 2021 07:56:44

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:56:56
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 16:03:25
User signature succeeded.	Michael Koren (b) (4)	31 Mar 2021 17:34:59
User entered 'No (N)'	(b) (4) Brenda Anderson (b) (4)	29 Mar 2021 17:46:40
	(b) (4)	

US3512248

Folder: OL-D29 (1)

Form: Exposure

Generated On: 10 Jun 2021 07:56:44

[If No, reason not given](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:56:56
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 16:03:25
User signature succeeded.	Michael Koren (b) (4)	31 Mar 2021 17:34:59
User entered 'Physician withheld dose due to Adverse Event (PHYSICIAN AE)'	(b) (4) Brenda Anderson (b) (4)	29 Mar 2021 17:46:40

US3512248

Folder: OL-D29 (1)

Form: Exposure

Generated On: 10 Jun 2021 07:56:44

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)	30 Apr 2021 14:56:56
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 16:03:25
User signature succeeded.	Michael Koren (b) (4)	31 Mar 2021 17:34:59
User entered 'due to septic arthritis in the left elbow both PI and PMD advised pt not to have 2nd vaccine'	(b) (4) Brenda Anderson (b) (4)	29 Mar 2021 17:46:40

**US3512248**

**Folder: OL-D29 (1)**

**Form: Exposure**

**Generated On: 10 Jun 2021 07:56:44**

[What was the study treatment? \(Unblinded\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:56:56
User entered empty.	System	29 Mar 2021 17:46:40
DataPoint set to visible.	System	27 Jan 2021 17:54:32

US3512248

Folder: OL-D29 (1)

Form: Exposure

Generated On: 10 Jun 2021 07:56:44

[What was the treatment date? \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:56:56
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 16:03:25
User signature succeeded.	Michael Koren (b) (4)	31 Mar 2021 17:34:59
User entered empty.	(b) (4) Brenda Anderson (b) (4)	29 Mar 2021 17:46:40
	(b) (4)	



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Folder: OL-D29 (1)

Form: Exposure

Generated On: 10 Jun 2021 07:56:44

[What was the treatment time? \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:56:56
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 16:03:25
User signature succeeded.	Michael Koren (b) (4)	31 Mar 2021 17:34:59
User entered empty.	(b) (4) Brenda Anderson (b) (4)	29 Mar 2021 17:46:40
	(b) (4)	

**US3512248**

**Folder: OL-D29 (1)**

**Form: Exposure**

**Generated On: 10 Jun 2021 07:56:44**

[Treatment Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:56:56
User entered empty.	System	29 Mar 2021 17:46:40

**US3512248**

**Folder: OL-D29 (1)**

**Form: Exposure**

**Generated On: 10 Jun 2021 07:56:44**

[Which arm was used to give treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:56:56
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 16:03:25
User signature succeeded.	Michael Koren (b) (4)	31 Mar 2021 17:34:59
User entered empty.	(b) (4) Brenda Anderson (b) (4)	29 Mar 2021 17:46:40

US3512248

Folder: OL-D29 (1)

Form: Exposure

Generated On: 10 Jun 2021 07:56:44

[What was the frequency of the study treatment dosing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:56:56
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 16:03:25
User entered empty.	System	29 Mar 2021 17:46:40

US3512248

Folder: OL-D29 (1)

Form: Exposure

Generated On: 10 Jun 2021 07:56:44

What was the route of administration for the study treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:56:56
User entered empty.	System	29 Mar 2021 17:46:40

**US3512248**

**Folder: OL-D29 (1)**

**Form: Continuing**

**Generated On: 10 Jun 2021 07:56:44**

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:56:56
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 16:03:30
User signature succeeded.	Michael Koren (b) (4)	31 Mar 2021 17:34:59
User entered 'Yes (Y)'	(b) (4) Brenda Anderson (b) (4)	29 Mar 2021 17:46:48

**US3512248**

**Folder: OL-D29 (1)**

**Form: Continuing**

**Generated On: 10 Jun 2021 07:56:44**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:56:56
User entered 'I'	System	29 Mar 2021 17:46:48

US3512248

Folder: Safety Call OL-D36 (1)

Form: Safety Call

Generated On: 10 Jun 2021 07:56:44

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 16:02:40
User signature succeeded.	Michael Koren (b) (4)	02 Apr 2021 19:30:27
User closed query 'Per CDM: Response noted. Data is required and Kindly consider to keep query open till data is updated.' (Site from DM).	(b) (4)	
Query 'Per CDM: Response noted. Data is required and Kindly consider to keep query open till data is updated.' answered with 'data has been entered OL-d29 occurred on 25 Mar 2021' (Site from DM).	(b) (4), (b) (6)	02 Apr 2021 08:05:04
User entered 'Yes (Y)' reason for change: Data Entry Error	Sheldon Warren (b) (4)	01 Apr 2021 16:52:54
User opened query 'Per CDM: Response noted. Data is required and Kindly consider to keep query open till data is updated.' (Site from DM).	(b) (4)	
User closed query 'Per CDM: Please update the data for the Safety call OL-Day 36.' (Site from DM).	(b) (4), (b) (6)	01 Apr 2021 16:51:45
Query 'Per CDM: Please update the data for the Safety call OL-Day 36.' answered with 'OL-D36 phone call scheduled for 01 April 2021. Visit has not occurred yet' (Site from DM).	Sheldon Warren (b) (4)	31 Mar 2021 09:47:31
User opened query 'Per CDM: Please update the data for the Safety call OL-Day 36.' (Site from DM).	(b) (4), (b) (6)	31 Mar 2021 09:47:31
User closed query 'Data is required. Please complete.' (Site from System).	Allison Crain (b) (4)	30 Mar 2021 14:56:39
Query 'Data is required. Please complete.' answered with 'not done yet, OL-d36 done on 25 Mar, 2021' (Site from System).	(b) (4)	
User opened query 'Data is required. Please complete.' (Site from System).	(b) (4), (b) (6)	30 Mar 2021 02:57:20
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4), (b) (6)	30 Mar 2021 02:56:01
Query 'Data is required. Please complete.' answered with 'not done yet, OL-d36 done on 25 Mar, 2021' (Site from System).	Sheldon Warren (b) (4)	29 Mar 2021 18:16:24
User opened query 'Data is required. Please complete.' (Site from System).	(b) (4)	
User entered empty; reason for change Data Entry Error	System	29 Mar 2021 18:15:52
User entered 'No (N)'	Sheldon Warren (b) (4)	29 Mar 2021 18:15:52
	(b) (4)	
	Brenda Anderson (b) (4)	29 Mar 2021 17:54:32
	(b) (4)	



**US3512248**

**Folder: Safety Call OL-D36 (1)**

**Form: Safety Call**

**Generated On: 10 Jun 2021 07:56:44**

[Date of Contact or Contact Attempt \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 16:02:40
User signature succeeded.	Michael Koren (b) (4)	02 Apr 2021 19:30:27
User entered '1 Apr 2021' reason for change: Data Entry Error	Sheldon Warren (b) (4)	01 Apr 2021 16:51:45
User entered empty.	Brenda Anderson (b) (4)	29 Mar 2021 17:54:32

**US3512248**

**Folder: Safety Call OL-D36 (1)**

**Form: Safety Call**

**Generated On: 10 Jun 2021 07:56:44**

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 16:02:40
User signature succeeded.	Michael Koren (b) (4)	02 Apr 2021 19:30:27
User entered 'Contact Made (CONTACT MADE)'	(b) (4)	
reason for change: Data Entry Error	Sheldon Warren (b) (4)	01 Apr 2021 16:51:45
User entered empty.	(b) (4)	
	Brenda Anderson (b) (4)	29 Mar 2021 17:54:32
	(b) (4)	

**US3512248**

**Folder: Safety Call OL-D36 (1)**

**Form: Safety Call**

**Generated On: 10 Jun 2021 07:56:44**

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 16:02:40
User signature succeeded.	Michael Koren (b) (4)	02 Apr 2021 19:30:27
User entered empty.	Brenda Anderson (b) (4)	29 Mar 2021 17:54:32

US3512248

Folder: Safety Call OL-D36 (1)

Form: Continuing

Generated On: 10 Jun 2021 07:56:44

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 16:02:46
User signature succeeded.	Michael Koren (b) (4)	02 Apr 2021 19:30:27
Signature has been broken.	Sheldon Warren (b) (4)	01 Apr 2021 23:12:36
User entered 'Yes (Y)' reason for change: Data Entry Error	Sheldon Warren (b) (4)	01 Apr 2021 23:12:36
User signature succeeded.	Michael Koren (b) (4)	31 Mar 2021 17:34:59
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4), (b) (6)	31 Mar 2021 09:48:18
Query 'Data is required. Please complete.' answered with 'phone call has not occurred yet' (Site from System).	Allison Crain (b) (4)	30 Mar 2021 14:57:03
User opened query 'Data is required. Please complete.' (Site from System).	System	30 Mar 2021 14:56:50
User entered empty; reason for change Data Entry Error	Allison Crain (b) (4)	30 Mar 2021 14:56:50
User entered 'Yes (Y)'	Brenda Anderson (b) (4)	29 Mar 2021 18:02:27

**US3512248**

**Folder: Safety Call OL-D36 (1)**

**Form: Continuing**

**Generated On: 10 Jun 2021 07:56:44**

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered 'I'	System	01 Apr 2021 23:12:36
User entered empty.	System	30 Mar 2021 14:56:50
User entered 'I'	System	29 Mar 2021 18:02:27

**US3512248**

**Folder: OL-D57 (1)**

**Form: Visit Date**

**Generated On: 10 Jun 2021 07:56:44**

[Was this visit performed?](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	03 May 2021 15:14:06
	(b) (4)	
User entered 'Yes (Y)'	Brenda Anderson (b) (4)	29 Apr 2021 15:34:25
	(b) (4)	

**US3512248**

**Folder: OL-D57 (1)**

**Form: Visit Date**

**Generated On: 10 Jun 2021 07:56:44**

[Visit date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	03 May 2021 15:14:06
	(b) (4)	
User entered '28 Apr 2021'	Brenda Anderson (b) (4)	29 Apr 2021 15:34:25
	(b) (4)	

**US3512248**

**Folder: OL-D57 (1)**

**Form: Visit Date**

**Generated On: 10 Jun 2021 07:56:44**

[Was visit performed at the participant's home or at the clinic?](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	03 May 2021 15:14:06
	(b) (4)	
User entered 'Clinic (Clinic)'	Brenda Anderson (b) (4)	29 Apr 2021 15:34:25
	(b) (4)	



**US3512248**

**Folder: OL-D57 (1)**

**Form: Visit Date**

**Generated On: 10 Jun 2021 07:56:44**

[Folder OID](#)

Audit	User	Time (GMT)
User entered 'OLD57'	System	29 Apr 2021 15:34:25

**US3512248**

**Folder: OL-D57 (1)**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 07:56:44**

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	03 May 2021 15:14:06
	(b) (4)	
User entered 'No (N)'	Brenda Anderson (b) (4)	29 Apr 2021 15:34:28
	(b) (4)	

**US3512248**

**Folder: OL-D57 (1)**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 07:56:44**

**Date of assessment** (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	03 May 2021 15:14:06
	(b) (4)	
User entered empty.	Brenda Anderson (b) (4)	29 Apr 2021 15:34:28
	(b) (4)	

**US3512248**

**Folder: OL-D57 (1)**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 07:56:44**

**Time of assessment (00:00-23:59)**

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4) (b) (4)	03 May 2021 15:14:06
User entered empty.	Brenda Anderson (b) (4) (b) (4)	29 Apr 2021 15:34:28

**US3512248**

**Folder: OL-D57 (1)**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 07:56:44**

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	29 Apr 2021 15:34:28

**US3512248**

**Folder: OL-D57 (1)**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 07:56:44**

[Temperature \(xxx.x\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	03 May 2021 15:14:06
	(b) (4)	
User entered empty.	Brenda Anderson (b) (4)	29 Apr 2021 15:34:28
	(b) (4)	

**US3512248**

**Folder: OL-D57 (1)**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 07:56:44**

[Route of measurement](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4) (b) (4)	03 May 2021 15:14:06
User entered empty.	Brenda Anderson (b) (4) (b) (4)	29 Apr 2021 15:34:28

**US3512248**

**Folder: OL-D57 (1)**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 07:56:44**

[If Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	03 May 2021 15:14:06
	(b) (4)	
User entered empty.	Brenda Anderson (b) (4)	29 Apr 2021 15:34:28
	(b) (4)	



**US3512248**

**Folder: OL-D57 (1)**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 07:56:44**

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	03 May 2021 15:14:06
	(b) (4)	
User entered empty.	Brenda Anderson (b) (4)	29 Apr 2021 15:34:28
	(b) (4)	

**US3512248**

**Folder: OL-D57 (1)**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 07:56:44**

[Pulse units](#)

Audit	User	Time (GMT)
User entered empty.	System	29 Apr 2021 15:34:28

**US3512248**

**Folder: OL-D57 (1)**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 07:56:44**

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	03 May 2021 15:14:06
	(b) (4)	
User entered empty.	Brenda Anderson (b) (4)	29 Apr 2021 15:34:28
	(b) (4)	

**US3512248**

**Folder: OL-D57 (1)**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 07:56:44**

[Respiratory Rate units](#)

Audit	User	Time (GMT)
User entered empty.	System	29 Apr 2021 15:34:28

**US3512248**

**Folder: OL-D57 (1)**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 07:56:44**

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	03 May 2021 15:14:06
	(b) (4)	
User entered empty.	Brenda Anderson (b) (4)	29 Apr 2021 15:34:28
	(b) (4)	

**US3512248**

**Folder: OL-D57 (1)**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 07:56:44**

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered empty.	System	29 Apr 2021 15:34:28

**US3512248**

**Folder: OL-D57 (1)**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 07:56:44**

[Diastolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	03 May 2021 15:14:06
	(b) (4)	
User entered empty.	Brenda Anderson (b) (4)	29 Apr 2021 15:34:28
	(b) (4)	

**US3512248**

**Folder: OL-D57 (1)**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 07:56:44**

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered empty.	System	29 Apr 2021 15:34:28



**US3512248**

**Folder: OL-D57 (1)**

**Form: Physical Examination**

**Generated On: 10 Jun 2021 07:56:44**

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	03 May 2021 15:14:06
	(b) (4)	
User entered 'No (N)'	Brenda Anderson (b) (4)	29 Apr 2021 15:34:31
	(b) (4)	

**US3512248**

**Folder: OL-D57 (1)**

**Form: Physical Examination**

**Generated On: 10 Jun 2021 07:56:44**

**Date of examination (dd MMM yyyy)**

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	03 May 2021 15:14:06
	(b) (4)	
User entered empty.	Brenda Anderson (b) (4)	29 Apr 2021 15:34:31
	(b) (4)	

**US3512248**

**Folder: OL-D57 (1)**

**Form: Immunogenicity Assessment**

**Generated On: 10 Jun 2021 07:56:44**

[Was the sample collected?](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	03 May 2021 15:14:06
	(b) (4)	
User entered 'Yes (Y)'	Brenda Anderson (b) (4)	29 Apr 2021 15:34:47
	(b) (4)	

**US3512248**

**Folder: OL-D57 (1)**

**Form: Immunogenicity Assessment**

**Generated On: 10 Jun 2021 07:56:44**

[Collection date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	03 May 2021 15:14:06
	(b) (4)	
User entered '28 Apr 2021'	Brenda Anderson (b) (4)	29 Apr 2021 15:34:47
	(b) (4)	

**US3512248**

**Folder: OL-D57 (1)**

**Form: Immunogenicity Assessment**

**Generated On: 10 Jun 2021 07:56:44**

[Collection time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	03 May 2021 15:14:06
	(b) (4)	
User entered '12:52'	Brenda Anderson (b) (4)	29 Apr 2021 15:34:47
	(b) (4)	

**US3512248**

**Folder: OL-D57 (1)**

**Form: Immunogenicity Assessment**

**Generated On: 10 Jun 2021 07:56:44**

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered '28 Apr 2021 12:52'	System	29 Apr 2021 15:34:47

US3512248

Folder: Adverse Events

Form: Adverse Events Summary

Generated On: 10 Jun 2021 07:56:44

[Did the participant experience any adverse events?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 07:34:28
User closed query 'Per protocol any Solicited local or systemic AR lasting beyond 7 days post-injection must be entered into the participant's source document and must also be recorded as an AE in the participant's Adverse Event eCRF. Per subject's DOSE 2 diary, JOINT ACHES lasting beyond day 7 post injection. Please reconcile and enter event as needed per Completion Guidelines (page 47/48) and ensure SAR box is checked.' (Site from DM).	(b) (4), (b) (6)	20 Apr 2021 11:08:40
Query 'Per protocol any Solicited local or systemic AR lasting beyond 7 days post-injection must be entered into the participant's source document and must also be recorded as an AE in the participant's Adverse Event eCRF. Per subject's DOSE 2 diary, JOINT ACHES lasting beyond day 7 post injection. Please reconcile and enter event as needed per Completion Guidelines (page 47/48) and ensure SAR box is checked.' answered with 'per source pt has a history of OA and the joint ache is not any different than his normal joint aches. please let site know if you still want it reported as an AE.' (Site from DM).	Brenda Anderson (b) (4) (b) (4)	19 Apr 2021 13:18:15
User opened query 'Per protocol any Solicited local or systemic AR lasting beyond 7 days post-injection must be entered into the participant's source document and must also be recorded as an AE in the participant's Adverse Event eCRF. Per subject's DOSE 2 diary, JOINT ACHES lasting beyond day 7 post injection. Please reconcile and enter event as needed per Completion Guidelines (page 47/48) and ensure SAR box is checked.' (Site from DM).	(b) (4), (b) (6)	17 Apr 2021 17:54:22
User signature succeeded.	Michael Koren (b) (4) (b) (4)	12 Feb 2021 22:12:02
DataPoint Verified.	(b) (4), (b) (6)	14 Dec 2020 16:39:56
User entered 'Yes (Y)'	Brenda Anderson (b) (4) (b) (4)	16 Nov 2020 19:37:33

**US3512248**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 10 Jun 2021 07:56:44**

[AEID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Apr 2021 17:18:28



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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 07:56:44

[Adverse event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Apr 2021 17:18:28
User signature succeeded.	Michael Koren (b) (4)	15 Mar 2021 12:52:32
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Mar 2021 13:41:02
User coded data point as SOC: Musculoskeletal and connective tissue disorders, HLGT: Synovial and bursal disorders, HLT: Bursal disorders, PT: Bursitis, LLT: Trochanteric bursitis - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	24 Feb 2021 17:48:59
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	24 Feb 2021 17:48:59
Data point term sent to Coder	System	24 Feb 2021 15:34:08
DataPoint Un-verified.	Brenda Anderson (b) (4)	24 Feb 2021 15:33:48
Coding entries removed.	(b) (4) Brenda Anderson (b) (4)	24 Feb 2021 15:33:48
Signature has been broken.	(b) (4) Brenda Anderson (b) (4)	24 Feb 2021 15:33:48
User entered 'RIGHT HIP TROCHANTERIC BURSITIS' reason for change: New Information	Brenda Anderson (b) (4)	24 Feb 2021 15:33:48
User signature succeeded.	(b) (4) Michael Koren (b) (4)	12 Feb 2021 22:12:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Dec 2020 16:40:14
User coded data point as SOC: Musculoskeletal and connective tissue disorders, HLGT: Joint disorders, HLT: Joint related signs and symptoms, PT: Arthralgia, LLT: Pain in hip - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	17 Nov 2020 01:31:53
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	17 Nov 2020 01:31:53
Data point term sent to Coder	System	16 Nov 2020 19:39:53
User entered 'right lateral hip pain'	Brenda Anderson (b) (4) (b) (4)	16 Nov 2020 19:39:27

**US3512248**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 10 Jun 2021 07:56:44**

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Apr 2021 17:18:28
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 22:12:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Dec 2020 16:40:14
User entered 'Yes (Y)' reason for change: Data Entry Error	Brenda Anderson (b) (4)	16 Nov 2020 19:45:12
User entered 'No (N)'	(b) (4) Brenda Anderson (b) (4)	16 Nov 2020 19:39:27
	(b) (4)	

**US3512248**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 10 Jun 2021 07:56:44**

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Apr 2021 17:18:28
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 22:12:02
DataPoint Verified.	(b) (4)	(b) (4), (b) (6)
	(b) (4), (b) (6)	14 Dec 2020 16:40:14
User entered 'No (N)'	Brenda Anderson (b) (4)	16 Nov 2020 19:39:27
	(b) (4)	

**US3512248**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 10 Jun 2021 07:56:44**

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Apr 2021 17:18:28
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 22:12:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Dec 2020 16:40:14
User entered 'No (N)'	Brenda Anderson (b) (4) (b) (4)	16 Nov 2020 19:39:27

**US3512248**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 10 Jun 2021 07:56:44**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Apr 2021 17:18:28
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 22:12:02
DataPoint Verified.	(b) (4)	(b) (4), (b) (6)
	(b) (4), (b) (6)	14 Dec 2020 16:40:14
User entered '5 Oct 2020'	Brenda Anderson (b) (4)	16 Nov 2020 19:39:27
	(b) (4)	

**US3512248**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 10 Jun 2021 07:56:44**

[Start time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Apr 2021 17:18:28
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 22:12:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Dec 2020 16:40:14
User entered empty.	Brenda Anderson (b) (4) (b) (4)	16 Nov 2020 19:39:27

**US3512248**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 10 Jun 2021 07:56:44**

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Apr 2021 17:18:28
User entered empty.	System	16 Nov 2020 19:39:27

US3512248

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 07:56:44

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Apr 2021 17:18:28
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 22:12:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Dec 2020 16:40:14
User closed query 'Ongoing is Yes, but End Date is provided. Please correct.' (Site from System).	System	16 Nov 2020 19:39:38
User entered 'No (N)' reason for change: Data Entry Error	Brenda Anderson (b) (4) (b) (4)	16 Nov 2020 19:39:38
User opened query 'Ongoing is Yes, but End Date is provided. Please correct.' (Site from System).	System	16 Nov 2020 19:39:27
User entered 'Yes (Y)'	Brenda Anderson (b) (4) (b) (4)	16 Nov 2020 19:39:27



**US3512248**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 10 Jun 2021 07:56:44**

*If not Ongoing, end date (dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Apr 2021 17:18:28
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 22:12:02
DataPoint Verified.	(b) (4)	(b) (4), (b) (6)
	(b) (4), (b) (6)	14 Dec 2020 16:40:14
User entered '5 Oct 2020'	Brenda Anderson (b) (4)	16 Nov 2020 19:39:27
	(b) (4)	

**US3512248**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 10 Jun 2021 07:56:44**

[End time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Apr 2021 17:18:28
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 22:12:02
DataPoint Verified.	(b) (4)	(b) (4), (b) (6)
	(b) (4), (b) (6)	14 Dec 2020 16:40:14
User entered empty.	Brenda Anderson (b) (4)	16 Nov 2020 19:39:27
	(b) (4)	

**US3512248**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 10 Jun 2021 07:56:44**

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Apr 2021 17:18:28
User entered empty.	System	16 Nov 2020 19:39:27

US3512248

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 07:56:44

[Severity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Apr 2021 17:18:28
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 22:12:02
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	14 Dec 2020 16:40:14
User entered 'Grade 2/Moderate (Grade 2/Moderate)'	Brenda Anderson (b) (4)	16 Nov 2020 19:39:27
	(b) (4)	

US3512248

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 07:56:44

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Apr 2021 17:18:28
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 22:12:02
DataPoint Verified.	(b) (4)	(b) (4), (b) (6)
	(b) (4), (b) (6)	14 Dec 2020 16:40:14
User entered 'No (N)'	Brenda Anderson (b) (4)	16 Nov 2020 19:39:27
	(b) (4)	

**US3512248**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 10 Jun 2021 07:56:44**

[Death](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Apr 2021 17:18:28
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 22:12:02
DataPoint Verified.	(b) (4)	(b) (4), (b) (6)
	(b) (4), (b) (6)	14 Dec 2020 16:40:14
User entered '0'	Brenda Anderson (b) (4)	16 Nov 2020 19:39:27
	(b) (4)	

**US3512248**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 10 Jun 2021 07:56:44**

[Life threatening](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Apr 2021 17:18:28
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 22:12:02
DataPoint Verified.	(b) (4)	(b) (4), (b) (6)
	(b) (4), (b) (6)	14 Dec 2020 16:40:14
User entered '0'	Brenda Anderson (b) (4)	16 Nov 2020 19:39:27
	(b) (4)	

**US3512248**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 10 Jun 2021 07:56:44**

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Apr 2021 17:18:28
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 22:12:02
DataPoint Verified.	(b) (4)	(b) (4), (b) (6)
	(b) (4), (b) (6)	14 Dec 2020 16:40:14
User entered '0'	Brenda Anderson (b) (4)	16 Nov 2020 19:39:27
	(b) (4)	



**US3512248**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 10 Jun 2021 07:56:44**

[Hospital Admission Date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Apr 2021 17:18:28
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 22:12:02
DataPoint Verified.	(b) (4)	(b) (4), (b) (6)
User entered empty.	Brenda Anderson (b) (4)	16 Nov 2020 19:39:27

**US3512248**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 10 Jun 2021 07:56:44**

[Hospital Discharge Date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Apr 2021 17:18:28
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 22:12:02
DataPoint Verified.	(b) (4)	(b) (4), (b) (6)
	(b) (4), (b) (6)	14 Dec 2020 16:40:14
User entered empty.	Brenda Anderson (b) (4)	16 Nov 2020 19:39:27
	(b) (4)	

**US3512248**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 10 Jun 2021 07:56:44**

[Admitted to ICU?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Apr 2021 17:18:28
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 22:12:02
DataPoint Verified.	(b) (4)	(b) (4), (b) (6)
User entered empty.	Brenda Anderson (b) (4)	16 Nov 2020 19:39:27
	(b) (4)	

**US3512248**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 10 Jun 2021 07:56:44**

[Number of Days in ICU](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Apr 2021 17:18:28
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 22:12:02
DataPoint Verified.	(b) (4)	(b) (4), (b) (6)
	(b) (4), (b) (6)	14 Dec 2020 16:40:14
User entered empty.	Brenda Anderson (b) (4)	16 Nov 2020 19:39:27
	(b) (4)	

US3512248

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 07:56:44

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Apr 2021 17:18:28
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 22:12:02
DataPoint Verified.	(b) (4)	(b) (4), (b) (6)
	(b) (4), (b) (6)	14 Dec 2020 16:40:14
User entered '0'	Brenda Anderson (b) (4)	16 Nov 2020 19:39:27
	(b) (4)	

**US3512248**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 10 Jun 2021 07:56:44**

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Apr 2021 17:18:28
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 22:12:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Dec 2020 16:40:14
User entered '0'	Brenda Anderson (b) (4) (b) (4)	16 Nov 2020 19:39:27

**US3512248**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 10 Jun 2021 07:56:44**

[Other medically important event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Apr 2021 17:18:28
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 22:12:02
DataPoint Verified.	(b) (4)	(b) (4), (b) (6)
	(b) (4), (b) (6)	14 Dec 2020 16:40:14
User entered '0'	Brenda Anderson (b) (4)	16 Nov 2020 19:39:27
	(b) (4)	

US3512248

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 07:56:44

[Relationship to investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Apr 2021 17:18:28
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 22:12:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Dec 2020 16:40:14
User closed query 'Data is required. Please complete.' (Site from System).	System	16 Nov 2020 19:41:27
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	16 Nov 2020 19:41:27
User entered 'Not Related (NOT RELATED)' reason for change: Data Entry Error	Brenda Anderson (b) (4) (b) (4)	16 Nov 2020 19:41:27
User opened query 'Data is required. Please complete.' (Site from System).	System	16 Nov 2020 19:39:27
User entered empty.	Brenda Anderson (b) (4) (b) (4)	16 Nov 2020 19:39:27



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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 07:56:44

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Apr 2021 17:18:28
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 22:12:02
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	14 Dec 2020 16:40:14
User closed query 'Data is required. Please complete.' (Site from System).	System	20 Nov 2020 20:36:32
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	20 Nov 2020 20:36:32
User entered 'Not Related (NOT RELATED)' reason for change: Data Entry Error	Brenda Anderson (b) (4)	20 Nov 2020 20:36:32
	(b) (4)	
User opened query 'Data is required. Please complete.' (Site from System).	System	16 Nov 2020 19:39:27
User entered empty.	Brenda Anderson (b) (4)	16 Nov 2020 19:39:27
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 07:56:44

Action taken with investigational product

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Apr 2021 17:18:28
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 22:12:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Dec 2020 16:40:14
User closed query 'Data is required. Please complete.' (Site from System).	System	16 Nov 2020 19:41:27
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	16 Nov 2020 19:41:27
User entered 'None (NONE)' reason for change: Data Entry Error	Brenda Anderson (b) (4) (b) (4)	16 Nov 2020 19:41:27
User opened query 'Data is required. Please complete.' (Site from System).	System	16 Nov 2020 19:39:27
User entered empty.	Brenda Anderson (b) (4) (b) (4)	16 Nov 2020 19:39:27

US3512248

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 07:56:44

None

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	20 Apr 2021 12:50:37
	(b) (4)	
Signature has been broken.	Brenda Anderson (b) (4)	19 Apr 2021 13:11:45
	(b) (4)	
Data hard locked.	(b) (4), (b) (6)	05 Apr 2021 17:18:28
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 22:12:02
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	14 Dec 2020 16:40:14
User entered '0'	Brenda Anderson (b) (4)	16 Nov 2020 19:39:27
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 07:56:44

[Concomitant Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Apr 2021 17:18:28
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 22:12:02
DataPoint Verified.	(b) (4)	(b) (4), (b) (6)
	(b) (4), (b) (6)	14 Dec 2020 16:40:14
User entered 'l'	Brenda Anderson (b) (4)	16 Nov 2020 19:39:27
	(b) (4)	

**US3512248**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 10 Jun 2021 07:56:44**

[Concomitant Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Apr 2021 17:18:28
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 22:12:02
DataPoint Verified.	(b) (4)	(b) (4), (b) (6)
	(b) (4), (b) (6)	14 Dec 2020 16:40:14
User entered '0'	Brenda Anderson (b) (4)	16 Nov 2020 19:39:27
	(b) (4)	

**US3512248**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 10 Jun 2021 07:56:44**

[Outcome](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Apr 2021 17:18:28
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 22:12:02
DataPoint Verified.	(b) (4)	(b) (4), (b) (6)
	(b) (4), (b) (6)	14 Dec 2020 16:40:14
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)'	Brenda Anderson (b) (4)	16 Nov 2020 19:39:27
	(b) (4)	

**US3512248**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 10 Jun 2021 07:56:44**

[If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Apr 2021 17:18:28
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 22:12:02
DataPoint Verified.	(b) (4)	(b) (4), (b) (6)
User entered empty.	Brenda Anderson (b) (4)	16 Nov 2020 19:39:27
	(b) (4)	

**US3512248**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 10 Jun 2021 07:56:44**

[Narrative](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Apr 2021 17:18:28
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 22:12:02
DataPoint Verified.	(b) (4)	(b) (4), (b) (6)
User entered empty.	Brenda Anderson (b) (4)	16 Nov 2020 19:39:27
	(b) (4)	



**US3512248**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 10 Jun 2021 07:56:44**

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Apr 2021 17:18:28
User entered '0'	System	16 Nov 2020 19:39:27

**US3512248**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 10 Jun 2021 07:56:44**

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Apr 2021 17:18:28
User entered '1'	System	16 Nov 2020 19:45:12
User entered '0'	System	16 Nov 2020 19:39:27

**US3512248**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 10 Jun 2021 07:56:44**

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Apr 2021 17:18:28

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 07:56:44

[Adverse event](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 22:12:02
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	14 Dec 2020 16:40:14
User coded data point as SOC: Vascular disorders, HLT: Vascular hypertensive disorders, HLT: Vascular hypertensive disorders NEC, PT: Hypertension, LLT: Hypertension - version MedDRA\\23.0.	Coder Import (b) (4)	16 Nov 2020 19:47:10
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	16 Nov 2020 19:47:10
Data point term sent to Coder	System	16 Nov 2020 19:46:04
User entered 'hypertension'	Brenda Anderson (b) (4)	16 Nov 2020 19:45:58
	(b) (4)	

**US3512248**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 10 Jun 2021 07:56:44**

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 22:12:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Dec 2020 16:40:14
User entered 'Yes (Y)'	Brenda Anderson (b) (4) (b) (4)	16 Nov 2020 19:45:58

**US3512248**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 10 Jun 2021 07:56:44**

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 22:12:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Dec 2020 16:40:14
User entered 'No (N)'	Brenda Anderson (b) (4) (b) (4)	16 Nov 2020 19:45:58

**US3512248**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 10 Jun 2021 07:56:44**

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 22:12:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Dec 2020 16:40:14
User entered 'No (N)'	Brenda Anderson (b) (4) (b) (4)	16 Nov 2020 19:45:58

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 07:56:44

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 22:12:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Dec 2020 16:40:14
User entered '17 Sep 2020'	Brenda Anderson (b) (4) (b) (4)	16 Nov 2020 19:45:58



**US3512248**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 10 Jun 2021 07:56:44**

[Start time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 22:12:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Dec 2020 16:40:14
User entered empty.	Brenda Anderson (b) (4) (b) (4)	16 Nov 2020 19:45:58

**US3512248**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 10 Jun 2021 07:56:44**

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	16 Nov 2020 19:45:58

**US3512248**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 10 Jun 2021 07:56:44**

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 22:12:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Dec 2020 16:40:14
User entered 'Yes (Y)'	Brenda Anderson (b) (4) (b) (4)	16 Nov 2020 19:45:58

**US3512248**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 10 Jun 2021 07:56:44**

*If not Ongoing, end date (dd MMM yyyy)*

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 22:12:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Dec 2020 16:40:14
User entered empty.	Brenda Anderson (b) (4) (b) (4)	16 Nov 2020 19:45:58

**US3512248**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 10 Jun 2021 07:56:44**

[End time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 22:12:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Dec 2020 16:40:14
User entered empty.	Brenda Anderson (b) (4) (b) (4)	16 Nov 2020 19:45:58

**US3512248**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 10 Jun 2021 07:56:44**

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	16 Nov 2020 19:45:58

**US3512248**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 10 Jun 2021 07:56:44**

[Severity](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 22:12:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Dec 2020 16:40:14
User entered 'Grade 2/Moderate (Grade 2/Moderate)'	Brenda Anderson (b) (4) (b) (4)	16 Nov 2020 19:45:58

US3512248

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 07:56:44

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 22:12:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Dec 2020 16:40:14
User entered 'No (N)'	Brenda Anderson (b) (4) (b) (4)	16 Nov 2020 19:45:58



**US3512248**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 10 Jun 2021 07:56:44**

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 22:12:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Dec 2020 16:40:14
User entered '0'	Brenda Anderson (b) (4) (b) (4)	16 Nov 2020 19:45:58

**US3512248**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 10 Jun 2021 07:56:44**

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 22:12:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Dec 2020 16:40:14
User entered '0'	Brenda Anderson (b) (4) (b) (4)	16 Nov 2020 19:45:58

**US3512248**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 10 Jun 2021 07:56:44**

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 22:12:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Dec 2020 16:40:14
User entered '0'	Brenda Anderson (b) (4) (b) (4)	16 Nov 2020 19:45:58

US3512248

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 07:56:44

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 22:12:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Dec 2020 16:40:14
User entered empty.	Brenda Anderson (b) (4) (b) (4)	16 Nov 2020 19:45:58

**US3512248**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 10 Jun 2021 07:56:44**

**Hospital Discharge Date (dd MMM yyyy)**

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 22:12:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Dec 2020 16:40:14
User entered empty.	Brenda Anderson (b) (4) (b) (4)	16 Nov 2020 19:45:58

**US3512248**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 10 Jun 2021 07:56:44**

[Admitted to ICU?](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 22:12:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Dec 2020 16:40:14
User entered empty.	Brenda Anderson (b) (4) (b) (4)	16 Nov 2020 19:45:58

US3512248

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 07:56:44

[Number of Days in ICU](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 22:12:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Dec 2020 16:40:14
User entered empty.	Brenda Anderson (b) (4) (b) (4)	16 Nov 2020 19:45:58

US3512248

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 07:56:44

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 22:12:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Dec 2020 16:40:14
User entered '0'	Brenda Anderson (b) (4) (b) (4)	16 Nov 2020 19:45:58



**US3512248**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 10 Jun 2021 07:56:44**

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 22:12:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Dec 2020 16:40:14
User entered '0'	Brenda Anderson (b) (4) (b) (4)	16 Nov 2020 19:45:58

**US3512248**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 10 Jun 2021 07:56:44**

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 22:12:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Dec 2020 16:40:14
User entered '0'	Brenda Anderson (b) (4) (b) (4)	16 Nov 2020 19:45:58

**US3512248**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 10 Jun 2021 07:56:44**

[Relationship to investigational product](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 22:12:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Dec 2020 16:40:14
User entered 'Not Related (NOT RELATED)'	Brenda Anderson (b) (4) (b) (4)	16 Nov 2020 19:45:58

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 07:56:44

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 22:12:02
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	14 Dec 2020 16:40:14
User closed query 'Data is required. Please complete.' (Site from System).	System	20 Nov 2020 20:36:54
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	20 Nov 2020 20:36:54
User entered 'Not Related (NOT RELATED)' reason for change: Data Entry Error	Brenda Anderson (b) (4)	20 Nov 2020 20:36:54
	(b) (4)	
User opened query 'Data is required. Please complete.' (Site from System).	System	16 Nov 2020 19:45:58
User entered empty.	Brenda Anderson (b) (4)	16 Nov 2020 19:45:58
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 07:56:44

[Action taken with investigational product](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 22:12:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Dec 2020 16:40:14
User closed query 'Data is required. Please complete.' (Site from System).	System	20 Nov 2020 20:37:07
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	20 Nov 2020 20:37:07
User entered 'None (NONE)' reason for change: Data Entry Error	Brenda Anderson (b) (4) (b) (4)	20 Nov 2020 20:37:07
User opened query 'Data is required. Please complete.' (Site from System).	System	16 Nov 2020 19:45:58
User entered empty.	Brenda Anderson (b) (4) (b) (4)	16 Nov 2020 19:45:58

**US3512248**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 10 Jun 2021 07:56:44**

[None](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 22:12:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Dec 2020 16:40:14
User entered '0'	Brenda Anderson (b) (4) (b) (4)	16 Nov 2020 19:45:58

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**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 10 Jun 2021 07:56:44**

[Concomitant Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 22:12:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Dec 2020 16:40:14
User entered 'I'	Brenda Anderson (b) (4) (b) (4)	16 Nov 2020 19:45:58

**US3512248**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 10 Jun 2021 07:56:44**

[Concomitant Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 22:12:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Dec 2020 16:40:14
User entered '0'	Brenda Anderson (b) (4) (b) (4)	16 Nov 2020 19:45:58



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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 07:56:44

[Outcome](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 22:12:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Dec 2020 16:40:14
User closed query 'Data is required. Please complete.' (Site from System).	System	20 Nov 2020 20:36:54
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	20 Nov 2020 20:36:54
User entered 'Not Recovered/Not Resolved (NOT RECOVERED/NOT RESOLVED)' reason for change: Data Entry Error	Brenda Anderson (b) (4) (b) (4)	20 Nov 2020 20:36:54
User opened query 'Data is required. Please complete.' (Site from System).	System	16 Nov 2020 19:45:58
User entered empty.	Brenda Anderson (b) (4) (b) (4)	16 Nov 2020 19:45:58

**US3512248**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 10 Jun 2021 07:56:44**

[If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 22:12:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Dec 2020 16:40:14
User entered empty.	Brenda Anderson (b) (4) (b) (4)	16 Nov 2020 19:45:58

**US3512248**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 10 Jun 2021 07:56:44**

[Narrative](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 22:12:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Dec 2020 16:40:14
User entered empty.	Brenda Anderson (b) (4) (b) (4)	16 Nov 2020 19:45:58

**US3512248**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 10 Jun 2021 07:56:44**

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '0'	System	16 Nov 2020 19:45:58

**US3512248**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 10 Jun 2021 07:56:44**

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered 'I'	System	16 Nov 2020 19:45:58

US3512248

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 07:56:44

[Adverse event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 19:47:25
User signature succeeded.	Michael Koren (b) (4)	15 Mar 2021 12:52:32
User closed query 'Per DM CLR: Please review if this AE is a worsening of the MH condition of Keratosis on Bilateral Arms and Legs. If yes, please update to reflect the term worsening as appropriate and ensure that Severity is greater than Grade 1/Mild. Please update applicable details as appropriate or provide clarification.' (Site from DM).	(b) (4) (b) (4), (b) (6)	15 Mar 2021 09:43:10
User coded data point as SOC: Skin and subcutaneous tissue disorders, HLGT: Cornification and dystrophic skin disorders, HLT: Skin preneoplastic conditions NEC, PT: Actinic keratosis, LLT: Actinic keratosis - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	15 Mar 2021 06:11:52
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	15 Mar 2021 06:11:52
Query 'Per DM CLR: Please review if this AE is a worsening of the MH condition of Keratosis on Bilateral Arms and Legs. If yes, please update to reflect the term worsening as appropriate and ensure that Severity is greater than Grade 1/Mild. Please update applicable details as appropriate or provide clarification.' answered with 'Updated' (Site from DM).	(b) (4), (b) (6)	12 Mar 2021 18:26:58
Data point term sent to Coder	System	12 Mar 2021 18:24:46
DataPoint Un-verified.	(b) (4), (b) (6)	12 Mar 2021 18:24:41
Coding entries removed.	(b) (4), (b) (6)	12 Mar 2021 18:24:41
Signature has been broken.	(b) (4), (b) (6)	12 Mar 2021 18:24:41
User entered 'Worsened RIGHT TEMPLE AND LEFT FOREARM ACTINIC KERATOSIS' reason for change: Data Entry Error	(b) (4), (b) (6)	12 Mar 2021 18:24:41
DataPoint Verified.	(b) (4), (b) (6)	12 Mar 2021 13:41:02

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 07:56:44

[Adverse event](#)

Audit	User	Time (GMT)
User opened query 'Per DM CLR: Please review if this AE is a worsening of the MH condition of Keratosis on Bilateral Arms and Legs. If yes, please update to reflect the term worsening as appropriate and ensure that Severity is greater than Grade 1/Mild. Please update applicable details as appropriate or provide clarification.' (Site from DM). User signature succeeded.	(b) (4), (b) (6) Michael Koren (b) (4)	22 Feb 2021 12:58:50 12 Feb 2021 22:12:02
User coded data point as SOC: Skin and subcutaneous tissue disorders, HLGT: Cornification and dystrophic skin disorders, HLT: Skin preneoplastic conditions NEC, PT: Actinic keratosis, LLT: Actinic keratosis - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	08 Feb 2021 00:24:56
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	08 Feb 2021 00:24:56
Data point term sent to Coder	System	03 Feb 2021 20:10:20
User entered 'right temple and left forearm actinic keratosis'	Sheldon Warren (b) (4) (b) (4)	03 Feb 2021 20:09:57

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**Folder: Adverse Events**

**Form: Adverse Events (3)**

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[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Mar 2021 13:41:02
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 22:12:02
User entered 'No (N)'	Sheldon Warren (b) (4)	03 Feb 2021 20:09:57



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**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 10 Jun 2021 07:56:44**

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Mar 2021 13:41:02
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 22:12:02
User entered 'No (N)'	Sheldon Warren (b) (4)	03 Feb 2021 20:09:57

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**Folder: Adverse Events**

**Form: Adverse Events (3)**

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[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Mar 2021 13:41:02
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 22:12:02
User entered 'No (N)'	Sheldon Warren (b) (4)	03 Feb 2021 20:09:57

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Folder: Adverse Events

Form: Adverse Events (3)

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Start date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Mar 2021 13:41:02
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 22:12:02
User entered '3 Feb 2021'	Sheldon Warren (b) (4)	03 Feb 2021 20:09:57

**US3512248**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 10 Jun 2021 07:56:44**

[Start time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Mar 2021 13:41:02
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 22:12:02
User entered empty.	Sheldon Warren (b) (4)	03 Feb 2021 20:09:57

**US3512248**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

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[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	03 Feb 2021 20:09:57

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**Folder: Adverse Events**

**Form: Adverse Events (3)**

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[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Mar 2021 13:41:02
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 22:12:02
User entered 'No (N)'	Sheldon Warren (b) (4)	03 Feb 2021 20:09:57

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**Folder: Adverse Events**

**Form: Adverse Events (3)**

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*If not Ongoing, end date (dd MMM yyyy)*

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Mar 2021 13:41:02
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 22:12:02
User entered '3 Feb 2021'	Sheldon Warren (b) (4)	03 Feb 2021 20:09:57

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**Folder: Adverse Events**

**Form: Adverse Events (3)**

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[End time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Mar 2021 13:41:02
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 22:12:02
User entered empty.	Sheldon Warren (b) (4)	03 Feb 2021 20:09:57



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**Folder: Adverse Events**

**Form: Adverse Events (3)**

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[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	03 Feb 2021 20:09:57

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Folder: Adverse Events

Form: Adverse Events (3)

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[Severity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 19:47:25
User signature succeeded.	Michael Koren (b) (4)	15 Mar 2021 12:52:32
DataPoint Un-verified.	(b) (4)	12 Mar 2021 18:24:41
Signature has been broken.	(b) (4), (b) (6)	12 Mar 2021 18:24:41
User entered 'Grade 2/Moderate (Grade 2/Moderate)'	(b) (4), (b) (6)	12 Mar 2021 18:24:41
reason for change: Data Entry Error	(b) (4), (b) (6)	12 Mar 2021 13:41:02
DataPoint Verified.	(b) (4), (b) (6)	12 Mar 2021 13:41:02
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 22:12:02
User entered 'Grade 1/Mild (Grade 1/Mild)'	Sheldon Warren (b) (4)	03 Feb 2021 20:09:57

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**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 10 Jun 2021 07:56:44**

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Mar 2021 13:41:02
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 22:12:02
User entered 'No (N)'	Sheldon Warren (b) (4)	03 Feb 2021 20:09:57

**US3512248**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 10 Jun 2021 07:56:44**

[Death](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Mar 2021 13:41:02
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 22:12:02
User entered '0'	Sheldon Warren (b) (4)	03 Feb 2021 20:09:57

**US3512248**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

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[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Mar 2021 13:41:02
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 22:12:02
User entered '0'	Sheldon Warren (b) (4)	03 Feb 2021 20:09:57

**US3512248**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 10 Jun 2021 07:56:44**

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Mar 2021 13:41:02
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 22:12:02
User entered '0'	Sheldon Warren (b) (4)	03 Feb 2021 20:09:57

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Folder: Adverse Events

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Generated On: 10 Jun 2021 07:56:44

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Mar 2021 13:41:02
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 22:12:02
User entered empty.	Sheldon Warren (b) (4)	03 Feb 2021 20:09:57

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**Form: Adverse Events (3)**

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[Hospital Discharge Date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Mar 2021 13:41:02
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 22:12:02
User entered empty.	Sheldon Warren (b) (4)	03 Feb 2021 20:09:57



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[Admitted to ICU?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Mar 2021 13:41:02
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 22:12:02
User entered empty.	Sheldon Warren (b) (4)	03 Feb 2021 20:09:57

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**Folder: Adverse Events**

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[Number of Days in ICU](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Mar 2021 13:41:02
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 22:12:02
User entered empty.	Sheldon Warren (b) (4)	03 Feb 2021 20:09:57

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**Folder: Adverse Events**

**Form: Adverse Events (3)**

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[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Mar 2021 13:41:02
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 22:12:02
User entered '0'	Sheldon Warren (b) (4)	03 Feb 2021 20:09:57

**US3512248**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 10 Jun 2021 07:56:44**

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Mar 2021 13:41:02
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 22:12:02
User entered '0'	Sheldon Warren (b) (4)	03 Feb 2021 20:09:57

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**Folder: Adverse Events**

**Form: Adverse Events (3)**

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[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Mar 2021 13:41:02
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 22:12:02
User entered '0'	Sheldon Warren (b) (4)	03 Feb 2021 20:09:57

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**Folder: Adverse Events**

**Form: Adverse Events (3)**

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[Relationship to investigational product](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Mar 2021 13:41:02
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 22:12:02
User entered 'Not Related (NOT RELATED)'	Sheldon Warren (b) (4)	03 Feb 2021 20:09:57

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**Folder: Adverse Events**

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**Generated On: 10 Jun 2021 07:56:44**

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Mar 2021 13:41:02
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 22:12:02
User entered 'Not Related (NOT RELATED)'	Sheldon Warren (b) (4)	03 Feb 2021 20:09:57

**US3512248**

**Folder: Adverse Events**

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[Action taken with investigational product](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Mar 2021 13:41:02
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 22:12:02
User entered 'None (NONE)'	Sheldon Warren (b) (4)	03 Feb 2021 20:09:57



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**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 10 Jun 2021 07:56:44**

[None](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Mar 2021 13:41:02
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 22:12:02
User entered '0'	Sheldon Warren (b) (4)	03 Feb 2021 20:09:57

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**Folder: Adverse Events**

**Form: Adverse Events (3)**

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[Concomitant Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Mar 2021 13:41:02
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 22:12:02
User entered '0'	Sheldon Warren (b) (4)	03 Feb 2021 20:09:57

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[Concomitant Procedure](#)

Audit	User	Time (GMT)
User closed query 'Per DM CLR: Other Action Taken = ConProc. However, the corresponding Concomitant Procedure record is not indicated for AE. Please reconcile with ConProc eCRF and update Indication accordingly. Otherwise, clarify.' (Site from DM).	(b) (4), (b) (6)	18 Mar 2021 05:46:18
Query 'Per DM CLR: Other Action Taken = ConProc. However, the corresponding Concomitant Procedure record is not indicated for AE. Please reconcile with ConProc eCRF and update Indication accordingly. Otherwise, clarify.' answered with 'Concomitant Procedure entry corrected to AE' (Site from DM).	(b) (4), (b) (6)	12 Mar 2021 18:26:50
DataPoint Verified.	(b) (4), (b) (6)	12 Mar 2021 13:41:02
User opened query 'Per DM CLR: Other Action Taken = ConProc. However, the corresponding Concomitant Procedure record is not indicated for AE. Please reconcile with ConProc eCRF and update Indication accordingly. Otherwise, clarify.' (Site from DM).	(b) (4), (b) (6)	22 Feb 2021 12:59:25
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 22:12:02
User entered 'I'	(b) (4) Sheldon Warren (b) (4)	03 Feb 2021 20:09:57

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**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 10 Jun 2021 07:56:44**

[Outcome](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Mar 2021 13:41:02
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 22:12:02
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)'	Sheldon Warren (b) (4)	03 Feb 2021 20:09:57

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**Form: Adverse Events (3)**

**Generated On: 10 Jun 2021 07:56:44**

[If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Mar 2021 13:41:02
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 22:12:02
User entered empty.	Sheldon Warren (b) (4)	03 Feb 2021 20:09:57

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**Folder: Adverse Events**

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[Narrative](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Mar 2021 13:41:02
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 22:12:02
User entered empty.	Sheldon Warren (b) (4)	03 Feb 2021 20:09:57

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**Folder: Adverse Events**

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[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '0'	System	03 Feb 2021 20:09:57

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**Folder: Adverse Events**

**Form: Adverse Events (3)**

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[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '0'	System	03 Feb 2021 20:09:57



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**Form: Adverse Events (4)**

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[AEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	15 Mar 2021 12:52:32
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	12 Mar 2021 13:41:02
Reviewed for Safety.	(b) (4), (b) (6)	12 Mar 2021 13:31:42
User entered	System	12 Mar 2021 13:31:37
'USA-US065-2021-mRNA-1273-P301000005'		
User entered 'New'	(b) (4), (b) (6)	12 Mar 2021 13:31:37

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Folder: Adverse Events

Form: Adverse Events (4)

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[Adverse event](#)

Audit	User	Time (GMT)
User coded data point as SOC: Infections and infestations, HLGT: Bacterial infectious disorders, HLT: Bacterial infections NEC, PT: Arthritis bacterial, LLT: Septic arthritis - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	18 Mar 2021 09:27:40
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	18 Mar 2021 09:27:40
User signature succeeded.	Michael Koren (b) (4) (b) (4)	15 Mar 2021 12:52:32
DataPoint Verified.	(b) (4), (b) (6)	12 Mar 2021 13:41:02
Data point term sent to Coder	System	11 Mar 2021 21:49:49
User entered 'Left Elbow Septic Arthritis'	Sheldon Warren (b) (4) (b) (4)	11 Mar 2021 21:49:33

**US3512248**

**Folder: Adverse Events**

**Form: Adverse Events (4)**

**Generated On: 10 Jun 2021 07:56:44**

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	15 Mar 2021 12:52:32
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Mar 2021 13:41:02
User entered 'Yes (Y)'	Sheldon Warren (b) (4) (b) (4)	11 Mar 2021 21:49:33

**US3512248**

**Folder: Adverse Events**

**Form: Adverse Events (4)**

**Generated On: 10 Jun 2021 07:56:44**

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	15 Mar 2021 12:52:32
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Mar 2021 13:41:02
User entered 'No (N)'	Sheldon Warren (b) (4) (b) (4)	11 Mar 2021 21:49:33

**US3512248**

**Folder: Adverse Events**

**Form: Adverse Events (4)**

**Generated On: 10 Jun 2021 07:56:44**

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	15 Mar 2021 12:52:32
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Mar 2021 13:41:02
User entered 'No (N)'	Sheldon Warren (b) (4) (b) (4)	11 Mar 2021 21:49:33

**US3512248**

**Folder: Adverse Events**

**Form: Adverse Events (4)**

**Generated On: 10 Jun 2021 07:56:44**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	15 Mar 2021 12:52:32
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Mar 2021 13:41:02
User entered '24 Feb 2021'	Sheldon Warren (b) (4) (b) (4)	11 Mar 2021 21:49:33

**US3512248**

**Folder: Adverse Events**

**Form: Adverse Events (4)**

**Generated On: 10 Jun 2021 07:56:44**

[Start time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	15 Mar 2021 12:52:32
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Mar 2021 13:41:02
User entered empty.	Sheldon Warren (b) (4) (b) (4)	11 Mar 2021 21:49:33

**US3512248**

**Folder: Adverse Events**

**Form: Adverse Events (4)**

**Generated On: 10 Jun 2021 07:56:44**

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	11 Mar 2021 21:49:33



US3512248

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 07:56:44

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	14 Apr 2021 16:45:45
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 16:02:14
DataPoint Un-verified.	Taylor Johnson (b) (4)	12 Apr 2021 15:24:10
	(b) (4)	
Signature has been broken.	Taylor Johnson (b) (4)	12 Apr 2021 15:24:10
	(b) (4)	
User entered 'No (N)' reason for change: Data Entry Error	Taylor Johnson (b) (4)	12 Apr 2021 15:24:10
	(b) (4)	
User signature succeeded.	Michael Koren (b) (4)	15 Mar 2021 12:52:32
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	12 Mar 2021 13:41:02
User entered 'Yes (Y)'	Sheldon Warren (b) (4)	11 Mar 2021 21:49:33
	(b) (4)	

US3512248

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 07:56:44

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	14 Apr 2021 16:45:45
User closed query 'PV Query: Please provide the event end date, when available. If a new baseline has been established (diagnosis of stabilized, chronic or recurrent condition) for the subject, then the SAE is considered resolved with sequelae and an end date should be associated at that time.?Please leave query open until information is available. ' (Site from Safety).	(b) (4) (b) (4), (b) (6)	13 Apr 2021 12:59:24
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 16:02:14
Query 'PV Query: Please provide the event end date, when available. If a new baseline has been established (diagnosis of stabilized, chronic or recurrent condition) for the subject, then the SAE is considered resolved with sequelae and an end date should be associated at that time.?Please leave query open until information is available. ' answered with 'data updated' (Site from Safety).	Taylor Johnson (b) (4) (b) (4)	12 Apr 2021 15:24:28
DataPoint Un-verified.	Taylor Johnson (b) (4) (b) (4)	12 Apr 2021 15:24:10
Signature has been broken.	Taylor Johnson (b) (4) (b) (4)	12 Apr 2021 15:24:10
User entered '12 Apr 2021' reason for change: Data Entry Error	Taylor Johnson (b) (4) (b) (4)	12 Apr 2021 15:24:10
User opened query 'PV Query: Please provide the event end date, when available. If a new baseline has been established (diagnosis of stabilized, chronic or recurrent condition) for the subject, then the SAE is considered resolved with sequelae and an end date should be associated at that time.?Please leave query open until information is available. ' (Site from Safety).	(b) (4), (b) (6)	19 Mar 2021 04:16:10
User signature succeeded.	Michael Koren (b) (4) (b) (4)	15 Mar 2021 12:52:32
DataPoint Verified.	(b) (4), (b) (6)	12 Mar 2021 13:41:02
User entered empty.	Sheldon Warren (b) (4) (b) (4)	11 Mar 2021 21:49:33

**US3512248**

**Folder: Adverse Events**

**Form: Adverse Events (4)**

**Generated On: 10 Jun 2021 07:56:44**

[End time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	15 Mar 2021 12:52:32
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Mar 2021 13:41:02
User entered empty.	Sheldon Warren (b) (4) (b) (4)	11 Mar 2021 21:49:33

**US3512248**

**Folder: Adverse Events**

**Form: Adverse Events (4)**

**Generated On: 10 Jun 2021 07:56:44**

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	11 Mar 2021 21:49:33

**US3512248**

**Folder: Adverse Events**

**Form: Adverse Events (4)**

**Generated On: 10 Jun 2021 07:56:44**

[Severity](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	15 Mar 2021 12:52:32
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Mar 2021 13:41:02
User entered 'Grade 3/Severe (Grade 3/Severe)'	Sheldon Warren (b) (4) (b) (4)	11 Mar 2021 21:49:33

US3512248

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 07:56:44

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	15 Mar 2021 12:52:32
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Mar 2021 13:41:02
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).	System	11 Mar 2021 21:50:52
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 Mar 2021 21:49:33
User entered 'Yes (Y)'	Sheldon Warren (b) (4) (b) (4)	11 Mar 2021 21:49:33

**US3512248**

**Folder: Adverse Events**

**Form: Adverse Events (4)**

**Generated On: 10 Jun 2021 07:56:44**

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	15 Mar 2021 12:52:32
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Mar 2021 13:41:02
User entered '0'	Sheldon Warren (b) (4) (b) (4)	11 Mar 2021 21:49:33

**US3512248**

**Folder: Adverse Events**

**Form: Adverse Events (4)**

**Generated On: 10 Jun 2021 07:56:44**

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	15 Mar 2021 12:52:32
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Mar 2021 13:41:02
User entered '0'	Sheldon Warren (b) (4) (b) (4)	11 Mar 2021 21:49:33



US3512248

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 07:56:44

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	15 Mar 2021 12:52:32
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Mar 2021 13:41:02
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 Mar 2021 21:50:52
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 Mar 2021 21:50:52
User entered '1' reason for change: Data Entry Error	Sheldon Warren (b) (4)	11 Mar 2021 21:50:52
User opened query 'Requires inpatient or prolongation of existing Hospitalization is not checked, but hospitalization data has been provided. Please correct.' (Site from System).	(b) (4) System	11 Mar 2021 21:49:33
User entered '0'	Sheldon Warren (b) (4) (b) (4)	11 Mar 2021 21:49:33

US3512248

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 07:56:44

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	15 Mar 2021 12:52:32
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Mar 2021 13:41:02
User entered '25 Feb 2021'	Sheldon Warren (b) (4) (b) (4)	11 Mar 2021 21:49:33

US3512248

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 07:56:44

Hospital Discharge Date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	15 Mar 2021 12:52:32
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Mar 2021 13:41:02
User entered '26 Feb 2021'	Sheldon Warren (b) (4) (b) (4)	11 Mar 2021 21:49:33

**US3512248**

**Folder: Adverse Events**

**Form: Adverse Events (4)**

**Generated On: 10 Jun 2021 07:56:44**

[Admitted to ICU?](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	15 Mar 2021 12:52:32
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Mar 2021 13:41:02
User entered 'No (N)'	Sheldon Warren (b) (4) (b) (4)	11 Mar 2021 21:49:33

**US3512248**

**Folder: Adverse Events**

**Form: Adverse Events (4)**

**Generated On: 10 Jun 2021 07:56:44**

[Number of Days in ICU](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	15 Mar 2021 12:52:32
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Mar 2021 13:41:02
User entered empty.	Sheldon Warren (b) (4) (b) (4)	11 Mar 2021 21:49:33

**US3512248**

**Folder: Adverse Events**

**Form: Adverse Events (4)**

**Generated On: 10 Jun 2021 07:56:44**

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	15 Mar 2021 12:52:32
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Mar 2021 13:41:02
User entered '0'	Sheldon Warren (b) (4) (b) (4)	11 Mar 2021 21:49:33

**US3512248**

**Folder: Adverse Events**

**Form: Adverse Events (4)**

**Generated On: 10 Jun 2021 07:56:44**

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	15 Mar 2021 12:52:32
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Mar 2021 13:41:02
User entered '0'	Sheldon Warren (b) (4) (b) (4)	11 Mar 2021 21:49:33

**US3512248**

**Folder: Adverse Events**

**Form: Adverse Events (4)**

**Generated On: 10 Jun 2021 07:56:44**

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	15 Mar 2021 12:52:32
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Mar 2021 13:41:02
User entered '0'	Sheldon Warren (b) (4) (b) (4)	11 Mar 2021 21:49:33



**US3512248**

**Folder: Adverse Events**

**Form: Adverse Events (4)**

**Generated On: 10 Jun 2021 07:56:44**

[Relationship to investigational product](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	15 Mar 2021 12:52:32
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Mar 2021 13:41:02
User entered 'Not Related (NOT RELATED)'	Sheldon Warren (b) (4) (b) (4)	11 Mar 2021 21:49:33

**US3512248**

**Folder: Adverse Events**

**Form: Adverse Events (4)**

**Generated On: 10 Jun 2021 07:56:44**

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	15 Mar 2021 12:52:32
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Mar 2021 13:41:02
User entered 'Not Related (NOT RELATED)'	Sheldon Warren (b) (4) (b) (4)	11 Mar 2021 21:49:33

US3512248

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 07:56:44

Action taken with investigational product

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	14 Apr 2021 16:45:45
User closed query 'Per DM CLR: Action Taken with Investigational Product=Investigational Product Withdrawn. Ensure this is reflected in treatment discontinuation if applicable. Review and update. Else, clarify. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	14 Apr 2021 03:37:32
Query 'Per DM CLR: Action Taken with Investigational Product=Investigational Product Withdrawn. Ensure this is reflected in treatment discontinuation if applicable. Review and update. Else, clarify. ' answered with 'Treatment discontinuation is not applicable as this is in Part B of the study per treatment discontinuation EDC guidelines' (Site from DM).	Allison Crain (b) (4) (b) (4)	09 Apr 2021 16:19:01
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 19:47:25
User opened query 'Per DM CLR: Action Taken with Investigational Product=Investigational Product Withdrawn. Ensure this is reflected in treatment discontinuation if applicable. Review and update. Else, clarify. ' (Site from DM).	(b) (4), (b) (6)	05 Apr 2021 09:21:46
DataPoint Un-verified.	Brenda Anderson (b) (4) (b) (4)	29 Mar 2021 17:50:49
Signature has been broken.	Brenda Anderson (b) (4) (b) (4)	29 Mar 2021 17:50:49
User entered 'Investigational Product Withdrawn (WITHDRAWN)' reason for change: New Information	Brenda Anderson (b) (4) (b) (4)	29 Mar 2021 17:50:49
User signature succeeded.	Michael Koren (b) (4) (b) (4)	15 Mar 2021 12:52:32
DataPoint Verified.	(b) (4), (b) (6)	12 Mar 2021 13:41:02
User entered 'Dose Delayed (DOSE DELAYED)'	Sheldon Warren (b) (4) (b) (4)	11 Mar 2021 21:49:33

**US3512248**

**Folder: Adverse Events**

**Form: Adverse Events (4)**

**Generated On: 10 Jun 2021 07:56:44**

[None](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	15 Mar 2021 12:52:32
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Mar 2021 13:41:02
User entered '0'	Sheldon Warren (b) (4) (b) (4)	11 Mar 2021 21:49:33

US3512248

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 07:56:44

[Concomitant Medication](#)

Audit	User	Time (GMT)
User closed query 'PV Query: Please consider adding "right hip trochanteric bursitis" to medical history as there were treatments reported for this problem on 05 Oct 2020. ' (Site from Safety).	(b) (4), (b) (6)	13 Apr 2021 12:59:27
Query 'PV Query: Please consider adding "right hip trochanteric bursitis" to medical history as there were treatments reported for this problem on 05 Oct 2020. ' answered with 'Added to AE log #1' (Site from Safety).	Allison Crain (b) (4)	09 Apr 2021 16:18:06
User opened query 'PV Query: Please consider adding "right hip trochanteric bursitis" to medical history as there were treatments reported for this problem on 05 Oct 2020. ' (Site from Safety).	(b) (4), (b) (6)	19 Mar 2021 04:17:02
User signature succeeded.	Michael Koren (b) (4)	15 Mar 2021 12:52:32
DataPoint Verified.	(b) (4), (b) (6)	12 Mar 2021 13:41:02
User entered 'I'	Sheldon Warren (b) (4)	11 Mar 2021 21:49:33

**US3512248**

**Folder: Adverse Events**

**Form: Adverse Events (4)**

**Generated On: 10 Jun 2021 07:56:44**

[Concomitant Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	15 Mar 2021 12:52:32
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Mar 2021 13:41:02
User entered '0'	Sheldon Warren (b) (4) (b) (4)	11 Mar 2021 21:49:33

US3512248

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 07:56:44

[Outcome](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	14 Apr 2021 16:45:45
User closed query 'PV Query: Please provide the final event outcome, when available. If the event has reached a new baseline where the subject has stabilized with ongoing symptoms/medications; then outcome would be Recovered/Resolved with sequelae with sequelae being the ongoing conditions. ' (Site from Safety).	(b) (4) (b) (4), (b) (6)	13 Apr 2021 12:59:28
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 16:02:14
Query 'PV Query: Please provide the final event outcome, when available. If the event has reached a new baseline where the subject has stabilized with ongoing symptoms/medications; then outcome would be Recovered/Resolved with sequelae with sequelae being the ongoing conditions. ' answered with 'data updated' (Site from Safety).	Taylor Johnson (b) (4) (b) (4)	12 Apr 2021 15:25:00
DataPoint Un-verified.	Taylor Johnson (b) (4) (b) (4)	12 Apr 2021 15:24:10
Signature has been broken.	Taylor Johnson (b) (4) (b) (4)	12 Apr 2021 15:24:10
User entered 'Recovered/Resolved with Sequelae (RECOVERED/RESOLVED WITH SEQUELAE)' reason for change: Data Entry Error	Taylor Johnson (b) (4) (b) (4)	12 Apr 2021 15:24:10
User opened query 'PV Query: Please provide the final event outcome, when available. If the event has reached a new baseline where the subject has stabilized with ongoing symptoms/medications; then outcome would be Recovered/Resolved with sequelae with sequelae being the ongoing conditions. ' (Site from Safety).	(b) (4), (b) (6)	19 Mar 2021 04:15:12
User signature succeeded.	Michael Koren (b) (4) (b) (4)	15 Mar 2021 12:52:32
DataPoint Verified.	(b) (4), (b) (6)	12 Mar 2021 13:41:02
User entered 'Not Recovered/Not Resolved (NOT RECOVERED/NOT RESOLVED)'	Sheldon Warren (b) (4) (b) (4)	11 Mar 2021 21:49:33

US3512248

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 07:56:44

If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	14 Apr 2021 16:45:45
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	12 Apr 2021 16:02:14
User closed query 'Outcome Recovered/Resolved with Sequelae, but specify the sequelae is missing. Please provide.' (Site from System).	System	12 Apr 2021 15:28:11
DataPoint Un-verified.	Taylor Johnson (b) (4)	12 Apr 2021 15:28:11
Signature has been broken.	(b) (4)	
	Taylor Johnson (b) (4)	12 Apr 2021 15:28:11
	(b) (4)	
User entered 'Subject discontinued all associated medications by 05MAR2021 and at last in clinic visit it was noted that the redness had resolved and the swelling and tenderness was moving towards resolution.' reason for change: Data Entry Error	Taylor Johnson (b) (4)	12 Apr 2021 15:28:11
User opened query 'Outcome Recovered/Resolved with Sequelae, but specify the sequelae is missing. Please provide.' (Site from System).	(b) (4)	
User signature succeeded.	System	12 Apr 2021 15:24:10
	Michael Koren (b) (4)	15 Mar 2021 12:52:32
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	12 Mar 2021 13:41:02
User entered empty.	Sheldon Warren (b) (4)	11 Mar 2021 21:49:33
	(b) (4)	



US3512248

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 07:56:44

[Narrative](#)

Audit	User	Time (GMT)
User closed query 'PV Query: please confirm that subject will not receive second dose of vaccine. thank you!' (Site from Safety).	(b) (4), (b) (6)	13 Apr 2021 13:00:10
User closed query 'PV Query: Please provide any relevant laboratory and diagnostic test results. Please include units and reference ranges if applicable. If needed, results with patient identifiers redacted and subject ID added can be sent to Safety_Moderna@iqvia.com or fax to 866.599.1342. If no results are available, please confirm in your response. ' (Site from Safety).	(b) (4), (b) (6)	13 Apr 2021 13:00:07
User closed query 'PV Query: Please provide the results of any COVID-19 testing performed during hospital admission, including date of collection and type of testing.? If not done, please state so. [mRNA-1273 protocols where subject was hospitalization during study participation] ' (Site from Safety).	(b) (4), (b) (6)	13 Apr 2021 13:00:05
Query 'PV Query: Please provide any relevant laboratory and diagnostic test results. Please include units and reference ranges if applicable. If needed, results with patient identifiers redacted and subject ID added can be sent to Safety_Moderna@iqvia.com or fax to 866.599.1342. If no results are available, please confirm in your response. ' answered with 'Sent via e-mail' (Site from Safety).	Allison Crain (b) (4) (b) (4)	09 Apr 2021 16:03:22
Query 'PV Query: please confirm that subject will not receive second dose of vaccine. thank you!' answered with 'Confirmed per PI and PMD' (Site from Safety).	Allison Crain (b) (4) (b) (4)	09 Apr 2021 15:48:31
Query 'PV Query: Please provide the results of any COVID-19 testing performed during hospital admission, including date of collection and type of testing.? If not done, please state so. [mRNA-1273 protocols where subject was hospitalization during study participation] ' answered with 'No Covid-19 testing performed in hospital' (Site from Safety).	Allison Crain (b) (4) (b) (4)	09 Apr 2021 15:38:27
User opened query 'PV Query: please confirm that subject will not receive second dose of vaccine. thank you!' (Site from Safety).	(b) (4), (b) (6)	06 Apr 2021 12:51:59

US3512248

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 07:56:44

[Narrative](#)

Audit	User	Time (GMT)
User opened query 'PV Query: Please provide any relevant laboratory and diagnostic test results. Please include units and reference ranges if applicable. If needed, results with patient identifiers redacted and subject ID added can be sent to Safety_Moderna@iqvia.com or fax to 866.599.1342. If no results are available, please confirm in your response.' (Site from Safety).	(b) (4), (b) (6)	19 Mar 2021 04:14:24
User opened query 'PV Query: Please provide the results of any COVID-19 testing performed during hospital admission, including date of collection and type of testing.? If not done, please state so. [mRNA-1273 protocols where subject was hospitalization during study participation] ' (Site from Safety).	(b) (4), (b) (6)	19 Mar 2021 04:13:55
User signature succeeded.	Michael Koren (b) (4)	15 Mar 2021 12:52:32
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	12 Mar 2021 13:41:02
User closed query 'AE Serious is Yes but SAE Narrative is missing. Please provide.' (Site from System).	System	11 Mar 2021 21:50:52
Query 'AE Serious is Yes but SAE Narrative is missing. Please provide.' answered by data change (Site from System).	System	11 Mar 2021 21:50:52

US3512248

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 07:56:44

[Narrative](#)

Audit	User	Time (GMT)
User entered 'First seen at the clinical site on 2/24/21 with warm, erythematous left elbow. Participant denied decreases in range of motion. He was examined by Dr. Koren on 2/24/21 noting an oral temperature of 99.5. Dr. Koren spoke to participants PCP and ordered 500mg Keflex BID for 7 days, advised moist heat to his arm and a follow up visit with his PCP on 2/25/21.   Participant was seen by PCP on 2/25/21 and referred to the hospital where he was admitted on 2/25/21 due to left elbow septic arthritis. He was given IV vancomycin. Discharged on 02/26/21 zyvox 600 mg BID for 7 days. Concern was that findings may have been related to initial bursitis which progressed to septic arthritis.  3/11/2021 at 11:18, OL-29 visit: participants vital signs were BP: 131/71 mmhg, HR: 71 b/min, oral temperature: 97.7, height: 71 inches. weight: 224.0 lbs. Participant still has evidence of joint symptoms of left elbow including swelling, erythema and discomfort. Suggested 2 week vaccine delay by investigator or as directed by his PCP.' reason for change: Data Entry Error	Sheldon Warren (b) (4)	11 Mar 2021 21:50:52
User opened query 'AE Serious is Yes but SAE Narrative is missing. Please provide.' (Site from System).	System	11 Mar 2021 21:49:33
User entered empty.	Sheldon Warren (b) (4)	11 Mar 2021 21:49:33

**US3512248**

**Folder: Adverse Events**

**Form: Adverse Events (4)**

**Generated On: 10 Jun 2021 07:56:44**

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered 'I'	System	11 Mar 2021 21:49:33

**US3512248**

**Folder: Adverse Events**

**Form: Adverse Events (4)**

**Generated On: 10 Jun 2021 07:56:44**

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered 'I'	System	11 Mar 2021 21:49:33

**US3512248**

**Folder: Adverse Events**

**Form: Adverse Events (4)**

**Generated On: 10 Jun 2021 07:56:44**

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '0'	System	11 Mar 2021 21:49:33

US3512248

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 07:56:44

[Adverse event](#)

Audit	User	Time (GMT)
User coded data point as SOC: Infections and infestations, HLGT: Viral infectious disorders, HLT: Coronavirus infections, PT: Suspected COVID-19, LLT: Suspected COVID-19 - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	07 Apr 2021 20:26:28
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	07 Apr 2021 20:26:28
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 19:47:25
User closed query 'Per MM: Please confirm if the subject was diagnosed with COVID-19. If no, please update the actual diagnosis or add the individual symptoms as separate entries. ' (Site from DM).	(b) (4), (b) (6)	05 Apr 2021 05:29:44
Query 'Per MM: Please confirm if the subject was diagnosed with COVID-19. If no, please update the actual diagnosis or add the individual symptoms as separate entries. ' answered with 'please see question number 3 on this page...Is this event a confirmed diagnosis of Symptomatic Covid-19? thanks' (Site from DM).	Brenda Anderson (b) (4) (b) (4)	01 Apr 2021 16:21:27
User opened query 'Per MM: Please confirm if the subject was diagnosed with COVID-19. If no, please update the actual diagnosis or add the individual symptoms as separate entries. ' (Site from DM).	(b) (4), (b) (6)	30 Mar 2021 12:17:15
User signature succeeded.	Michael Koren (b) (4) (b) (4)	15 Mar 2021 12:52:32
User coded data point as SOC: Infections and infestations, HLGT: Viral infectious disorders, HLT: Coronavirus infections, PT: COVID-19, LLT: COVID-19 - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	15 Mar 2021 07:15:26
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	15 Mar 2021 07:15:26
Data point term sent to Coder	System	12 Mar 2021 18:31:00
User entered 'Covid like-illness'	(b) (4), (b) (6)	12 Mar 2021 18:30:39

**US3512248**

**Folder: Adverse Events**

**Form: Adverse Events (5)**

**Generated On: 10 Jun 2021 07:56:44**

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 19:47:25
User signature succeeded.	Michael Koren (b) (4)	15 Mar 2021 12:52:32
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	12 Mar 2021 18:30:39



**US3512248**

**Folder: Adverse Events**

**Form: Adverse Events (5)**

**Generated On: 10 Jun 2021 07:56:44**

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 19:47:25
User signature succeeded.	Michael Koren (b) (4)	15 Mar 2021 12:52:32
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	12 Mar 2021 18:30:39

**US3512248**

**Folder: Adverse Events**

**Form: Adverse Events (5)**

**Generated On: 10 Jun 2021 07:56:44**

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 19:47:25
User signature succeeded.	Michael Koren (b) (4)	15 Mar 2021 12:52:32
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	12 Mar 2021 18:30:39

**US3512248**

**Folder: Adverse Events**

**Form: Adverse Events (5)**

**Generated On: 10 Jun 2021 07:56:44**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 19:47:25
User signature succeeded.	Michael Koren (b) (4)	15 Mar 2021 12:52:32
User entered '23 Jan 2021'	(b) (4) (b) (4), (b) (6)	12 Mar 2021 18:30:39

**US3512248**

**Folder: Adverse Events**

**Form: Adverse Events (5)**

**Generated On: 10 Jun 2021 07:56:44**

[Start time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 19:47:25
User signature succeeded.	Michael Koren (b) (4)	15 Mar 2021 12:52:32
User entered empty.	(b) (4) (b) (4), (b) (6)	12 Mar 2021 18:30:39

**US3512248**

**Folder: Adverse Events**

**Form: Adverse Events (5)**

**Generated On: 10 Jun 2021 07:56:44**

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	12 Mar 2021 18:30:39

**US3512248**

**Folder: Adverse Events**

**Form: Adverse Events (5)**

**Generated On: 10 Jun 2021 07:56:44**

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 19:47:25
User signature succeeded.	Michael Koren (b) (4)	15 Mar 2021 12:52:32
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	12 Mar 2021 18:30:39

**US3512248**

**Folder: Adverse Events**

**Form: Adverse Events (5)**

**Generated On: 10 Jun 2021 07:56:44**

*If not Ongoing, end date (dd MMM yyyy)*

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 19:47:25
User signature succeeded.	Michael Koren (b) (4)	15 Mar 2021 12:52:32
User entered '14 Feb 2021'	(b) (4) (b) (4), (b) (6)	12 Mar 2021 18:30:39

**US3512248**

**Folder: Adverse Events**

**Form: Adverse Events (5)**

**Generated On: 10 Jun 2021 07:56:44**

[End time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 19:47:25
User signature succeeded.	Michael Koren (b) (4)	15 Mar 2021 12:52:32
User entered empty.	(b) (4) (b) (4), (b) (6)	12 Mar 2021 18:30:39



**US3512248**

**Folder: Adverse Events**

**Form: Adverse Events (5)**

**Generated On: 10 Jun 2021 07:56:44**

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	12 Mar 2021 18:30:39

**US3512248**

**Folder: Adverse Events**

**Form: Adverse Events (5)**

**Generated On: 10 Jun 2021 07:56:44**

[Severity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 19:47:25
User signature succeeded.	Michael Koren (b) (4)	15 Mar 2021 12:52:32
User entered 'Grade 1/Mild (Grade 1/Mild)'	(b) (4) (b) (4), (b) (6)	12 Mar 2021 18:30:39

**US3512248**

**Folder: Adverse Events**

**Form: Adverse Events (5)**

**Generated On: 10 Jun 2021 07:56:44**

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 19:47:25
User signature succeeded.	Michael Koren (b) (4)	15 Mar 2021 12:52:32
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	12 Mar 2021 18:30:39

**US3512248**

**Folder: Adverse Events**

**Form: Adverse Events (5)**

**Generated On: 10 Jun 2021 07:56:44**

[Death](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 19:47:25
User signature succeeded.	Michael Koren (b) (4)	15 Mar 2021 12:52:32
User entered '0'	(b) (4) (b) (4), (b) (6)	12 Mar 2021 18:30:39

**US3512248**

**Folder: Adverse Events**

**Form: Adverse Events (5)**

**Generated On: 10 Jun 2021 07:56:44**

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 19:47:25
User signature succeeded.	Michael Koren (b) (4)	15 Mar 2021 12:52:32
User entered '0'	(b) (4) (b) (4), (b) (6)	12 Mar 2021 18:30:39

**US3512248**

**Folder: Adverse Events**

**Form: Adverse Events (5)**

**Generated On: 10 Jun 2021 07:56:44**

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 19:47:25
User signature succeeded.	Michael Koren (b) (4)	15 Mar 2021 12:52:32
User entered '0'	(b) (4), (b) (6)	12 Mar 2021 18:30:39

**US3512248**

**Folder: Adverse Events**

**Form: Adverse Events (5)**

**Generated On: 10 Jun 2021 07:56:44**

**Hospital Admission Date** (*dd MMM yyyy*)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 19:47:25
User signature succeeded.	Michael Koren (b) (4)	15 Mar 2021 12:52:32
User entered empty.	(b) (4) (b) (4), (b) (6)	12 Mar 2021 18:30:39

**US3512248**

**Folder: Adverse Events**

**Form: Adverse Events (5)**

**Generated On: 10 Jun 2021 07:56:44**

**Hospital Discharge Date (dd MMM yyyy)**

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 19:47:25
User signature succeeded.	Michael Koren (b) (4)	15 Mar 2021 12:52:32
User entered empty.	(b) (4) (b) (4), (b) (6)	12 Mar 2021 18:30:39



**US3512248**

**Folder: Adverse Events**

**Form: Adverse Events (5)**

**Generated On: 10 Jun 2021 07:56:44**

[Admitted to ICU?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 19:47:25
User signature succeeded.	Michael Koren (b) (4)	15 Mar 2021 12:52:32
User entered empty.	(b) (4) (b) (4), (b) (6)	12 Mar 2021 18:30:39

**US3512248**

**Folder: Adverse Events**

**Form: Adverse Events (5)**

**Generated On: 10 Jun 2021 07:56:44**

[Number of Days in ICU](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 19:47:25
User signature succeeded.	Michael Koren (b) (4)	15 Mar 2021 12:52:32
User entered empty.	(b) (4) (b) (4), (b) (6)	12 Mar 2021 18:30:39

**US3512248**

**Folder: Adverse Events**

**Form: Adverse Events (5)**

**Generated On: 10 Jun 2021 07:56:44**

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 19:47:25
User signature succeeded.	Michael Koren (b) (4)	15 Mar 2021 12:52:32
User entered '0'	(b) (4) (b) (4), (b) (6)	12 Mar 2021 18:30:39

**US3512248**

**Folder: Adverse Events**

**Form: Adverse Events (5)**

**Generated On: 10 Jun 2021 07:56:44**

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 19:47:25
User signature succeeded.	Michael Koren (b) (4)	15 Mar 2021 12:52:32
User entered '0'	(b) (4) (b) (4), (b) (6)	12 Mar 2021 18:30:39

**US3512248**

**Folder: Adverse Events**

**Form: Adverse Events (5)**

**Generated On: 10 Jun 2021 07:56:44**

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 19:47:25
User signature succeeded.	Michael Koren (b) (4)	15 Mar 2021 12:52:32
User entered '0'	(b) (4) (b) (4), (b) (6)	12 Mar 2021 18:30:39

**US3512248**

**Folder: Adverse Events**

**Form: Adverse Events (5)**

**Generated On: 10 Jun 2021 07:56:44**

[Relationship to investigational product](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 19:47:25
User signature succeeded.	Michael Koren (b) (4)	15 Mar 2021 12:52:32
User entered 'Not Related (NOT RELATED)'	(b) (4) (b) (4), (b) (6)	12 Mar 2021 18:30:39

**US3512248**

**Folder: Adverse Events**

**Form: Adverse Events (5)**

**Generated On: 10 Jun 2021 07:56:44**

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 19:47:25
User signature succeeded.	Michael Koren (b) (4)	15 Mar 2021 12:52:32
User entered 'Not Related (NOT RELATED)'	(b) (4) (b) (4), (b) (6)	12 Mar 2021 18:30:39

**US3512248**

**Folder: Adverse Events**

**Form: Adverse Events (5)**

**Generated On: 10 Jun 2021 07:56:44**

[Action taken with investigational product](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 19:47:25
User signature succeeded.	Michael Koren (b) (4)	15 Mar 2021 12:52:32
User entered 'None (NONE)'	(b) (4) (b) (4), (b) (6)	12 Mar 2021 18:30:39



**US3512248**

**Folder: Adverse Events**

**Form: Adverse Events (5)**

**Generated On: 10 Jun 2021 07:56:44**

[None](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 19:47:25
User signature succeeded.	Michael Koren (b) (4)	15 Mar 2021 12:52:32
User entered '0'	(b) (4) (b) (4), (b) (6)	12 Mar 2021 18:30:39

**US3512248**

**Folder: Adverse Events**

**Form: Adverse Events (5)**

**Generated On: 10 Jun 2021 07:56:44**

[Concomitant Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 19:47:25
User signature succeeded.	Michael Koren (b) (4)	15 Mar 2021 12:52:32
User entered 'I'	(b) (4) (b) (4), (b) (6)	12 Mar 2021 18:30:39

**US3512248**

**Folder: Adverse Events**

**Form: Adverse Events (5)**

**Generated On: 10 Jun 2021 07:56:44**

[Concomitant Procedure](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 19:47:25
User signature succeeded.	Michael Koren (b) (4)	15 Mar 2021 12:52:32
User entered '0'	(b) (4) (b) (4), (b) (6)	12 Mar 2021 18:30:39

**US3512248**

**Folder: Adverse Events**

**Form: Adverse Events (5)**

**Generated On: 10 Jun 2021 07:56:44**

[Outcome](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 19:47:25
User signature succeeded.	Michael Koren (b) (4)	15 Mar 2021 12:52:32
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)'	(b) (4) (b) (4), (b) (6)	12 Mar 2021 18:30:39

**US3512248**

**Folder: Adverse Events**

**Form: Adverse Events (5)**

**Generated On: 10 Jun 2021 07:56:44**

[If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 19:47:25
User signature succeeded.	Michael Koren (b) (4)	15 Mar 2021 12:52:32
User entered empty.	(b) (4) (b) (4), (b) (6)	12 Mar 2021 18:30:39

**US3512248**

**Folder: Adverse Events**

**Form: Adverse Events (5)**

**Generated On: 10 Jun 2021 07:56:44**

[Narrative](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 19:47:25
User signature succeeded.	Michael Koren (b) (4)	15 Mar 2021 12:52:32
User entered empty.	(b) (4) (b) (4), (b) (6)	12 Mar 2021 18:30:39

**US3512248**

**Folder: Adverse Events**

**Form: Adverse Events (5)**

**Generated On: 10 Jun 2021 07:56:44**

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '0'	System	12 Mar 2021 18:30:39

**US3512248**

**Folder: Adverse Events**

**Form: Adverse Events (5)**

**Generated On: 10 Jun 2021 07:56:44**

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '0'	System	12 Mar 2021 18:30:39



US3512248

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Generated On: 10 Jun 2021 07:56:44

Were any prior/concomitant medications and/or vaccinations taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 07:34:28
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 22:12:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Oct 2020 13:48:11
User closed query 'Per CDM: Were any prior/concomitant medications and/or vaccinations taken? is yes however prior/concomitant medications and vaccination form not completed. Please consider to update else clarify.' (Site from DM).	(b) (4), (b) (6)	24 Sep 2020 07:37:49
Query 'Per CDM: Were any prior/concomitant medications and/or vaccinations taken? is yes however prior/concomitant medications and vaccination form not completed. Please consider to update else clarify.' answered with 'Updated' (Site from DM).	Allison Crain (b) (4) (b) (4)	23 Sep 2020 12:09:27
User opened query 'Per CDM: Were any prior/concomitant medications and/or vaccinations taken? is yes however prior/concomitant medications and vaccination form not completed. Please consider to update else clarify.' (Site from DM).	(b) (4), (b) (6)	16 Sep 2020 04:42:24
User entered 'Yes (Y)'	Allison Crain (b) (4) (b) (4)	10 Sep 2020 17:15:39

US3512248

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 07:56:44

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	26 Feb 2021 20:02:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Oct 2020 13:48:27
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: LIPID MODIFYING AGENTS, ATC: LIPID MODIFYING AGENTS, PLAIN, ATC: HMG COA REDUCTASE INHIBITORS, PRODUCT: ATORVASTATIN - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	18 Sep 2020 17:35:39
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	18 Sep 2020 17:35:39
Data point term sent to Coder	System	18 Sep 2020 17:34:56
User entered 'atorvastatin'	Taylor Johnson (b) (4) (b) (4)	18 Sep 2020 17:34:51

**US3512248**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 10 Jun 2021 07:56:44**

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	26 Feb 2021 20:02:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Oct 2020 13:48:27
User entered 'No (N)'	Taylor Johnson (b) (4) (b) (4)	18 Sep 2020 17:34:51

US3512248

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 07:56:44

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	26 Feb 2021 20:02:47
User closed query 'Per CDM CR: Please note that this condition is not recorded on the MH eCRF. Please review Con Med use and add a medical condition and all applicable details to the appropriate MH eCRF.' (Site from DM).	(b) (4) (b) (4), (b) (6)	10 Nov 2020 04:18:45
Query 'Per CDM CR: Please note that this condition is not recorded on the MH eCRF. Please review Con Med use and add a medical condition and all applicable details to the appropriate MH eCRF.' answered with 'added to medical history' (Site from DM).	Brenda Anderson (b) (4) (b) (4)	05 Nov 2020 21:49:43
User opened query 'Per CDM CR: Please note that this condition is not recorded on the MH eCRF. Please review Con Med use and add a medical condition and all applicable details to the appropriate MH eCRF.' (Site from DM).	(b) (4), (b) (6)	20 Oct 2020 14:46:07
DataPoint Verified.	(b) (4), (b) (6)	07 Oct 2020 13:48:27
User entered 'hypercholesterolemia'	Taylor Johnson (b) (4) (b) (4)	18 Sep 2020 17:34:51

**US3512248**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 10 Jun 2021 07:56:44**

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	26 Feb 2021 20:02:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Oct 2020 13:48:27
User entered '5'	Taylor Johnson (b) (4) (b) (4)	18 Sep 2020 17:34:51

US3512248

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 07:56:44

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	26 Feb 2021 20:02:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Oct 2020 13:48:27
User entered 'mg (mg)'	Taylor Johnson (b) (4) (b) (4)	18 Sep 2020 17:34:51

US3512248

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 10 Jun 2021 07:56:44**

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	26 Feb 2021 20:02:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Oct 2020 13:48:27
User entered empty.	Taylor Johnson (b) (4) (b) (4)	18 Sep 2020 17:34:51

US3512248

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 07:56:44

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	26 Feb 2021 20:02:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Oct 2020 13:48:27
User entered 'once daily (QD)'	Taylor Johnson (b) (4) (b) (4)	18 Sep 2020 17:34:51



US3512248

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 07:56:44

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	26 Feb 2021 20:02:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Oct 2020 13:48:27
User entered empty.	Taylor Johnson (b) (4) (b) (4)	18 Sep 2020 17:34:51

US3512248

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 07:56:44

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	26 Feb 2021 20:02:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Oct 2020 13:48:27
User entered 'Oral (ORAL)'	Taylor Johnson (b) (4) (b) (4)	18 Sep 2020 17:34:51

**US3512248**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 10 Jun 2021 07:56:44**

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	26 Feb 2021 20:02:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Oct 2020 13:48:27
User entered empty.	Taylor Johnson (b) (4) (b) (4)	18 Sep 2020 17:34:51

US3512248

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 07:56:44

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	26 Feb 2021 20:02:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Oct 2020 13:48:27
User entered 'un Jan 2006'	Taylor Johnson (b) (4) (b) (4)	18 Sep 2020 17:34:51

**US3512248**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 10 Jun 2021 07:56:44**

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	26 Feb 2021 20:02:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Oct 2020 13:48:27
User entered '0'	Taylor Johnson (b) (4) (b) (4)	18 Sep 2020 17:34:51

**US3512248**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 10 Jun 2021 07:56:44**

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	26 Feb 2021 20:02:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Oct 2020 13:48:27
User entered 'Yes (Y)'	Taylor Johnson (b) (4) (b) (4)	18 Sep 2020 17:34:51

**US3512248**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 10 Jun 2021 07:56:44**

*If not Ongoing, End date (dd MMM yyyy)*

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	26 Feb 2021 20:02:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Oct 2020 13:48:27
User entered empty.	Taylor Johnson (b) (4) (b) (4)	18 Sep 2020 17:34:51

US3512248

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 07:56:44

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	26 Feb 2021 20:02:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Oct 2020 13:48:27
User entered 'No (N)'	Taylor Johnson (b) (4) (b) (4)	18 Sep 2020 17:34:51



**US3512248**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 10 Jun 2021 07:56:44**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	18 Sep 2020 17:34:51

US3512248

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 10 Jun 2021 07:56:44**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	18 Sep 2020 17:34:51

**US3512248**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 10 Jun 2021 07:56:44**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	18 Sep 2020 17:34:51

US3512248

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 07:56:44

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	26 Feb 2021 20:02:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Oct 2020 13:48:27
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.	Coder Import (b) (4) (b) (4)	18 Sep 2020 17:37:45
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	18 Sep 2020 17:37:45
Data point term sent to Coder	System	18 Sep 2020 17:36:58
User entered 'omeprazole'	Taylor Johnson (b) (4) (b) (4)	18 Sep 2020 17:36:02

US3512248

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 07:56:44

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	26 Feb 2021 20:02:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Oct 2020 13:48:27
User entered 'No (N)'	Taylor Johnson (b) (4) (b) (4)	18 Sep 2020 17:36:02

US3512248

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 07:56:44

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	26 Feb 2021 20:02:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Oct 2020 13:48:27
User entered 'Gastroesophageal reflux disease'	Taylor Johnson (b) (4) (b) (4)	18 Sep 2020 17:36:02

**US3512248**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 10 Jun 2021 07:56:44**

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	26 Feb 2021 20:02:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Oct 2020 13:48:27
User entered '20'	Taylor Johnson (b) (4) (b) (4)	18 Sep 2020 17:36:02

US3512248

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 07:56:44

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	26 Feb 2021 20:02:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Oct 2020 13:48:27
User entered 'mg (mg)'	Taylor Johnson (b) (4) (b) (4)	18 Sep 2020 17:36:02



US3512248

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 07:56:44

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	26 Feb 2021 20:02:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Oct 2020 13:48:27
User entered empty.	Taylor Johnson (b) (4) (b) (4)	18 Sep 2020 17:36:02

US3512248

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 07:56:44

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	26 Feb 2021 20:02:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Oct 2020 13:48:27
User entered 'once daily (QD)'	Taylor Johnson (b) (4) (b) (4)	18 Sep 2020 17:36:02

**US3512248**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 10 Jun 2021 07:56:44**

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	26 Feb 2021 20:02:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Oct 2020 13:48:27
User entered empty.	Taylor Johnson (b) (4) (b) (4)	18 Sep 2020 17:36:02

US3512248

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 07:56:44

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	26 Feb 2021 20:02:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Oct 2020 13:48:27
User entered 'Oral (ORAL)'	Taylor Johnson (b) (4) (b) (4)	18 Sep 2020 17:36:02

US3512248

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 07:56:44

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	26 Feb 2021 20:02:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Oct 2020 13:48:27
User entered empty.	Taylor Johnson (b) (4) (b) (4)	18 Sep 2020 17:36:02

**US3512248**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 10 Jun 2021 07:56:44**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	26 Feb 2021 20:02:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Oct 2020 13:48:27
User entered 'un Jan 2008'	Taylor Johnson (b) (4) (b) (4)	18 Sep 2020 17:36:02

**US3512248**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 10 Jun 2021 07:56:44**

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	26 Feb 2021 20:02:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Oct 2020 13:48:27
User entered '0'	Taylor Johnson (b) (4) (b) (4)	18 Sep 2020 17:36:02

**US3512248**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 10 Jun 2021 07:56:44**

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	26 Feb 2021 20:02:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Oct 2020 13:48:27
User entered 'Yes (Y)'	Taylor Johnson (b) (4) (b) (4)	18 Sep 2020 17:36:02



**US3512248**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 10 Jun 2021 07:56:44**

*If not Ongoing, End date (dd MMM yyyy)*

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	26 Feb 2021 20:02:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Oct 2020 13:48:27
User entered empty.	Taylor Johnson (b) (4) (b) (4)	18 Sep 2020 17:36:02

US3512248

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 07:56:44

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	26 Feb 2021 20:02:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Oct 2020 13:48:27
User entered 'No (N)'	Taylor Johnson (b) (4) (b) (4)	18 Sep 2020 17:36:02

**US3512248**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 10 Jun 2021 07:56:44**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	18 Sep 2020 17:36:02

US3512248

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 10 Jun 2021 07:56:44**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	18 Sep 2020 17:36:02

**US3512248**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 10 Jun 2021 07:56:44**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	18 Sep 2020 17:36:02

US3512248

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 07:56:44

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	26 Feb 2021 20:02:47
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	07 Oct 2020 13:48:27
User coded data point as ATC: GENITO URINARY SYSTEM AND SEX HORMONES, ATC: UROLOGICALS, ATC: DRUGS USED IN BENIGN PROSTATIC HYPERTROPHY, ATC: ALPHA-ADRENORECEPTOR ANTAGONISTS, PRODUCT: TAMSULOSIN HYDROCHLORIDE, PRODUCTSYNONYM: TAMULOSIN - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	18 Sep 2020 17:37:45
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	18 Sep 2020 17:37:45
Data point term sent to Coder	System	18 Sep 2020 17:36:59
User entered 'tamulosin'	Taylor Johnson (b) (4)	18 Sep 2020 17:36:53
	(b) (4)	

**US3512248**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 10 Jun 2021 07:56:44**

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	26 Feb 2021 20:02:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Oct 2020 13:48:27
User entered 'No (N)'	Taylor Johnson (b) (4) (b) (4)	18 Sep 2020 17:36:53

US3512248

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 07:56:44

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	26 Feb 2021 20:02:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Oct 2020 13:48:27
User entered 'Benign prostatic hyperplasia'	Taylor Johnson (b) (4) (b) (4)	18 Sep 2020 17:36:53



**US3512248**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 10 Jun 2021 07:56:44**

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	26 Feb 2021 20:02:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Oct 2020 13:48:27
User entered '0.4'	Taylor Johnson (b) (4) (b) (4)	18 Sep 2020 17:36:53

US3512248

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 07:56:44

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	26 Feb 2021 20:02:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Oct 2020 13:48:27
User entered 'mg (mg)'	Taylor Johnson (b) (4) (b) (4)	18 Sep 2020 17:36:53

US3512248

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 07:56:44

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	26 Feb 2021 20:02:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Oct 2020 13:48:27
User entered empty.	Taylor Johnson (b) (4) (b) (4)	18 Sep 2020 17:36:53

US3512248

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 07:56:44

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	26 Feb 2021 20:02:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Oct 2020 13:48:27
User entered 'once daily (QD)'	Taylor Johnson (b) (4) (b) (4)	18 Sep 2020 17:36:53

US3512248

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 07:56:44

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	26 Feb 2021 20:02:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Oct 2020 13:48:27
User entered empty.	Taylor Johnson (b) (4) (b) (4)	18 Sep 2020 17:36:53

US3512248

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 07:56:44

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	26 Feb 2021 20:02:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Oct 2020 13:48:27
User entered 'Oral (ORAL)'	Taylor Johnson (b) (4) (b) (4)	18 Sep 2020 17:36:53

US3512248

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 10 Jun 2021 07:56:44**

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	26 Feb 2021 20:02:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Oct 2020 13:48:27
User entered empty.	Taylor Johnson (b) (4) (b) (4)	18 Sep 2020 17:36:53

US3512248

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 07:56:44

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	26 Feb 2021 20:02:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Oct 2020 13:48:27
User entered 'un Jan 2014'	Taylor Johnson (b) (4) (b) (4)	18 Sep 2020 17:36:53



**US3512248**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 10 Jun 2021 07:56:44**

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	26 Feb 2021 20:02:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Oct 2020 13:48:27
User entered '0'	Taylor Johnson (b) (4) (b) (4)	18 Sep 2020 17:36:53

**US3512248**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 10 Jun 2021 07:56:44**

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	26 Feb 2021 20:02:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Oct 2020 13:48:27
User entered 'Yes (Y)'	Taylor Johnson (b) (4) (b) (4)	18 Sep 2020 17:36:53

**US3512248**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 10 Jun 2021 07:56:44**

*If not Ongoing, End date (dd MMM yyyy)*

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	26 Feb 2021 20:02:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Oct 2020 13:48:27
User entered empty.	Taylor Johnson (b) (4) (b) (4)	18 Sep 2020 17:36:53

US3512248

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 07:56:44

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	26 Feb 2021 20:02:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Oct 2020 13:48:27
User entered 'No (N)'	Taylor Johnson (b) (4) (b) (4)	18 Sep 2020 17:36:53

**US3512248**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 10 Jun 2021 07:56:44**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	18 Sep 2020 17:36:53

**US3512248**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 10 Jun 2021 07:56:44**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	18 Sep 2020 17:36:53

**US3512248**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 10 Jun 2021 07:56:44**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	18 Sep 2020 17:36:53

US3512248

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 07:56:44

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	26 Feb 2021 20:02:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Oct 2020 13:48:27
User coded data point as ATC: RESPIRATORY SYSTEM, ATC: DRUGS FOR OBSTRUCTIVE AIRWAY DISEASES, ATC: ADRENERGICS, INHALANTS, ATC: ADRENERGICS IN COMBINATION WITH CORTICOSTEROIDS OR OTHER DRUGS, EXCL. ANTICHOLINERGICS, PRODUCT: BUDESONIDE;FORMOTEROL FUMARATE, PRODUCTSYNONYM: SYMBICORT - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	19 Sep 2020 09:07:52
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	19 Sep 2020 09:07:52
Data point term sent to Coder	System	18 Sep 2020 17:42:15
User entered 'symbicort (160mcg/4.5mcg)'	Taylor Johnson (b) (4) (b) (4)	18 Sep 2020 17:41:59



US3512248

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 07:56:44

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	26 Feb 2021 20:02:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Oct 2020 13:48:27
User entered 'No (N)'	Taylor Johnson (b) (4) (b) (4)	18 Sep 2020 17:41:59

US3512248

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 07:56:44

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	26 Feb 2021 20:02:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Oct 2020 13:48:27
User entered 'chronic obstructive pulmonary disease'	Taylor Johnson (b) (4) (b) (4)	18 Sep 2020 17:41:59

**US3512248**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 10 Jun 2021 07:56:44**

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	26 Feb 2021 20:02:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Oct 2020 13:48:27
User entered '2'	Taylor Johnson (b) (4) (b) (4)	18 Sep 2020 17:41:59

**US3512248**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 10 Jun 2021 07:56:44**

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	26 Feb 2021 20:02:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Oct 2020 13:48:27
User entered 'puff (PUFF)'	Taylor Johnson (b) (4) (b) (4)	18 Sep 2020 17:41:59

US3512248

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 07:56:44

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	26 Feb 2021 20:02:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Oct 2020 13:48:27
User entered empty.	Taylor Johnson (b) (4) (b) (4)	18 Sep 2020 17:41:59

**US3512248**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 10 Jun 2021 07:56:44**

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	26 Feb 2021 20:02:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Oct 2020 13:48:27
User entered 'once daily (QD)'	Taylor Johnson (b) (4) (b) (4)	18 Sep 2020 17:41:59

US3512248

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 07:56:44

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	26 Feb 2021 20:02:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Oct 2020 13:48:27
User entered empty.	Taylor Johnson (b) (4) (b) (4)	18 Sep 2020 17:41:59

**US3512248**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 10 Jun 2021 07:56:44**

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	26 Feb 2021 20:02:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Oct 2020 13:48:27
User entered 'Respiratory (Inhalation) (RESPIRATORY (INHALATION))'	Taylor Johnson (b) (4) (b) (4)	18 Sep 2020 17:41:59



**US3512248**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 10 Jun 2021 07:56:44**

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	26 Feb 2021 20:02:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Oct 2020 13:48:27
User entered empty.	Taylor Johnson (b) (4) (b) (4)	18 Sep 2020 17:41:59

US3512248

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 07:56:44

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	26 Feb 2021 20:02:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Oct 2020 13:48:27
User entered 'un Aug 2020'	Taylor Johnson (b) (4) (b) (4)	18 Sep 2020 17:41:59

**US3512248**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 10 Jun 2021 07:56:44**

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	26 Feb 2021 20:02:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Oct 2020 13:48:27
User entered '0'	Taylor Johnson (b) (4) (b) (4)	18 Sep 2020 17:41:59

**US3512248**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 10 Jun 2021 07:56:44**

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	26 Feb 2021 20:02:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Oct 2020 13:48:27
User entered 'Yes (Y)'	Taylor Johnson (b) (4) (b) (4)	18 Sep 2020 17:41:59

**US3512248**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 10 Jun 2021 07:56:44**

*If not Ongoing, End date (dd MMM yyyy)*

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	26 Feb 2021 20:02:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Oct 2020 13:48:27
User entered empty.	Taylor Johnson (b) (4) (b) (4)	18 Sep 2020 17:41:59

US3512248

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 07:56:44

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	26 Feb 2021 20:02:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Oct 2020 13:48:27
User entered 'No (N)'	Taylor Johnson (b) (4) (b) (4)	18 Sep 2020 17:41:59

**US3512248**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 10 Jun 2021 07:56:44**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	18 Sep 2020 17:41:59

**US3512248**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 10 Jun 2021 07:56:44**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	18 Sep 2020 17:41:59



**US3512248**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 10 Jun 2021 07:56:44**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	18 Sep 2020 17:41:59

US3512248

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 07:56:44

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	26 Feb 2021 20:02:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Oct 2020 13:48:27
User coded data point as ATC: RESPIRATORY SYSTEM, ATC: DRUGS FOR OBSTRUCTIVE AIRWAY DISEASES, ATC: ADRENERGICS, INHALANTS, ATC: SELECTIVE BETA-2-ADRENORECEPTOR AGONISTS, PRODUCT: SALBUTAMOL, PRODUCTSYNONYM: ALBUTEROL [SALBUTAMOL] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	18 Sep 2020 17:46:41
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	18 Sep 2020 17:46:41
Data point term sent to Coder	System	18 Sep 2020 17:45:24
User entered 'albuterol'	Taylor Johnson (b) (4) (b) (4)	18 Sep 2020 17:44:26

**US3512248**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 10 Jun 2021 07:56:44**

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	26 Feb 2021 20:02:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Oct 2020 13:48:27
User entered 'No (N)'	Taylor Johnson (b) (4) (b) (4)	18 Sep 2020 17:44:26

US3512248

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 07:56:44

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	26 Feb 2021 20:02:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Oct 2020 13:48:27
User entered 'chronic obstructive pulmonary disease'	Taylor Johnson (b) (4) (b) (4)	18 Sep 2020 17:44:26

**US3512248**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 10 Jun 2021 07:56:44**

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	26 Feb 2021 20:02:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Oct 2020 13:48:27
User entered '90'	Taylor Johnson (b) (4) (b) (4)	18 Sep 2020 17:44:26

**US3512248**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 10 Jun 2021 07:56:44**

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	26 Feb 2021 20:02:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Oct 2020 13:48:27
User entered 'ug (ug)'	Taylor Johnson (b) (4) (b) (4)	18 Sep 2020 17:44:26

**US3512248**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 10 Jun 2021 07:56:44**

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	26 Feb 2021 20:02:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Oct 2020 13:48:27
User entered empty.	Taylor Johnson (b) (4) (b) (4)	18 Sep 2020 17:44:26

US3512248

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 07:56:44

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	26 Feb 2021 20:02:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Oct 2020 13:48:27
User entered 'as needed (PRN)'	Taylor Johnson (b) (4) (b) (4)	18 Sep 2020 17:44:26



**US3512248**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 10 Jun 2021 07:56:44**

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	26 Feb 2021 20:02:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Oct 2020 13:48:27
User entered empty.	Taylor Johnson (b) (4) (b) (4)	18 Sep 2020 17:44:26

**US3512248**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 10 Jun 2021 07:56:44**

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	26 Feb 2021 20:02:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Oct 2020 13:48:27
User entered 'Respiratory (Inhalation) (RESPIRATORY (INHALATION))'	Taylor Johnson (b) (4) (b) (4)	18 Sep 2020 17:44:26

**US3512248**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 10 Jun 2021 07:56:44**

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	26 Feb 2021 20:02:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Oct 2020 13:48:27
User entered empty.	Taylor Johnson (b) (4) (b) (4)	18 Sep 2020 17:44:26

**US3512248**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 10 Jun 2021 07:56:44**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	26 Feb 2021 20:02:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Oct 2020 13:48:27
User entered 'un May 2018'	Taylor Johnson (b) (4) (b) (4)	18 Sep 2020 17:44:26

**US3512248**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 10 Jun 2021 07:56:44**

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	26 Feb 2021 20:02:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Oct 2020 13:48:27
User entered '0'	Taylor Johnson (b) (4) (b) (4)	18 Sep 2020 17:44:26

**US3512248**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 10 Jun 2021 07:56:44**

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	26 Feb 2021 20:02:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Oct 2020 13:48:27
User entered 'Yes (Y)'	Taylor Johnson (b) (4) (b) (4)	18 Sep 2020 17:44:26

**US3512248**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 10 Jun 2021 07:56:44**

*If not Ongoing, End date (dd MMM yyyy)*

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	26 Feb 2021 20:02:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Oct 2020 13:48:27
User entered empty.	Taylor Johnson (b) (4) (b) (4)	18 Sep 2020 17:44:26

**US3512248**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 10 Jun 2021 07:56:44**

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	26 Feb 2021 20:02:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Oct 2020 13:48:27
User entered 'No (N)'	Taylor Johnson (b) (4) (b) (4)	18 Sep 2020 17:44:26



**US3512248**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 10 Jun 2021 07:56:44**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	18 Sep 2020 17:44:26

**US3512248**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 10 Jun 2021 07:56:44**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	18 Sep 2020 17:44:26

**US3512248**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 10 Jun 2021 07:56:44**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	18 Sep 2020 17:44:26

US3512248

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 07:56:44

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	26 Feb 2021 20:02:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Oct 2020 13:48:27
User coded data point as ATC: BLOOD AND BLOOD FORMING ORGANS, ATC: ANTIANEMIC PREPARATIONS, ATC: VITAMIN B12 AND FOLIC ACID, ATC: VITAMIN B12 (CYANOCOBALAMIN AND ANALOGUES), PRODUCT: VITAMIN B12 NOS, PRODUCTSYNONYM: VITAMIN B12 [VITAMIN B12 NOS] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	18 Sep 2020 17:46:42
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	18 Sep 2020 17:46:42
Data point term sent to Coder	System	18 Sep 2020 17:45:25
User entered 'b12'	Taylor Johnson (b) (4) (b) (4)	18 Sep 2020 17:45:04

US3512248

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 07:56:44

[Prophylaxis](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Mar 2021 13:50:48
User signature succeeded.	Michael Koren (b) (4)	26 Feb 2021 20:02:47
DataPoint Un-verified.	Brenda Anderson (b) (4)	13 Nov 2020 14:54:13
User entered 'Yes (Y)' reason for change: New Information	Brenda Anderson (b) (4)	13 Nov 2020 14:54:13
Query 'Per DM CLR: Indication = SUPPLEMENT. Please review if this Con Med is taken as prophylaxis. If so, kindly update the response to 'Yes'. Update ConMed eCRF as appropriate.' canceled (Site from DM).	(b) (4), (b) (6)	20 Oct 2020 14:47:44
User opened query 'Per DM CLR: Indication = SUPPLEMENT. Please review if this Con Med is taken as prophylaxis. If so, kindly update the response to 'Yes'. Update ConMed eCRF as appropriate.' (Site from DM).	(b) (4), (b) (6)	20 Oct 2020 14:47:33
DataPoint Verified.	(b) (4), (b) (6)	07 Oct 2020 13:48:27
User entered 'No (N)'	Taylor Johnson (b) (4)	18 Sep 2020 17:45:04

US3512248

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 07:56:44

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	26 Feb 2021 20:02:47
User closed query 'Per DM CLR: Indication = SUPPLEMENT. Please review if this Con Med is taken as prophylaxis. If so, kindly update the response to 'Yes'. Update ConMed eCRF as appropriate.' (Site from DM).	(b) (4) (b) (4), (b) (6)	30 Oct 2020 05:00:58
Query 'Per DM CLR: Indication = SUPPLEMENT. Please review if this Con Med is taken as prophylaxis. If so, kindly update the response to 'Yes'. Update ConMed eCRF as appropriate.' answered with 'confirm as is' (Site from DM).	Brenda Anderson (b) (4) (b) (4)	28 Oct 2020 11:59:10
User opened query 'Per DM CLR: Indication = SUPPLEMENT. Please review if this Con Med is taken as prophylaxis. If so, kindly update the response to 'Yes'. Update ConMed eCRF as appropriate.' (Site from DM).	(b) (4), (b) (6)	20 Oct 2020 14:47:50
DataPoint Verified.	(b) (4), (b) (6)	07 Oct 2020 13:48:27
User entered 'supplement'	Taylor Johnson (b) (4) (b) (4)	18 Sep 2020 17:45:04

US3512248

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 07:56:44

[Dose per administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Mar 2021 13:50:48
User signature succeeded.	Michael Koren (b) (4)	26 Feb 2021 20:02:47
DataPoint Un-verified.	Brenda Anderson (b) (4)	05 Nov 2020 21:50:23
User entered '1000' reason for change: New Information	Brenda Anderson (b) (4)	05 Nov 2020 21:50:23
DataPoint Verified.	(b) (4), (b) (6)	07 Oct 2020 13:48:27
User entered '1'	Taylor Johnson (b) (4)	18 Sep 2020 17:45:04

US3512248

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 07:56:44

[Dose unit](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Mar 2021 13:50:48
User signature succeeded.	Michael Koren (b) (4)	26 Feb 2021 20:02:47
User closed query 'Per CDM CR: Please provide the actual dose for this medication instead of tablet count, as there are multiple dosage options for this drug. Update the Dose and Dose Unit fields as appropriate.' (Site from DM).	(b) (4) (b) (4), (b) (6)	10 Nov 2020 05:56:28
Query 'Per CDM CR: Please provide the actual dose for this medication instead of tablet count, as there are multiple dosage options for this drug. Update the Dose and Dose Unit fields as appropriate.' answered with 'corrected' (Site from DM).	Brenda Anderson (b) (4)	05 Nov 2020 21:50:34
DataPoint Un-verified.	Brenda Anderson (b) (4)	05 Nov 2020 21:50:23
User entered 'ug (ug)' reason for change: New Information	Brenda Anderson (b) (4)	05 Nov 2020 21:50:23
User opened query 'Per CDM CR: Please provide the actual dose for this medication instead of tablet count, as there are multiple dosage options for this drug. Update the Dose and Dose Unit fields as appropriate.' (Site from DM).	(b) (4), (b) (6)	20 Oct 2020 14:48:02
DataPoint Verified.	(b) (4), (b) (6)	07 Oct 2020 13:48:27
User entered 'tablet (TABLET)'	Taylor Johnson (b) (4)	18 Sep 2020 17:45:04



US3512248

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 07:56:44

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	26 Feb 2021 20:02:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Oct 2020 13:48:27
User entered empty.	Taylor Johnson (b) (4) (b) (4)	18 Sep 2020 17:45:04

US3512248

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 07:56:44

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	26 Feb 2021 20:02:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Oct 2020 13:48:27
User entered 'once daily (QD)'	Taylor Johnson (b) (4) (b) (4)	18 Sep 2020 17:45:04

US3512248

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 07:56:44

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	26 Feb 2021 20:02:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Oct 2020 13:48:27
User entered empty.	Taylor Johnson (b) (4) (b) (4)	18 Sep 2020 17:45:04

**US3512248**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 10 Jun 2021 07:56:44**

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	26 Feb 2021 20:02:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Oct 2020 13:48:27
User entered 'Oral (ORAL)'	Taylor Johnson (b) (4) (b) (4)	18 Sep 2020 17:45:04

**US3512248**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 10 Jun 2021 07:56:44**

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	26 Feb 2021 20:02:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Oct 2020 13:48:27
User entered empty.	Taylor Johnson (b) (4) (b) (4)	18 Sep 2020 17:45:04

**US3512248**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 10 Jun 2021 07:56:44**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	26 Feb 2021 20:02:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Oct 2020 13:48:27
User entered 'un Jan 2017'	Taylor Johnson (b) (4) (b) (4)	18 Sep 2020 17:45:04

**US3512248**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 10 Jun 2021 07:56:44**

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	26 Feb 2021 20:02:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Oct 2020 13:48:27
User entered '0'	Taylor Johnson (b) (4) (b) (4)	18 Sep 2020 17:45:04

**US3512248**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 10 Jun 2021 07:56:44**

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	26 Feb 2021 20:02:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Oct 2020 13:48:27
User entered 'Yes (Y)'	Taylor Johnson (b) (4) (b) (4)	18 Sep 2020 17:45:04



**US3512248**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 10 Jun 2021 07:56:44**

*If not Ongoing, End date (dd MMM yyyy)*

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	26 Feb 2021 20:02:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Oct 2020 13:48:27
User entered empty.	Taylor Johnson (b) (4) (b) (4)	18 Sep 2020 17:45:04

US3512248

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 07:56:44

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	26 Feb 2021 20:02:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Oct 2020 13:48:27
User entered 'No (N)'	Taylor Johnson (b) (4) (b) (4)	18 Sep 2020 17:45:04

**US3512248**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 10 Jun 2021 07:56:44**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	18 Sep 2020 17:45:04

**US3512248**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 10 Jun 2021 07:56:44**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	18 Sep 2020 17:45:04

US3512248

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 10 Jun 2021 07:56:44**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	18 Sep 2020 17:45:04

US3512248

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 07:56:44

Name of Medication

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	26 Feb 2021 20:02:47
User coded data point as ATC: SENSORY ORGANS, ATC: OPHTHALMOLOGICALS, ATC: OTHER OPHTHALMOLOGICALS, ATC: OTHER OPHTHALMOLOGICALS, PRODUCT: OTHER OPHTHALMOLOGICALS - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	24 Nov 2020 08:47:10
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	24 Nov 2020 08:47:10
DataPoint Verified.	(b) (4), (b) (6)	07 Oct 2020 13:48:27
Data point term sent to Coder	System	01 Oct 2020 12:47:08
User closed query 'CDM Coding: This medication can be referred as multiple ingredients in the standard coding dictionary. Please enter all the active ingredient(s) with drug name in drug name field and please make your changes to the reported term. Thank you.' (Site from System).	System	01 Oct 2020 12:46:51
Query 'CDM Coding: This medication can be referred as multiple ingredients in the standard coding dictionary. Please enter all the active ingredient(s) with drug name in drug name field and please make your changes to the reported term. Thank you.' answered with 'data updated' (Site from System).	Taylor Johnson (b) (4)	01 Oct 2020 12:46:51
User entered 'OCUVITE PRESERvision Eye vitamin AREDS 2 (zinc 17.4 mg; vitamin C 113 mg; vitamin E 100 IU; omega-3 250 mg; lutein 2.5 mg; zeaxanthin 2 mg)' reason for change: Data Entry Error	Taylor Johnson (b) (4)	01 Oct 2020 12:46:40
User opened query 'CDM Coding: This medication can be referred as multiple ingredients in the standard coding dictionary. Please enter all the active ingredient(s) with drug name in drug name field and please make your changes to the reported term. Thank you.' (Site from System).	Coder Import (b) (4)	24 Sep 2020 11:49:43
Data point term sent to Coder	System	18 Sep 2020 17:46:27
User entered 'ocuvite preservation'	Taylor Johnson (b) (4)	18 Sep 2020 17:46:00

US3512248

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 07:56:44

[Prophylaxis](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Mar 2021 13:50:48
User signature succeeded.	Michael Koren (b) (4)	26 Feb 2021 20:02:47
DataPoint Un-verified.	Brenda Anderson (b) (4)	13 Nov 2020 14:54:22
User entered 'Yes (Y)' reason for change: New Information	Brenda Anderson (b) (4)	13 Nov 2020 14:54:22
DataPoint Verified.	(b) (4), (b) (6)	07 Oct 2020 13:48:27
User entered 'No (N)'	Taylor Johnson (b) (4)	18 Sep 2020 17:46:00

US3512248

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 07:56:44

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	26 Feb 2021 20:02:47
User closed query 'Per DM CLR: Indication = SUPPLEMENT. Please review if this Con Med is taken as prophylaxis. If so, kindly update the response to 'Yes'. Update ConMed eCRF as appropriate.' (Site from DM).	(b) (4) (b) (4), (b) (6)	02 Nov 2020 05:50:43
Query 'Per DM CLR: Indication = SUPPLEMENT. Please review if this Con Med is taken as prophylaxis. If so, kindly update the response to 'Yes'. Update ConMed eCRF as appropriate.' answered with 'confirm as is' (Site from DM).	Brenda Anderson (b) (4) (b) (4)	28 Oct 2020 11:59:50
User opened query 'Per DM CLR: Indication = SUPPLEMENT. Please review if this Con Med is taken as prophylaxis. If so, kindly update the response to 'Yes'. Update ConMed eCRF as appropriate.' (Site from DM).	(b) (4), (b) (6)	20 Oct 2020 14:48:37
DataPoint Verified.	(b) (4), (b) (6)	07 Oct 2020 13:48:27
User entered 'supplement'	Taylor Johnson (b) (4) (b) (4)	18 Sep 2020 17:46:00



US3512248

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 07:56:44

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	26 Feb 2021 20:02:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Oct 2020 13:48:27
User entered 'I'	Taylor Johnson (b) (4) (b) (4)	18 Sep 2020 17:46:00

**US3512248**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 10 Jun 2021 07:56:44**

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	26 Feb 2021 20:02:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Oct 2020 13:48:27
User entered 'tablet (TABLET)'	Taylor Johnson (b) (4) (b) (4)	18 Sep 2020 17:46:00

US3512248

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 07:56:44

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	26 Feb 2021 20:02:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Oct 2020 13:48:27
User entered empty.	Taylor Johnson (b) (4) (b) (4)	18 Sep 2020 17:46:00

US3512248

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 07:56:44

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	26 Feb 2021 20:02:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Oct 2020 13:48:27
User entered 'once daily (QD)'	Taylor Johnson (b) (4) (b) (4)	18 Sep 2020 17:46:00

US3512248

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 07:56:44

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	26 Feb 2021 20:02:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Oct 2020 13:48:27
User entered empty.	Taylor Johnson (b) (4) (b) (4)	18 Sep 2020 17:46:00

**US3512248**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 10 Jun 2021 07:56:44**

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	26 Feb 2021 20:02:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Oct 2020 13:48:27
User entered 'Oral (ORAL)'	Taylor Johnson (b) (4) (b) (4)	18 Sep 2020 17:46:00

**US3512248**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 10 Jun 2021 07:56:44**

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	26 Feb 2021 20:02:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Oct 2020 13:48:27
User entered empty.	Taylor Johnson (b) (4) (b) (4)	18 Sep 2020 17:46:00

**US3512248**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 10 Jun 2021 07:56:44**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	26 Feb 2021 20:02:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Oct 2020 13:48:27
User entered 'un Apr 2018'	Taylor Johnson (b) (4) (b) (4)	18 Sep 2020 17:46:00



**US3512248**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 10 Jun 2021 07:56:44**

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	26 Feb 2021 20:02:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Oct 2020 13:48:27
User entered '0'	Taylor Johnson (b) (4) (b) (4)	18 Sep 2020 17:46:00

**US3512248**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 10 Jun 2021 07:56:44**

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	26 Feb 2021 20:02:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Oct 2020 13:48:27
User entered 'Yes (Y)'	Taylor Johnson (b) (4) (b) (4)	18 Sep 2020 17:46:00

**US3512248**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 10 Jun 2021 07:56:44**

*If not Ongoing, End date (dd MMM yyyy)*

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	26 Feb 2021 20:02:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Oct 2020 13:48:27
User entered empty.	Taylor Johnson (b) (4) (b) (4)	18 Sep 2020 17:46:00

**US3512248**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 10 Jun 2021 07:56:44**

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	26 Feb 2021 20:02:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Oct 2020 13:48:27
User entered 'No (N)'	Taylor Johnson (b) (4) (b) (4)	18 Sep 2020 17:46:00

**US3512248**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 10 Jun 2021 07:56:44**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	18 Sep 2020 17:46:00

**US3512248**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 10 Jun 2021 07:56:44**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	18 Sep 2020 17:46:00

**US3512248**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 10 Jun 2021 07:56:44**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	18 Sep 2020 17:46:00

US3512248

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 07:56:44

Name of Medication

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	26 Feb 2021 20:02:47
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	07 Oct 2020 13:48:27
User coded data point as ATC: MUSCULO-SKELETAL SYSTEM, ATC: ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, ATC: ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, NON-STEROIDS, ATC: PROPIONIC ACID DERIVATIVES, PRODUCT: IBUPROFEN - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	18 Sep 2020 17:48:33
	(b) (4)	
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	18 Sep 2020 17:48:33
	(b) (4)	
Data point term sent to Coder	System	18 Sep 2020 17:47:28
User entered 'ibuprofen'	Taylor Johnson (b) (4)	18 Sep 2020 17:46:40
	(b) (4)	



US3512248

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 07:56:44

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	26 Feb 2021 20:02:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Oct 2020 13:48:27
User entered 'No (N)'	Taylor Johnson (b) (4) (b) (4)	18 Sep 2020 17:46:40

US3512248

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 07:56:44

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	26 Feb 2021 20:02:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Oct 2020 13:48:27
User entered 'general aches and pains'	Taylor Johnson (b) (4) (b) (4)	18 Sep 2020 17:46:40

US3512248

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 07:56:44

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	26 Feb 2021 20:02:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Oct 2020 13:48:27
User entered '200'	Taylor Johnson (b) (4) (b) (4)	18 Sep 2020 17:46:40

US3512248

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 07:56:44

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	26 Feb 2021 20:02:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Oct 2020 13:48:27
User entered 'mg (mg)'	Taylor Johnson (b) (4) (b) (4)	18 Sep 2020 17:46:40

US3512248

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 07:56:44

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	26 Feb 2021 20:02:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Oct 2020 13:48:27
User entered empty.	Taylor Johnson (b) (4) (b) (4)	18 Sep 2020 17:46:40

US3512248

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 07:56:44

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	26 Feb 2021 20:02:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Oct 2020 13:48:27
User entered 'as needed (PRN)'	Taylor Johnson (b) (4) (b) (4)	18 Sep 2020 17:46:40

**US3512248**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (8)**

**Generated On: 10 Jun 2021 07:56:44**

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	26 Feb 2021 20:02:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Oct 2020 13:48:27
User entered empty.	Taylor Johnson (b) (4) (b) (4)	18 Sep 2020 17:46:40

**US3512248**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (8)**

**Generated On: 10 Jun 2021 07:56:44**

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	26 Feb 2021 20:02:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Oct 2020 13:48:27
User entered 'Oral (ORAL)'	Taylor Johnson (b) (4) (b) (4)	18 Sep 2020 17:46:40



US3512248

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 07:56:44

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	26 Feb 2021 20:02:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Oct 2020 13:48:27
User entered empty.	Taylor Johnson (b) (4) (b) (4)	18 Sep 2020 17:46:40

**US3512248**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (8)**

**Generated On: 10 Jun 2021 07:56:44**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	26 Feb 2021 20:02:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Oct 2020 13:48:27
User entered 'un UNK 2006'	Taylor Johnson (b) (4) (b) (4)	18 Sep 2020 17:46:40

**US3512248**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (8)**

**Generated On: 10 Jun 2021 07:56:44**

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	26 Feb 2021 20:02:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Oct 2020 13:48:27
User entered '0'	Taylor Johnson (b) (4) (b) (4)	18 Sep 2020 17:46:40

US3512248

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 07:56:44

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	26 Feb 2021 20:02:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Oct 2020 13:48:27
User entered 'Yes (Y)'	Taylor Johnson (b) (4) (b) (4)	18 Sep 2020 17:46:40

**US3512248**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (8)**

**Generated On: 10 Jun 2021 07:56:44**

*If not Ongoing, End date (dd MMM yyyy)*

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	26 Feb 2021 20:02:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Oct 2020 13:48:27
User entered empty.	Taylor Johnson (b) (4) (b) (4)	18 Sep 2020 17:46:40

US3512248

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 07:56:44

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	26 Feb 2021 20:02:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Oct 2020 13:48:27
User entered 'No (N)'	Taylor Johnson (b) (4) (b) (4)	18 Sep 2020 17:46:40

**US3512248**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (8)**

**Generated On: 10 Jun 2021 07:56:44**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	18 Sep 2020 17:46:40

US3512248

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (8)**

**Generated On: 10 Jun 2021 07:56:44**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	18 Sep 2020 17:46:40



**US3512248**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (8)**

**Generated On: 10 Jun 2021 07:56:44**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	18 Sep 2020 17:46:40

US3512248

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 07:56:44

[Name of Medication](#)

Audit	User	Time (GMT)
User coded data point as ATC: BLOOD AND BLOOD FORMING ORGANS, ATC: ANTITHROMBOTIC AGENTS, ATC: ANTITHROMBOTIC AGENTS, ATC: DIRECT FACTOR XA INHIBITORS, PRODUCT: APIXABAN, PRODUCTSYNONYM: ELIQUIS - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	11 Mar 2021 20:37:59
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	11 Mar 2021 20:37:59
Data point term sent to Coder	System	11 Mar 2021 20:36:54
Coding entries removed.	Sheldon Warren (b) (4)	11 Mar 2021 20:36:53
User signature succeeded.	Michael Koren (b) (4)	26 Feb 2021 20:02:47
DataPoint Verified.	(b) (4), (b) (6)	07 Oct 2020 13:48:27
User coded data point as ATC: BLOOD AND BLOOD FORMING ORGANS, ATC: ANTITHROMBOTIC AGENTS, ATC: ANTITHROMBOTIC AGENTS, ATC: DIRECT FACTOR XA INHIBITORS, PRODUCT: APIXABAN, PRODUCTSYNONYM: ELIQUIS - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	18 Sep 2020 17:49:34
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	18 Sep 2020 17:49:34
Data point term sent to Coder	System	18 Sep 2020 17:48:32
User entered 'eliquis'	Taylor Johnson (b) (4)	18 Sep 2020 17:47:41

US3512248

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 07:56:44

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	26 Feb 2021 20:02:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Oct 2020 13:48:27
User entered 'No (N)'	Taylor Johnson (b) (4) (b) (4)	18 Sep 2020 17:47:41

US3512248

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 07:56:44

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	15 Mar 2021 12:52:32
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Mar 2021 13:50:48
DataPoint Un-verified.	Sheldon Warren (b) (4)	11 Mar 2021 20:36:53
Signature has been broken.	(b) (4) Sheldon Warren (b) (4)	11 Mar 2021 20:36:53
User entered 'ATRIAL FIBRILLATION' reason for change: Data Entry Error	(b) (4) Sheldon Warren (b) (4)	11 Mar 2021 20:36:53
User signature succeeded.	Michael Koren (b) (4)	26 Feb 2021 20:02:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Oct 2020 13:48:27
User entered 'atrial fibrillation'	Taylor Johnson (b) (4) (b) (4)	18 Sep 2020 17:47:41

**US3512248**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (9)**

**Generated On: 10 Jun 2021 07:56:44**

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	26 Feb 2021 20:02:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Oct 2020 13:48:27
User entered '5'	Taylor Johnson (b) (4) (b) (4)	18 Sep 2020 17:47:41

US3512248

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 07:56:44

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	26 Feb 2021 20:02:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Oct 2020 13:48:27
User entered 'mg (mg)'	Taylor Johnson (b) (4) (b) (4)	18 Sep 2020 17:47:41

US3512248

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 07:56:44

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	26 Feb 2021 20:02:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Oct 2020 13:48:27
User entered empty.	Taylor Johnson (b) (4) (b) (4)	18 Sep 2020 17:47:41

US3512248

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 07:56:44

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	26 Feb 2021 20:02:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Oct 2020 13:48:27
User entered 'twice daily (BID)'	Taylor Johnson (b) (4) (b) (4)	18 Sep 2020 17:47:41



**US3512248**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (9)**

**Generated On: 10 Jun 2021 07:56:44**

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	26 Feb 2021 20:02:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Oct 2020 13:48:27
User entered empty.	Taylor Johnson (b) (4) (b) (4)	18 Sep 2020 17:47:41

**US3512248**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (9)**

**Generated On: 10 Jun 2021 07:56:44**

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	26 Feb 2021 20:02:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Oct 2020 13:48:27
User entered 'Oral (ORAL)'	Taylor Johnson (b) (4) (b) (4)	18 Sep 2020 17:47:41

**US3512248**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (9)**

**Generated On: 10 Jun 2021 07:56:44**

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	26 Feb 2021 20:02:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Oct 2020 13:48:27
User entered empty.	Taylor Johnson (b) (4) (b) (4)	18 Sep 2020 17:47:41

US3512248

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 07:56:44

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User closed query 'Per DM CLR: Con Med start date is prior to the start date of the corresponding MH condition. Please review and reconcile Con Med and MH start dates as appropriate. Otherwise, clarify. ' (Site from DM).	(b) (4), (b) (6)	05 Apr 2021 05:26:23
Query 'Per DM CLR: Con Med start date is prior to the start date of the corresponding MH condition. Please review and reconcile Con Med and MH start dates as appropriate. Otherwise, clarify. ' answered with 'changed medical history date' (Site from DM).	Brenda Anderson (b) (4)	02 Apr 2021 14:09:35
User opened query 'Per DM CLR: Con Med start date is prior to the start date of the corresponding MH condition. Please review and reconcile Con Med and MH start dates as appropriate. Otherwise, clarify. ' (Site from DM).	(b) (4), (b) (6)	02 Apr 2021 04:00:21
User signature succeeded.	Michael Koren (b) (4)	26 Feb 2021 20:02:47
DataPoint Verified.	(b) (4), (b) (6)	07 Oct 2020 13:48:27
User entered 'un Apr 2018'	Taylor Johnson (b) (4)	18 Sep 2020 17:47:41

**US3512248**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (9)**

**Generated On: 10 Jun 2021 07:56:44**

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	26 Feb 2021 20:02:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Oct 2020 13:48:27
User entered '0'	Taylor Johnson (b) (4) (b) (4)	18 Sep 2020 17:47:41

**US3512248**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (9)**

**Generated On: 10 Jun 2021 07:56:44**

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	26 Feb 2021 20:02:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Oct 2020 13:48:27
User entered 'Yes (Y)'	Taylor Johnson (b) (4) (b) (4)	18 Sep 2020 17:47:41

**US3512248**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (9)**

**Generated On: 10 Jun 2021 07:56:44**

*If not Ongoing, End date (dd MMM yyyy)*

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	26 Feb 2021 20:02:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Oct 2020 13:48:27
User entered empty.	Taylor Johnson (b) (4) (b) (4)	18 Sep 2020 17:47:41

**US3512248**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (9)**

**Generated On: 10 Jun 2021 07:56:44**

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	26 Feb 2021 20:02:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Oct 2020 13:48:27
User entered 'No (N)'	Taylor Johnson (b) (4) (b) (4)	18 Sep 2020 17:47:41



**US3512248**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (9)**

**Generated On: 10 Jun 2021 07:56:44**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '2'	System	18 Sep 2020 17:47:41

**US3512248**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (9)**

**Generated On: 10 Jun 2021 07:56:44**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	18 Sep 2020 17:47:41

**US3512248**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (9)**

**Generated On: 10 Jun 2021 07:56:44**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	18 Sep 2020 17:47:41

US3512248

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 07:56:44

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	26 Feb 2021 20:02:47
User coded data point as ATC: BLOOD AND BLOOD FORMING ORGANS, ATC: ANTITHROMBOTIC AGENTS, ATC: ANTITHROMBOTIC AGENTS, ATC: PLATELET AGGREGATION INHIBITORS EXCL. HEPARIN, PRODUCT: ACETYLSALICYLIC ACID, PRODUCTSYNONYM: ASPIRIN [ACETYLSALICYLIC ACID] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	05 Nov 2020 22:01:43
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	05 Nov 2020 22:01:43
Data point term sent to Coder Coding entries removed.	System Brenda Anderson (b) (4)	05 Nov 2020 21:59:54 05 Nov 2020 21:58:59
User coded data point as ATC: BLOOD AND BLOOD FORMING ORGANS, ATC: ANTITHROMBOTIC AGENTS, ATC: ANTITHROMBOTIC AGENTS, ATC: PLATELET AGGREGATION INHIBITORS EXCL. HEPARIN, PRODUCT: ACETYLSALICYLIC ACID, PRODUCTSYNONYM: ASPIRIN [ACETYLSALICYLIC ACID] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	05 Nov 2020 21:55:45
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	05 Nov 2020 21:55:45
Data point term sent to Coder Coding entries removed.	System Brenda Anderson (b) (4)	05 Nov 2020 21:54:40 05 Nov 2020 21:53:44
DataPoint Verified.	(b) (4), (b) (6)	07 Oct 2020 13:48:27

US3512248

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 07:56:44

[Name of Medication](#)

Audit	User	Time (GMT)
User coded data point as ATC: BLOOD AND BLOOD FORMING ORGANS, ATC: ANTITHROMBOTIC AGENTS, ATC: ANTITHROMBOTIC AGENTS, ATC: PLATELET AGGREGATION INHIBITORS EXCL. HEPARIN, PRODUCT: ACETYLSALICYLIC ACID, PRODUCTSYNONYM: ASPIRIN [ACETYLSALICYLIC ACID] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	18 Sep 2020 17:50:38
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	18 Sep 2020 17:50:38
Data point term sent to Coder	System	18 Sep 2020 17:49:35
User entered 'aspirin'	Taylor Johnson (b) (4)	18 Sep 2020 17:49:15

**US3512248**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (10)**

**Generated On: 10 Jun 2021 07:56:44**

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	26 Feb 2021 20:02:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Oct 2020 13:48:27
User entered 'No (N)'	Taylor Johnson (b) (4) (b) (4)	18 Sep 2020 17:49:15

US3512248

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 07:56:44

[Indication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Mar 2021 13:50:48
User signature succeeded.	Michael Koren (b) (4)	26 Feb 2021 20:02:47
User entered 'Coronary Artery Disease' reason for change: New Information	Brenda Anderson (b) (4)	05 Nov 2020 21:58:59
DataPoint Un-verified.	Brenda Anderson (b) (4)	05 Nov 2020 21:53:44
User entered 'CAD' reason for change: New Information	Brenda Anderson (b) (4)	05 Nov 2020 21:53:44
DataPoint Verified.	(b) (4), (b) (6)	07 Oct 2020 13:48:27
User entered 'atrial fibrillation'	Taylor Johnson (b) (4)	18 Sep 2020 17:49:15

**US3512248**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (10)**

**Generated On: 10 Jun 2021 07:56:44**

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	26 Feb 2021 20:02:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Oct 2020 13:48:27
User entered '81'	Taylor Johnson (b) (4) (b) (4)	18 Sep 2020 17:49:15



US3512248

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 07:56:44

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	26 Feb 2021 20:02:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Oct 2020 13:48:27
User entered 'mg (mg)'	Taylor Johnson (b) (4) (b) (4)	18 Sep 2020 17:49:15

US3512248

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 07:56:44

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	26 Feb 2021 20:02:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Oct 2020 13:48:27
User entered empty.	Taylor Johnson (b) (4) (b) (4)	18 Sep 2020 17:49:15

US3512248

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 07:56:44

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	26 Feb 2021 20:02:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Oct 2020 13:48:27
User entered 'once daily (QD)'	Taylor Johnson (b) (4) (b) (4)	18 Sep 2020 17:49:15

US3512248

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 07:56:44

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	26 Feb 2021 20:02:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Oct 2020 13:48:27
User entered empty.	Taylor Johnson (b) (4) (b) (4)	18 Sep 2020 17:49:15

US3512248

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 07:56:44

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	26 Feb 2021 20:02:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Oct 2020 13:48:27
User entered 'Oral (ORAL)'	Taylor Johnson (b) (4) (b) (4)	18 Sep 2020 17:49:15

US3512248

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 07:56:44

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	26 Feb 2021 20:02:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Oct 2020 13:48:27
User entered empty.	Taylor Johnson (b) (4) (b) (4)	18 Sep 2020 17:49:15

US3512248

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 07:56:44

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	26 Feb 2021 20:02:47
User closed query 'Per CDM CR: Con Med start date is prior to the start date of the Med History condition of ATRIAL FIBRILLATION-UN OCT 2018. Please review and reconcile Con Med and Med History start dates as appropriate.' (Site from DM).	(b) (4) (b) (4), (b) (6)	10 Nov 2020 05:57:55
Query 'Per CDM CR: Con Med start date is prior to the start date of the Med History condition of ATRIAL FIBRILLATION-UN OCT 2018. Please review and reconcile Con Med and Med History start dates as appropriate.' answered with 'changed indication' (Site from DM).	Brenda Anderson (b) (4) (b) (4)	05 Nov 2020 21:54:03
User opened query 'Per CDM CR: Con Med start date is prior to the start date of the Med History condition of ATRIAL FIBRILLATION-UN OCT 2018. Please review and reconcile Con Med and Med History start dates as appropriate.' (Site from DM).	(b) (4), (b) (6)	20 Oct 2020 14:50:27
DataPoint Verified.	(b) (4), (b) (6)	07 Oct 2020 13:48:27
User entered 'un Jan 2009'	Taylor Johnson (b) (4) (b) (4)	18 Sep 2020 17:49:15

**US3512248**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (10)**

**Generated On: 10 Jun 2021 07:56:44**

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	26 Feb 2021 20:02:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Oct 2020 13:48:27
User entered '0'	Taylor Johnson (b) (4) (b) (4)	18 Sep 2020 17:49:15



**US3512248**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (10)**

**Generated On: 10 Jun 2021 07:56:44**

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	26 Feb 2021 20:02:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Oct 2020 13:48:27
User entered 'Yes (Y)'	Taylor Johnson (b) (4) (b) (4)	18 Sep 2020 17:49:15

**US3512248**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (10)**

**Generated On: 10 Jun 2021 07:56:44**

*If not Ongoing, End date (dd MMM yyyy)*

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	26 Feb 2021 20:02:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Oct 2020 13:48:27
User entered empty.	Taylor Johnson (b) (4) (b) (4)	18 Sep 2020 17:49:15

US3512248

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 07:56:44

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	26 Feb 2021 20:02:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Oct 2020 13:48:27
User entered 'No (N)'	Taylor Johnson (b) (4) (b) (4)	18 Sep 2020 17:49:15

**US3512248**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (10)**

**Generated On: 10 Jun 2021 07:56:44**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	18 Sep 2020 17:49:15

**US3512248**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (10)**

**Generated On: 10 Jun 2021 07:56:44**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	18 Sep 2020 17:49:15

**US3512248**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (10)**

**Generated On: 10 Jun 2021 07:56:44**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	18 Sep 2020 17:49:15

US3512248

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 07:56:44

Name of Medication

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	26 Feb 2021 20:02:47
User coded data point as ATC: MUSCULO-SKELETAL SYSTEM, ATC: ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, ATC: ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, NON-STEROIDS, ATC: PROPIONIC ACID DERIVATIVES, PRODUCT: IBUPROFEN, PRODUCTSYNONYM: MOTRIN [IBUPROFEN] - version WHODrug-Global-B3\202003.	(b) (4) Coder Import (b) (4) (b) (4)	23 Nov 2020 08:45:09
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	23 Nov 2020 08:45:09
Data point term sent to Coder Coding entries removed.	System Allison Crain (b) (4)	13 Nov 2020 21:23:14 13 Nov 2020 21:22:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Oct 2020 13:48:27
User coded data point as ATC: MUSCULO-SKELETAL SYSTEM, ATC: ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, ATC: ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, NON-STEROIDS, ATC: PROPIONIC ACID DERIVATIVES, PRODUCT: IBUPROFEN, PRODUCTSYNONYM: MOTRIN [IBUPROFEN] - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	18 Sep 2020 23:19:38
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	18 Sep 2020 23:19:38
Data point term sent to Coder User entered 'motrin'	System Taylor Johnson (b) (4) (b) (4)	18 Sep 2020 17:50:37 18 Sep 2020 17:50:03

**US3512248**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (11)**

**Generated On: 10 Jun 2021 07:56:44**

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	26 Feb 2021 20:02:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Oct 2020 13:48:27
User entered 'No (N)'	Taylor Johnson (b) (4) (b) (4)	18 Sep 2020 17:50:03



US3512248

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 07:56:44

[Indication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Mar 2021 13:50:48
User signature succeeded.	Michael Koren (b) (4)	26 Feb 2021 20:02:47
User closed query 'Per CDM CR: Please note that this condition is not recorded on the MH eCRF. Please review Con Med use and add a medical condition and all applicable details to the appropriate MH eCRF.' (Site from DM).	(b) (4) (b) (4), (b) (6)	17 Nov 2020 09:14:59
Query 'Per CDM CR: Please note that this condition is not recorded on the MH eCRF. Please review Con Med use and add a medical condition and all applicable details to the appropriate MH eCRF.' answered with 'UPDATED, WILL ADD TO MH' (Site from DM).	Allison Crain (b) (4) (b) (4)	13 Nov 2020 21:22:33
DataPoint Un-verified.	Allison Crain (b) (4) (b) (4)	13 Nov 2020 21:22:16
User entered 'LEFT MENISCUS TEAR' reason for change: Data Entry Error	Allison Crain (b) (4) (b) (4)	13 Nov 2020 21:22:16
User opened query 'Per CDM CR: Please note that this condition is not recorded on the MH eCRF. Please review Con Med use and add a medical condition and all applicable details to the appropriate MH eCRF.' (Site from DM).	(b) (4), (b) (6)	20 Oct 2020 14:51:27
DataPoint Verified.	(b) (4), (b) (6)	07 Oct 2020 13:48:27
User entered 'left knee injury'	Taylor Johnson (b) (4) (b) (4)	18 Sep 2020 17:50:03

**US3512248**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (11)**

**Generated On: 10 Jun 2021 07:56:44**

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	26 Feb 2021 20:02:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Oct 2020 13:48:27
User entered '200'	Taylor Johnson (b) (4) (b) (4)	18 Sep 2020 17:50:03

US3512248

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 07:56:44

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	26 Feb 2021 20:02:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Oct 2020 13:48:27
User entered 'mg (mg)'	Taylor Johnson (b) (4) (b) (4)	18 Sep 2020 17:50:03

US3512248

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 07:56:44

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	26 Feb 2021 20:02:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Oct 2020 13:48:27
User entered empty.	Taylor Johnson (b) (4) (b) (4)	18 Sep 2020 17:50:03

US3512248

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 07:56:44

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	26 Feb 2021 20:02:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Oct 2020 13:48:27
User entered 'as needed (PRN)'	Taylor Johnson (b) (4) (b) (4)	18 Sep 2020 17:50:03

US3512248

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 07:56:44

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	26 Feb 2021 20:02:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Oct 2020 13:48:27
User entered empty.	Taylor Johnson (b) (4) (b) (4)	18 Sep 2020 17:50:03

**US3512248**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (11)**

**Generated On: 10 Jun 2021 07:56:44**

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	26 Feb 2021 20:02:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Oct 2020 13:48:27
User entered 'Oral (ORAL)'	Taylor Johnson (b) (4) (b) (4)	18 Sep 2020 17:50:03

US3512248

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 07:56:44

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	26 Feb 2021 20:02:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Oct 2020 13:48:27
User entered empty.	Taylor Johnson (b) (4) (b) (4)	18 Sep 2020 17:50:03



US3512248

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 07:56:44

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	26 Feb 2021 20:02:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Oct 2020 13:48:27
User entered '16 Jul 2019'	Taylor Johnson (b) (4) (b) (4)	18 Sep 2020 17:50:03

**US3512248**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (11)**

**Generated On: 10 Jun 2021 07:56:44**

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	26 Feb 2021 20:02:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Oct 2020 13:48:27
User entered '0'	Taylor Johnson (b) (4) (b) (4)	18 Sep 2020 17:50:03

**US3512248**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (11)**

**Generated On: 10 Jun 2021 07:56:44**

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	26 Feb 2021 20:02:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Oct 2020 13:48:27
User entered 'Yes (Y)'	Taylor Johnson (b) (4) (b) (4)	18 Sep 2020 17:50:03

US3512248

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 07:56:44

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	26 Feb 2021 20:02:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Oct 2020 13:48:27
User entered empty.	Taylor Johnson (b) (4) (b) (4)	18 Sep 2020 17:50:03

US3512248

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 07:56:44

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	26 Feb 2021 20:02:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Oct 2020 13:48:27
User entered 'No (N)'	Taylor Johnson (b) (4) (b) (4)	18 Sep 2020 17:50:03

**US3512248**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (11)**

**Generated On: 10 Jun 2021 07:56:44**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	18 Sep 2020 17:50:03

**US3512248**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (11)**

**Generated On: 10 Jun 2021 07:56:44**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	18 Sep 2020 17:50:03

**US3512248**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (11)**

**Generated On: 10 Jun 2021 07:56:44**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	18 Sep 2020 17:50:03



US3512248

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 07:56:44

Name of Medication

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	26 Feb 2021 20:02:47
User closed query 'Per DM CLR: This Con Med was added after the first dose of study vaccination. Please clarify if there was a WORSENING/EXACERBATION of the medical history condition requiring a change in medications. If yes, please add the applicable AE entry or explain the reason for change in regimen.' (Site from DM). Query 'Per DM CLR: This Con Med was added after the first dose of study vaccination. Please clarify if there was a WORSENING/EXACERBATION of the medical history condition requiring a change in medications. If yes, please add the applicable AE entry or explain the reason for change in regimen.' answered with 'This is an AE and not MH. Corrected in EDC.' (Site from DM).	(b) (4) (b) (4), (b) (6)	18 Nov 2020 04:26:33
User opened query 'Per DM CLR: This Con Med was added after the first dose of study vaccination. Please clarify if there was a WORSENING/EXACERBATION of the medical history condition requiring a change in medications. If yes, please add the applicable AE entry or explain the reason for change in regimen.' (Site from DM).	Allison Crain (b) (4) (b) (4)	13 Nov 2020 21:24:43
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: AGENTS ACTING ON THE RENIN-ANGIOTENSIN SYSTEM, ATC: ANGIOTENSIN II RECEPTOR BLOCKERS (ARBS), PLAIN, ATC: ANGIOTENSIN II RECEPTOR BLOCKERS (ARBS), PLAIN, PRODUCT: LOSARTAN - version WHODrug-Global-B3\\202003.	(b) (4), (b) (6)	11 Nov 2020 06:47:21
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003. Data point term sent to Coder Coding entries removed.	Coder Import (b) (4) (b) (4)	05 Nov 2020 21:58:39
DataPoint Verified.	Coder Import (b) (4) (b) (4)	05 Nov 2020 21:58:39
	System	05 Nov 2020 21:57:44
	Brenda Anderson (b) (4) (b) (4)	05 Nov 2020 21:57:32
	(b) (4), (b) (6)	07 Oct 2020 13:48:27

US3512248

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 07:56:44

[Name of Medication](#)

Audit	User	Time (GMT)
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: AGENTS ACTING ON THE RENIN-ANGIOTENSIN SYSTEM, ATC: ANGIOTENSIN II RECEPTOR BLOCKERS (ARBS), PLAIN, ATC: ANGIOTENSIN II RECEPTOR BLOCKERS (ARBS), PLAIN, PRODUCT: LOSARTAN - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	19 Sep 2020 09:40:44
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	19 Sep 2020 09:40:44
Data point term sent to Coder	System	18 Sep 2020 17:50:43
User entered 'losartan'	Taylor Johnson (b) (4) (b) (4)	18 Sep 2020 17:50:42

US3512248

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 07:56:44

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	26 Feb 2021 20:02:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Oct 2020 13:48:27
User entered 'No (N)'	Taylor Johnson (b) (4) (b) (4)	18 Sep 2020 17:50:42

US3512248

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 07:56:44

[Indication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Mar 2021 13:50:48
User signature succeeded.	Michael Koren (b) (4)	26 Feb 2021 20:02:47
User closed query 'Per DM CLR: Please note there is no ongoing MH condition or AE that matches this Con Med indication. Please review the Con Med use and add a medical condition and all applicable details to the appropriate MH or AE eCRF.' (Site from DM).	(b) (4)	04 Dec 2020 06:10:35
Query 'Per DM CLR: Please note there is no ongoing MH condition or AE that matches this Con Med indication. Please review the Con Med use and add a medical condition and all applicable details to the appropriate MH or AE eCRF.' answered with 'Please see AE #2 HYPERTENSION' (Site from DM).	Allison Crain (b) (4)	02 Dec 2020 19:38:26
User opened query 'Per DM CLR: Please note there is no ongoing MH condition or AE that matches this Con Med indication. Please review the Con Med use and add a medical condition and all applicable details to the appropriate MH or AE eCRF.' (Site from DM).	(b) (4)	28 Nov 2020 14:09:01
User closed query 'Per CDM CR: Please note that there is no AE that matches this Con Med indication during this time frame. Please review Con Med use and add a medical condition and all applicable details to the AE eCRF as appropriate.' (Site from DM).	(b) (4), (b) (6)	11 Nov 2020 04:52:01
Query 'Per CDM CR: Please note that there is no AE that matches this Con Med indication during this time frame. Please review Con Med use and add a medical condition and all applicable details to the AE eCRF as appropriate.' answered with 'added to MH' (Site from DM).	Brenda Anderson (b) (4)	05 Nov 2020 21:57:36
DataPoint Un-verified.	(b) (4)	05 Nov 2020 21:57:32
User entered 'hypertension' reason for change: Data Entry Error	Brenda Anderson (b) (4)	05 Nov 2020 21:57:32
User opened query 'Per CDM CR: Please note that there is no AE that matches this Con Med indication during this time frame. Please review Con Med use and add a medical condition and all applicable details to the AE eCRF as appropriate.' (Site from DM).	(b) (4)	20 Oct 2020 14:52:05
DataPoint Verified.	(b) (4), (b) (6)	07 Oct 2020 13:48:27

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EAB) (1725)

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**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (12)**

**Generated On: 10 Jun 2021 07:56:44**

[Indication](#)

Audit	User	Time (GMT)
User entered 'elevated blood pressure'	Taylor Johnson (b) (4) (b) (4)	18 Sep 2020 17:50:42

**US3512248**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (12)**

**Generated On: 10 Jun 2021 07:56:44**

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	26 Feb 2021 20:02:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Oct 2020 13:48:27
User entered '25'	Taylor Johnson (b) (4) (b) (4)	18 Sep 2020 17:50:42

US3512248

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 07:56:44

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	26 Feb 2021 20:02:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Oct 2020 13:48:27
User entered 'mg (mg)'	Taylor Johnson (b) (4) (b) (4)	18 Sep 2020 17:50:42

**US3512248**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (12)**

**Generated On: 10 Jun 2021 07:56:44**

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	26 Feb 2021 20:02:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Oct 2020 13:48:27
User entered empty.	Taylor Johnson (b) (4) (b) (4)	18 Sep 2020 17:50:42



US3512248

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 07:56:44

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	26 Feb 2021 20:02:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Oct 2020 13:48:27
User entered 'once daily (QD)'	Taylor Johnson (b) (4) (b) (4)	18 Sep 2020 17:50:42

US3512248

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 07:56:44

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	26 Feb 2021 20:02:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Oct 2020 13:48:27
User entered empty.	Taylor Johnson (b) (4) (b) (4)	18 Sep 2020 17:50:42

US3512248

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 07:56:44

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	26 Feb 2021 20:02:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Oct 2020 13:48:27
User entered 'Oral (ORAL)'	Taylor Johnson (b) (4) (b) (4)	18 Sep 2020 17:50:42

US3512248

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 07:56:44

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	26 Feb 2021 20:02:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Oct 2020 13:48:27
User entered empty.	Taylor Johnson (b) (4) (b) (4)	18 Sep 2020 17:50:42

US3512248

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 07:56:44

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	26 Feb 2021 20:02:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Oct 2020 13:48:27
User entered '17 Sep 2020'	Taylor Johnson (b) (4) (b) (4)	18 Sep 2020 17:50:42

**US3512248**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (12)**

**Generated On: 10 Jun 2021 07:56:44**

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	26 Feb 2021 20:02:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Oct 2020 13:48:27
User entered '0'	Taylor Johnson (b) (4) (b) (4)	18 Sep 2020 17:50:42

**US3512248**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (12)**

**Generated On: 10 Jun 2021 07:56:44**

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	26 Feb 2021 20:02:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Oct 2020 13:48:27
User entered 'Yes (Y)'	Taylor Johnson (b) (4) (b) (4)	18 Sep 2020 17:50:42

US3512248

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 07:56:44

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	26 Feb 2021 20:02:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Oct 2020 13:48:27
User entered empty.	Taylor Johnson (b) (4) (b) (4)	18 Sep 2020 17:50:42



US3512248

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 07:56:44

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	26 Feb 2021 20:02:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Oct 2020 13:48:27
User entered 'No (N)'	Taylor Johnson (b) (4) (b) (4)	18 Sep 2020 17:50:42

**US3512248**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (12)**

**Generated On: 10 Jun 2021 07:56:44**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	18 Sep 2020 17:50:42

US3512248

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (12)**

**Generated On: 10 Jun 2021 07:56:44**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	18 Sep 2020 17:50:42

**US3512248**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (12)**

**Generated On: 10 Jun 2021 07:56:44**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	18 Sep 2020 17:50:42

US3512248

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 07:56:44

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 18:13:56
DataPoint Verified.	(b) (4), (b) (6)	12 Mar 2021 13:50:48
User signature succeeded.	Michael Koren (b) (4)	26 Feb 2021 20:02:47
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANESTHETICS, ATC: ANESTHETICS, LOCAL, ATC: AMIDES, PRODUCT: LIDOCAINE - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4) (b) (4)	17 Nov 2020 07:59:11
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	17 Nov 2020 07:59:11
Data point term sent to Coder	System	16 Nov 2020 19:20:11
Data point term sent to Coder	System	16 Nov 2020 18:57:38
User entered 'lidocaine 1%'	Brenda Anderson (b) (4) (b) (4)	16 Nov 2020 18:56:51

US3512248

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 07:56:44

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 18:13:56
DataPoint Verified.	(b) (4), (b) (6)	12 Mar 2021 13:50:48
User signature succeeded.	Michael Koren (b) (4)	26 Feb 2021 20:02:47
User entered 'No (N)'	(b) (4) Brenda Anderson (b) (4)	16 Nov 2020 18:56:51

US3512248

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 07:56:44

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 18:13:56
DataPoint Verified.	(b) (4), (b) (6)	12 Mar 2021 13:50:48
User signature succeeded.	Michael Koren (b) (4)	26 Feb 2021 20:02:47
User entered 'RIGHT HIP TROCHANTERIC BURSITIS' reason for change: Data Entry Error	(b) (4)	
User entered 'right hip trochanteric'	Brenda Anderson (b) (4)	16 Nov 2020 19:19:27
	(b) (4)	
	Brenda Anderson (b) (4)	16 Nov 2020 18:56:51
	(b) (4)	

**US3512248**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (13)**

**Generated On: 10 Jun 2021 07:56:44**

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 18:13:56
DataPoint Verified.	(b) (4), (b) (6)	12 Mar 2021 13:50:48
User signature succeeded.	Michael Koren (b) (4)	26 Feb 2021 20:02:47
User entered '4'	Brenda Anderson (b) (4)	16 Nov 2020 18:56:51



US3512248

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 07:56:44

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 18:13:56
DataPoint Verified.	(b) (4), (b) (6)	12 Mar 2021 13:50:48
User signature succeeded.	Michael Koren (b) (4)	26 Feb 2021 20:02:47
User entered 'Other (OTHER)'	Brenda Anderson (b) (4)	16 Nov 2020 18:56:51

US3512248

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 07:56:44

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 18:13:56
DataPoint Verified.	(b) (4), (b) (6)	12 Mar 2021 13:50:48
User signature succeeded.	Michael Koren (b) (4)	26 Feb 2021 20:02:47
User entered 'cc'	(b) (4) Brenda Anderson (b) (4)	16 Nov 2020 18:56:51

US3512248

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 07:56:44

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 18:13:56
DataPoint Verified.	(b) (4), (b) (6)	12 Mar 2021 13:50:48
User signature succeeded.	Michael Koren (b) (4)	26 Feb 2021 20:02:47
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	16 Nov 2020 19:33:58
User entered 'once (ONCE)' reason for change: Data Entry Error	Brenda Anderson (b) (4)	16 Nov 2020 19:33:58
User opened query 'Data is required. Please complete.' (Site from System).	(b) (4)	
User entered empty.	System	16 Nov 2020 18:56:51
	Brenda Anderson (b) (4)	16 Nov 2020 18:56:51
	(b) (4)	

US3512248

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 07:56:44

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 18:13:56
DataPoint Verified.	(b) (4), (b) (6)	12 Mar 2021 13:50:48
User signature succeeded.	Michael Koren (b) (4)	26 Feb 2021 20:02:47
User entered empty.	(b) (4) Brenda Anderson (b) (4)	16 Nov 2020 18:56:51

US3512248

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 07:56:44

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 18:13:56
DataPoint Verified.	(b) (4), (b) (6)	12 Mar 2021 13:50:48
User signature succeeded.	Michael Koren (b) (4)	26 Feb 2021 20:02:47
User entered 'Other (OTHER)'	Brenda Anderson (b) (4)	16 Nov 2020 18:56:51

US3512248

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 07:56:44

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 18:13:56
DataPoint Verified.	(b) (4), (b) (6)	12 Mar 2021 13:50:48
User signature succeeded.	Michael Koren (b) (4)	26 Feb 2021 20:02:47
User entered 'intrabursal'	(b) (4) Brenda Anderson (b) (4) (b) (4)	16 Nov 2020 18:56:51

US3512248

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 07:56:44

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 18:13:56
DataPoint Verified.	(b) (4), (b) (6)	12 Mar 2021 13:50:48
User signature succeeded.	Michael Koren (b) (4)	26 Feb 2021 20:02:47
User entered '05 Oct 2020' reason for change: Data Entry Error	(b) (4)	
	Brenda Anderson (b) (4)	16 Nov 2020 19:19:27
User entered '10 May 2020'	(b) (4)	
	Brenda Anderson (b) (4)	16 Nov 2020 18:56:51
	(b) (4)	

**US3512248**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (13)**

**Generated On: 10 Jun 2021 07:56:44**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 18:13:56
DataPoint Verified.	(b) (4), (b) (6)	12 Mar 2021 13:50:48
User signature succeeded.	Michael Koren (b) (4)	26 Feb 2021 20:02:47
User entered '0'	Brenda Anderson (b) (4)	16 Nov 2020 18:56:51



US3512248

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 07:56:44

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 18:13:56
DataPoint Verified.	(b) (4), (b) (6)	12 Mar 2021 13:50:48
User signature succeeded.	Michael Koren (b) (4)	26 Feb 2021 20:02:47
User entered 'No (N)' reason for change: Data Entry Error	(b) (4)	
	Brenda Anderson (b) (4)	16 Nov 2020 19:33:58
User entered 'Yes (Y)'	(b) (4)	
	Brenda Anderson (b) (4)	16 Nov 2020 18:56:51
	(b) (4)	

US3512248

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 07:56:44

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 18:13:56
DataPoint Verified.	(b) (4), (b) (6)	12 Mar 2021 13:50:48
User signature succeeded.	Michael Koren (b) (4)	26 Feb 2021 20:02:47
User entered '5 Oct 2020' reason for change: Data Entry Error	(b) (4)	
User entered empty.	Brenda Anderson (b) (4)	16 Nov 2020 19:33:58
	(b) (4)	
	Brenda Anderson (b) (4)	16 Nov 2020 18:56:51
	(b) (4)	

US3512248

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 07:56:44

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 18:13:56
DataPoint Verified.	(b) (4), (b) (6)	12 Mar 2021 13:50:48
User signature succeeded.	Michael Koren (b) (4)	26 Feb 2021 20:02:47
User entered 'No (N)'	(b) (4) Brenda Anderson (b) (4) (b) (4)	16 Nov 2020 18:56:51

**US3512248**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (13)**

**Generated On: 10 Jun 2021 07:56:44**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 18:13:56
User entered empty.	System	16 Nov 2020 18:56:51

**US3512248**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (13)**

**Generated On: 10 Jun 2021 07:56:44**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 18:13:56
User entered empty.	System	16 Nov 2020 18:56:51

**US3512248**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (13)**

**Generated On: 10 Jun 2021 07:56:44**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 18:13:56
User entered empty.	System	16 Nov 2020 18:56:51

US3512248

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 07:56:44

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 18:14:01
DataPoint Verified.	(b) (4), (b) (6)	12 Mar 2021 13:50:48
User signature succeeded.	Michael Koren (b) (4)	26 Feb 2021 20:02:47
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: TRIAMCINOLONE ACETONIDE, PRODUCTSYNONYM: KENALOG [TRIAMCINOLONE ACETONIDE] - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	17 Nov 2020 07:59:11
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	17 Nov 2020 07:59:11
Data point term sent to Coder	System	16 Nov 2020 19:04:48
User entered 'kenalog'	Brenda Anderson (b) (4) (b) (4)	16 Nov 2020 19:04:38

US3512248

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 07:56:44

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 18:14:01
DataPoint Verified.	(b) (4), (b) (6)	12 Mar 2021 13:50:48
User signature succeeded.	Michael Koren (b) (4)	26 Feb 2021 20:02:47
User entered 'No (N)'	(b) (4) Brenda Anderson (b) (4) (b) (4)	16 Nov 2020 19:04:38



US3512248

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 07:56:44

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 18:14:01
DataPoint Verified.	(b) (4), (b) (6)	12 Mar 2021 13:50:48
User signature succeeded.	Michael Koren (b) (4)	26 Feb 2021 20:02:47
User closed query 'Per DM CLR: Please note that there is no AE that matches this Con Med indication during this time frame. Please review Con Med use and add a medical condition and all applicable details to the AE eCRF as appropriate.' (Site from DM).	(b) (4)	
Query 'Per DM CLR: Please note that there is no AE that matches this Con Med indication during this time frame. Please review Con Med use and add a medical condition and all applicable details to the AE eCRF as appropriate.' answered with 'corrected # 1 ' (Site from DM).	Brenda Anderson (b) (4)	24 Feb 2021 15:34:38
User opened query 'Per DM CLR: Please note that there is no AE that matches this Con Med indication during this time frame. Please review Con Med use and add a medical condition and all applicable details to the AE eCRF as appropriate.' (Site from DM).	(b) (4), (b) (6)	27 Jan 2021 04:09:58
User entered 'right hip trochanteric bursitis'	Brenda Anderson (b) (4)	16 Nov 2020 19:04:38

**US3512248**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (14)**

**Generated On: 10 Jun 2021 07:56:44**

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 18:14:01
DataPoint Verified.	(b) (4), (b) (6)	12 Mar 2021 13:50:48
User signature succeeded.	Michael Koren (b) (4)	26 Feb 2021 20:02:47
User entered '40'	Brenda Anderson (b) (4)	16 Nov 2020 19:04:38

US3512248

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 07:56:44

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 18:14:01
DataPoint Verified.	(b) (4), (b) (6)	12 Mar 2021 13:50:48
User signature succeeded.	Michael Koren (b) (4)	26 Feb 2021 20:02:47
User entered 'mg (mg)'	(b) (4) Brenda Anderson (b) (4)	16 Nov 2020 19:04:38

US3512248

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 07:56:44

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 18:14:01
DataPoint Verified.	(b) (4), (b) (6)	12 Mar 2021 13:50:48
User signature succeeded.	Michael Koren (b) (4)	26 Feb 2021 20:02:47
User entered empty.	(b) (4) Brenda Anderson (b) (4)	16 Nov 2020 19:04:38

US3512248

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 07:56:44

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 18:14:01
DataPoint Verified.	(b) (4), (b) (6)	12 Mar 2021 13:50:48
User signature succeeded.	Michael Koren (b) (4)	26 Feb 2021 20:02:47
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	16 Nov 2020 19:34:25
User entered 'once (ONCE)' reason for change: Data Entry Error	Brenda Anderson (b) (4)	16 Nov 2020 19:34:25
User opened query 'Data is required. Please complete.' (Site from System).	(b) (4)	
User entered empty.	System	16 Nov 2020 19:04:38
	Brenda Anderson (b) (4)	16 Nov 2020 19:04:38
	(b) (4)	

US3512248

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 07:56:44

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 18:14:01
DataPoint Verified.	(b) (4), (b) (6)	12 Mar 2021 13:50:48
User signature succeeded.	Michael Koren (b) (4)	26 Feb 2021 20:02:47
User entered empty.	(b) (4) Brenda Anderson (b) (4) (b) (4)	16 Nov 2020 19:04:38

**US3512248**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (14)**

**Generated On: 10 Jun 2021 07:56:44**

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 18:14:01
DataPoint Verified.	(b) (4), (b) (6)	12 Mar 2021 13:50:48
User signature succeeded.	Michael Koren (b) (4)	26 Feb 2021 20:02:47
User entered 'Other (OTHER)'	Brenda Anderson (b) (4)	16 Nov 2020 19:04:38

US3512248

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 07:56:44

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 18:14:01
DataPoint Verified.	(b) (4), (b) (6)	12 Mar 2021 13:50:48
User signature succeeded.	Michael Koren (b) (4)	26 Feb 2021 20:02:47
User entered 'intrabursal'	(b) (4) Brenda Anderson (b) (4) (b) (4)	16 Nov 2020 19:04:38



US3512248

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 07:56:44

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 18:14:01
DataPoint Verified.	(b) (4), (b) (6)	12 Mar 2021 13:50:48
User signature succeeded.	Michael Koren (b) (4)	26 Feb 2021 20:02:47
User entered '05 Oct 2020' reason for change: Data Entry Error	(b) (4)	
	Brenda Anderson (b) (4)	16 Nov 2020 19:34:25
User entered '10 May 2020'	(b) (4)	
	Brenda Anderson (b) (4)	16 Nov 2020 19:04:38
	(b) (4)	

**US3512248**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (14)**

**Generated On: 10 Jun 2021 07:56:44**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 18:14:01
DataPoint Verified.	(b) (4), (b) (6)	12 Mar 2021 13:50:48
User signature succeeded.	Michael Koren (b) (4)	26 Feb 2021 20:02:47
User entered '0'	(b) (4) Brenda Anderson (b) (4) (b) (4)	16 Nov 2020 19:04:38

US3512248

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 07:56:44

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 18:14:01
DataPoint Verified.	(b) (4), (b) (6)	12 Mar 2021 13:50:48
User signature succeeded.	Michael Koren (b) (4)	26 Feb 2021 20:02:47
User entered 'No (N)' reason for change: Data Entry Error	(b) (4)	
	Brenda Anderson (b) (4)	16 Nov 2020 19:34:25
User entered 'Yes (Y)'	(b) (4)	
	Brenda Anderson (b) (4)	16 Nov 2020 19:04:38
	(b) (4)	

US3512248

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 07:56:44

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 18:14:01
DataPoint Verified.	(b) (4), (b) (6)	12 Mar 2021 13:50:48
User signature succeeded.	Michael Koren (b) (4)	26 Feb 2021 20:02:47
User entered '5 Oct 2020' reason for change: Data Entry Error	(b) (4)	
User entered empty.	Brenda Anderson (b) (4)	16 Nov 2020 19:34:25
	(b) (4)	
	Brenda Anderson (b) (4)	16 Nov 2020 19:04:38
	(b) (4)	

US3512248

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 07:56:44

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 18:14:01
DataPoint Verified.	(b) (4), (b) (6)	12 Mar 2021 13:50:48
User signature succeeded.	Michael Koren (b) (4)	26 Feb 2021 20:02:47
User entered 'No (N)'	(b) (4) Brenda Anderson (b) (4) (b) (4)	16 Nov 2020 19:04:38

**US3512248**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (14)**

**Generated On: 10 Jun 2021 07:56:44**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 18:14:01
User entered empty.	System	16 Nov 2020 19:04:38

**US3512248**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (14)**

**Generated On: 10 Jun 2021 07:56:44**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 18:14:01
User entered empty.	System	16 Nov 2020 19:04:38

**US3512248**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (14)**

**Generated On: 10 Jun 2021 07:56:44**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 18:14:01
User entered empty.	System	16 Nov 2020 19:04:38



US3512248

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 07:56:44

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 18:14:06
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 19:47:41
User coded data point as ATC: RESPIRATORY SYSTEM, ATC: COUGH AND COLD PREPARATIONS, ATC: COUGH SUPPRESSANTS AND EXPECTORANTS, COMBINATIONS, ATC: OPIUM DERIVATIVES AND EXPECTORANTS, PRODUCT: DEXTROMETHORPHAN HYDROBROMIDE;GUAIFENESIN, PRODUCTSYNONYM: ROBITUSSIN DM - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	05 Apr 2021 13:41:20
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	05 Apr 2021 13:41:20
User signature succeeded.	Michael Koren (b) (4) (b) (4)	02 Apr 2021 19:30:27
Data point term sent to Coder	System	02 Apr 2021 14:23:01
DataPoint Un-verified.	Brenda Anderson (b) (4) (b) (4)	02 Apr 2021 14:22:28
Coding entries removed.	Brenda Anderson (b) (4) (b) (4)	02 Apr 2021 14:22:28
Signature has been broken.	Brenda Anderson (b) (4) (b) (4)	02 Apr 2021 14:22:28
User entered 'ROBITUSSIN (DEXTROMETHOPHRAN GUAIFENESIN 20/200' reason for change: Data Entry Error	Brenda Anderson (b) (4) (b) (4)	02 Apr 2021 14:22:28
User coded data point as ATC: RESPIRATORY SYSTEM, ATC: COUGH AND COLD PREPARATIONS, ATC: COUGH SUPPRESSANTS AND EXPECTORANTS, COMBINATIONS, ATC: OPIUM DERIVATIVES AND EXPECTORANTS, PRODUCT: DEXTROMETHORPHAN;GUAIFENESIN - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	19 Mar 2021 09:13:29
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	19 Mar 2021 09:13:29
Data point term sent to Coder	System	12 Mar 2021 18:34:05
Coding entries removed.	(b) (4), (b) (6) (b) (4), (b) (6)	12 Mar 2021 18:34:03

PRODUCTION RELEASE (v12.003  
EAB) (1725)

3596 of 3746

US3512248

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 07:56:44

Name of Medication

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Mar 2021 13:50:48
User signature succeeded.	Michael Koren (b) (4)	26 Feb 2021 20:02:47
User coded data point as ATC: RESPIRATORY SYSTEM, ATC: COUGH AND COLD PREPARATIONS, ATC: COUGH SUPPRESSANTS AND EXPECTORANTS, COMBINATIONS, ATC: OPIUM DERIVATIVES AND EXPECTORANTS, PRODUCT: DEXTROMETHORPHAN HYDROBROMIDE;GUAIFENESIN, PRODUCTSYNONYM: ROBITUSSIN-DM - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	10 Feb 2021 12:08:46
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	10 Feb 2021 12:08:46
Data point term sent to Coder	System	02 Feb 2021 23:08:12
User entered 'robitussin (dextromethophran-guaifenesen: 20 mg)'	Sheldon Warren (b) (4)	02 Feb 2021 23:08:08

US3512248

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 07:56:44

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 18:14:06
DataPoint Verified.	(b) (4), (b) (6)	12 Mar 2021 13:50:48
User signature succeeded.	Michael Koren (b) (4)	26 Feb 2021 20:02:47
User entered 'No (N)'	(b) (4) Sheldon Warren (b) (4) (b) (4)	02 Feb 2021 23:08:08

US3512248

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 07:56:44

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 18:14:06
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 19:47:41
User signature succeeded.	Michael Koren (b) (4)	15 Mar 2021 12:52:32
DataPoint Un-verified.	(b) (4), (b) (6)	12 Mar 2021 18:34:03
Signature has been broken.	(b) (4), (b) (6)	12 Mar 2021 18:34:03
User entered 'Covid like-illness' reason for change:	(b) (4), (b) (6)	12 Mar 2021 18:34:03
Data Entry Error		
DataPoint Verified.	(b) (4), (b) (6)	12 Mar 2021 13:50:48
User signature succeeded.	Michael Koren (b) (4)	26 Feb 2021 20:02:47
User entered 'cough'	Sheldon Warren (b) (4)	02 Feb 2021 23:08:08

US3512248

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 07:56:44

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 18:14:06
User signature succeeded.	Michael Koren (b) (4)	08 Apr 2021 12:06:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Apr 2021 19:47:41
User closed query 'Per DM CLR RQ: Please update this field to include all the components as appropriate.' (Site from DM).	(b) (4), (b) (6)	07 Apr 2021 10:19:09
Query 'Per DM CLR RQ: Please update this field to include all the components as appropriate.' answered with 'I included it in the name of medication field like you directed. ' (Site from DM).	Brenda Anderson (b) (4)	05 Apr 2021 21:17:20
DataPoint Un-verified.	(b) (4)	
	Brenda Anderson (b) (4)	05 Apr 2021 21:16:58
Signature has been broken.	(b) (4)	
	Brenda Anderson (b) (4)	05 Apr 2021 21:16:58
User entered '20/200' reason for change: Data Entry Error	(b) (4)	
	Brenda Anderson (b) (4)	05 Apr 2021 21:16:58
User opened query 'Per DM CLR RQ: Please update this field to include all the components as appropriate.' (Site from DM).	(b) (4)	
	(b) (4), (b) (6)	05 Apr 2021 05:28:43
User closed query 'Per DM CLR: Please note this is a combination drug; however, only one component has been reported. Please update the medication name field to include all the components (20/200). ' (Site from DM).	(b) (4), (b) (6)	05 Apr 2021 05:28:43
Query 'Per DM CLR: Please note this is a combination drug; however, only one component has been reported. Please update the medication name field to include all the components (20/200). ' answered with 'corrected per query' (Site from DM).	Brenda Anderson (b) (4)	02 Apr 2021 14:22:56
	(b) (4)	
User opened query 'Per DM CLR: Please note this is a combination drug; however, only one component has been reported. Please update the medication name field to include all the components (20/200). ' (Site from DM).	(b) (4), (b) (6)	02 Apr 2021 04:01:40
DataPoint Verified.	(b) (4), (b) (6)	12 Mar 2021 13:50:48
User signature succeeded.	(b) (4)	
	Michael Koren (b) (4)	26 Feb 2021 20:02:47
User entered '20'	(b) (4)	
	Sheldon Warren (b) (4)	02 Feb 2021 23:08:08
	(b) (4)	

PRODUCTION RELEASE (v12.003  
EAB) (1725)

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US3512248

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 07:56:44

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 18:14:06
DataPoint Verified.	(b) (4), (b) (6)	12 Mar 2021 13:50:48
User signature succeeded.	Michael Koren (b) (4)	26 Feb 2021 20:02:47
User entered 'mL (mL)'	(b) (4) Sheldon Warren (b) (4) (b) (4)	02 Feb 2021 23:08:08

US3512248

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 07:56:44

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 18:14:06
DataPoint Verified.	(b) (4), (b) (6)	12 Mar 2021 13:50:48
User signature succeeded.	Michael Koren (b) (4)	26 Feb 2021 20:02:47
User entered empty.	(b) (4) Sheldon Warren (b) (4) (b) (4)	02 Feb 2021 23:08:08

US3512248

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 07:56:44

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 18:14:06
DataPoint Verified.	(b) (4), (b) (6)	12 Mar 2021 13:50:48
User signature succeeded.	Michael Koren (b) (4)	26 Feb 2021 20:02:47
User entered 'as needed (PRN)'	(b) (4) Sheldon Warren (b) (4) (b) (4)	02 Feb 2021 23:08:08



US3512248

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 07:56:44

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 18:14:06
DataPoint Verified.	(b) (4), (b) (6)	12 Mar 2021 13:50:48
User signature succeeded.	Michael Koren (b) (4)	26 Feb 2021 20:02:47
User entered empty.	(b) (4) Sheldon Warren (b) (4) (b) (4)	02 Feb 2021 23:08:08

**US3512248**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (15)**

**Generated On: 10 Jun 2021 07:56:44**

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 18:14:06
DataPoint Verified.	(b) (4), (b) (6)	12 Mar 2021 13:50:48
User signature succeeded.	Michael Koren (b) (4)	26 Feb 2021 20:02:47
User entered 'Oral (ORAL)'	(b) (4) Sheldon Warren (b) (4) (b) (4)	02 Feb 2021 23:08:08

US3512248

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 07:56:44

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 18:14:06
DataPoint Verified.	(b) (4), (b) (6)	12 Mar 2021 13:50:48
User signature succeeded.	Michael Koren (b) (4)	26 Feb 2021 20:02:47
User entered empty.	(b) (4) Sheldon Warren (b) (4) (b) (4)	02 Feb 2021 23:08:08

**US3512248**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (15)**

**Generated On: 10 Jun 2021 07:56:44**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 18:14:06
DataPoint Verified.	(b) (4), (b) (6)	12 Mar 2021 13:50:48
User signature succeeded.	Michael Koren (b) (4)	26 Feb 2021 20:02:47
User entered '1 Feb 2021'	(b) (4) Sheldon Warren (b) (4) (b) (4)	02 Feb 2021 23:08:08

**US3512248**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (15)**

**Generated On: 10 Jun 2021 07:56:44**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 18:14:06
DataPoint Verified.	(b) (4), (b) (6)	12 Mar 2021 13:50:48
User signature succeeded.	Michael Koren (b) (4)	26 Feb 2021 20:02:47
User entered '0'	(b) (4) Sheldon Warren (b) (4) (b) (4)	02 Feb 2021 23:08:08

US3512248

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 07:56:44

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 18:14:06
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 19:47:41
User signature succeeded.	Michael Koren (b) (4)	15 Mar 2021 12:52:32
DataPoint Un-verified.	(b) (4), (b) (6)	12 Mar 2021 18:34:11
Signature has been broken.	(b) (4), (b) (6)	12 Mar 2021 18:34:11
User entered 'No (N)' reason for change: Data Entry Error	(b) (4), (b) (6)	12 Mar 2021 18:34:11
DataPoint Verified.	(b) (4), (b) (6)	12 Mar 2021 13:50:48
User signature succeeded.	Michael Koren (b) (4)	26 Feb 2021 20:02:47
User entered 'Yes (Y)'	Sheldon Warren (b) (4)	02 Feb 2021 23:08:08

US3512248

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 07:56:44

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 18:14:06
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 19:47:41
User signature succeeded.	Michael Koren (b) (4)	15 Mar 2021 12:52:32
DataPoint Un-verified.	(b) (4), (b) (6)	12 Mar 2021 18:34:11
Signature has been broken.	(b) (4), (b) (6)	12 Mar 2021 18:34:11
User entered '14 Feb 2021' reason for change: Data Entry Error	(b) (4), (b) (6)	12 Mar 2021 18:34:11
DataPoint Verified.	(b) (4), (b) (6)	12 Mar 2021 13:50:48
User signature succeeded.	Michael Koren (b) (4)	26 Feb 2021 20:02:47
User entered empty.	Sheldon Warren (b) (4)	02 Feb 2021 23:08:08

US3512248

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 07:56:44

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 18:14:06
DataPoint Verified.	(b) (4), (b) (6)	12 Mar 2021 13:50:48
User signature succeeded.	Michael Koren (b) (4)	26 Feb 2021 20:02:47
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4)	02 Feb 2021 23:08:14
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	02 Feb 2021 23:08:14
User entered 'No (N)' reason for change: Data Entry Error	Sheldon Warren (b) (4)	02 Feb 2021 23:08:14
User opened query 'Data is required. Please complete.' (Site from System).	(b) (4)	02 Feb 2021 23:08:08
User entered empty.	System	02 Feb 2021 23:08:08
	Sheldon Warren (b) (4)	02 Feb 2021 23:08:08
	(b) (4)	



**US3512248**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (15)**

**Generated On: 10 Jun 2021 07:56:44**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 18:14:06
User entered empty.	System	02 Feb 2021 23:08:08

**US3512248**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (15)**

**Generated On: 10 Jun 2021 07:56:44**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 18:14:06
User entered empty.	System	02 Feb 2021 23:08:08

**US3512248**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (15)**

**Generated On: 10 Jun 2021 07:56:44**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 18:14:06
User entered empty.	System	02 Feb 2021 23:08:08

US3512248

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 10 Jun 2021 07:56:44

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 18:14:13
User coded data point as ATC: ANTIINFECTIVES FOR SYSTEMIC USE, ATC: ANTIBACTERIALS FOR SYSTEMIC USE, ATC: OTHER BETA-LACTAM ANTIBACTERIALS, ATC: FIRST-GENERATION CEPHALOSPORINS, PRODUCT: CEFALEXIN, PRODUCTSYNONYM: KEFLEX [CEFALEXIN] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	17 Mar 2021 11:10:42
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	17 Mar 2021 11:10:42
User signature succeeded.	Michael Koren (b) (4) (b) (4)	15 Mar 2021 12:52:32
DataPoint Verified.	(b) (4), (b) (6)	12 Mar 2021 13:50:48
Data point term sent to Coder	System	11 Mar 2021 20:48:18
User entered 'Keflex'	Sheldon Warren (b) (4) (b) (4)	11 Mar 2021 20:48:05

**US3512248**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (16)**

**Generated On: 10 Jun 2021 07:56:44**

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 18:14:13
User signature succeeded.	Michael Koren (b) (4)	15 Mar 2021 12:52:32
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Mar 2021 13:50:48
User entered 'No (N)'	Sheldon Warren (b) (4) (b) (4)	11 Mar 2021 20:48:05

US3512248

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 10 Jun 2021 07:56:44

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 18:14:13
User signature succeeded.	Michael Koren (b) (4)	15 Mar 2021 12:52:32
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Mar 2021 13:50:48
User entered 'Left elbow septic arthritis'	Sheldon Warren (b) (4) (b) (4)	11 Mar 2021 20:48:05

US3512248

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 10 Jun 2021 07:56:44

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 18:14:13
User signature succeeded.	Michael Koren (b) (4)	15 Mar 2021 12:52:32
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Mar 2021 13:50:48
User entered '500'	Sheldon Warren (b) (4) (b) (4)	11 Mar 2021 20:48:05

US3512248

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 10 Jun 2021 07:56:44

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 18:14:13
User signature succeeded.	Michael Koren (b) (4)	15 Mar 2021 12:52:32
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Mar 2021 13:50:48
User entered 'mg (mg)'	Sheldon Warren (b) (4) (b) (4)	11 Mar 2021 20:48:05



**US3512248**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (16)**

**Generated On: 10 Jun 2021 07:56:44**

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 18:14:13
User signature succeeded.	Michael Koren (b) (4)	15 Mar 2021 12:52:32
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Mar 2021 13:50:48
User entered empty.	Sheldon Warren (b) (4) (b) (4)	11 Mar 2021 20:48:05

US3512248

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 10 Jun 2021 07:56:44

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 18:14:13
User signature succeeded.	Michael Koren (b) (4)	15 Mar 2021 12:52:32
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Mar 2021 13:50:48
User entered 'twice daily (BID)'	Sheldon Warren (b) (4) (b) (4)	11 Mar 2021 20:48:05

US3512248

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 10 Jun 2021 07:56:44

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 18:14:13
User signature succeeded.	Michael Koren (b) (4)	15 Mar 2021 12:52:32
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Mar 2021 13:50:48
User entered empty.	Sheldon Warren (b) (4) (b) (4)	11 Mar 2021 20:48:05

US3512248

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 10 Jun 2021 07:56:44

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 18:14:13
User signature succeeded.	Michael Koren (b) (4)	15 Mar 2021 12:52:32
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Mar 2021 13:50:48
User entered 'Oral (ORAL)'	Sheldon Warren (b) (4) (b) (4)	11 Mar 2021 20:48:05

**US3512248**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (16)**

**Generated On: 10 Jun 2021 07:56:44**

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 18:14:13
User signature succeeded.	Michael Koren (b) (4)	15 Mar 2021 12:52:32
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Mar 2021 13:50:48
User entered empty.	Sheldon Warren (b) (4) (b) (4)	11 Mar 2021 20:48:05

US3512248

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 10 Jun 2021 07:56:44

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 18:14:13
User signature succeeded.	Michael Koren (b) (4)	15 Mar 2021 12:52:32
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Mar 2021 13:50:48
User entered '24 Feb 2021'	Sheldon Warren (b) (4) (b) (4)	11 Mar 2021 20:48:05

**US3512248**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (16)**

**Generated On: 10 Jun 2021 07:56:44**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 18:14:13
User signature succeeded.	Michael Koren (b) (4)	15 Mar 2021 12:52:32
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Mar 2021 13:50:48
User entered '0'	Sheldon Warren (b) (4) (b) (4)	11 Mar 2021 20:48:05

**US3512248**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (16)**

**Generated On: 10 Jun 2021 07:56:44**

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 18:14:13
User signature succeeded.	Michael Koren (b) (4)	15 Mar 2021 12:52:32
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Mar 2021 13:50:48
User entered 'No (N)'	Sheldon Warren (b) (4) (b) (4)	11 Mar 2021 20:48:05



**US3512248**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (16)**

**Generated On: 10 Jun 2021 07:56:44**

*If not Ongoing, End date (dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 18:14:13
User signature succeeded.	Michael Koren (b) (4)	15 Mar 2021 12:52:32
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Mar 2021 13:50:48
User entered '3 Mar 2021'	Sheldon Warren (b) (4) (b) (4)	11 Mar 2021 20:48:05

**US3512248**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (16)**

**Generated On: 10 Jun 2021 07:56:44**

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 18:14:13
User signature succeeded.	Michael Koren (b) (4)	15 Mar 2021 12:52:32
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Mar 2021 13:50:48
User entered 'No (N)'	Sheldon Warren (b) (4) (b) (4)	11 Mar 2021 20:48:05

US3512248

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 10 Jun 2021 07:56:44

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 18:14:13
User entered '2'	System	11 Mar 2021 20:48:05

US3512248

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 10 Jun 2021 07:56:44

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 18:14:13
User entered '1'	System	11 Mar 2021 20:48:05

US3512248

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 10 Jun 2021 07:56:44

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 18:14:13
User entered '804 (804)'	System	11 Mar 2021 20:48:05

US3512248

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 10 Jun 2021 07:56:44

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 18:14:19
User signature succeeded.	Michael Koren (b) (4)	15 Mar 2021 12:52:32
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Mar 2021 13:50:48
User coded data point as ATC: ANTIINFECTIVES FOR SYSTEMIC USE, ATC: ANTIBACTERIALS FOR SYSTEMIC USE, ATC: OTHER ANTIBACTERIALS, ATC: GLYCOPEPTIDE ANTIBACTERIALS, PRODUCT: VANCOMYCIN - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	12 Mar 2021 07:07:47
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	12 Mar 2021 07:07:47
Data point term sent to Coder	System	11 Mar 2021 20:50:20
User entered 'Vancomycin'	Sheldon Warren (b) (4) (b) (4)	11 Mar 2021 20:49:48

US3512248

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 10 Jun 2021 07:56:44

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 18:14:19
User signature succeeded.	Michael Koren (b) (4)	15 Mar 2021 12:52:32
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Mar 2021 13:50:48
User entered 'No (N)'	Sheldon Warren (b) (4) (b) (4)	11 Mar 2021 20:49:48

US3512248

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 10 Jun 2021 07:56:44

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 18:14:19
User signature succeeded.	Michael Koren (b) (4)	15 Mar 2021 12:52:32
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Mar 2021 13:50:48
User entered 'Left elbow septic arthritis'	Sheldon Warren (b) (4) (b) (4)	11 Mar 2021 20:49:48



US3512248

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 10 Jun 2021 07:56:44

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 18:14:19
User signature succeeded.	Michael Koren (b) (4)	15 Mar 2021 12:52:32
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Mar 2021 13:50:48
User entered 'l'	Sheldon Warren (b) (4) (b) (4)	11 Mar 2021 20:49:48

**US3512248**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (17)**

**Generated On: 10 Jun 2021 07:56:44**

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 18:14:19
User signature succeeded.	Michael Koren (b) (4)	15 Mar 2021 12:52:32
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Mar 2021 13:50:48
User entered 'Other (OTHER)'	Sheldon Warren (b) (4) (b) (4)	11 Mar 2021 20:49:48

US3512248

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 10 Jun 2021 07:56:44

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 18:14:19
User signature succeeded.	Michael Koren (b) (4)	15 Mar 2021 12:52:32
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Mar 2021 13:50:48
User entered 'gram'	Sheldon Warren (b) (4) (b) (4)	11 Mar 2021 20:49:48

US3512248

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 10 Jun 2021 07:56:44

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 18:14:19
User signature succeeded.	Michael Koren (b) (4)	15 Mar 2021 12:52:32
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Mar 2021 13:50:48
User entered 'once (ONCE)'	Sheldon Warren (b) (4) (b) (4)	11 Mar 2021 20:49:48

US3512248

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 10 Jun 2021 07:56:44

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 18:14:19
User signature succeeded.	Michael Koren (b) (4)	15 Mar 2021 12:52:32
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Mar 2021 13:50:48
User entered empty.	Sheldon Warren (b) (4) (b) (4)	11 Mar 2021 20:49:48

US3512248

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 10 Jun 2021 07:56:44

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 18:14:19
User signature succeeded.	Michael Koren (b) (4)	15 Mar 2021 12:52:32
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Mar 2021 13:50:48
User entered 'Intravenous (INTRAVENOUS)'	Sheldon Warren (b) (4) (b) (4)	11 Mar 2021 20:49:48

US3512248

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 10 Jun 2021 07:56:44

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 18:14:19
User signature succeeded.	Michael Koren (b) (4)	15 Mar 2021 12:52:32
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Mar 2021 13:50:48
User entered empty.	Sheldon Warren (b) (4) (b) (4)	11 Mar 2021 20:49:48

**US3512248**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (17)**

**Generated On: 10 Jun 2021 07:56:44**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 18:14:19
User signature succeeded.	Michael Koren (b) (4)	15 Mar 2021 12:52:32
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Mar 2021 13:50:48
User entered '25 Feb 2021'	Sheldon Warren (b) (4) (b) (4)	11 Mar 2021 20:49:48



**US3512248**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (17)**

**Generated On: 10 Jun 2021 07:56:44**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 18:14:19
User signature succeeded.	Michael Koren (b) (4)	15 Mar 2021 12:52:32
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Mar 2021 13:50:48
User entered '0'	Sheldon Warren (b) (4) (b) (4)	11 Mar 2021 20:49:48

**US3512248**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (17)**

**Generated On: 10 Jun 2021 07:56:44**

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 18:14:19
User signature succeeded.	Michael Koren (b) (4)	15 Mar 2021 12:52:32
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Mar 2021 13:50:48
User entered 'No (N)'	Sheldon Warren (b) (4) (b) (4)	11 Mar 2021 20:49:48

**US3512248**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (17)**

**Generated On: 10 Jun 2021 07:56:44**

*If not Ongoing, End date (dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 18:14:19
User signature succeeded.	Michael Koren (b) (4)	15 Mar 2021 12:52:32
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Mar 2021 13:50:48
User entered '25 Feb 2021'	Sheldon Warren (b) (4) (b) (4)	11 Mar 2021 20:49:48

US3512248

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 10 Jun 2021 07:56:44

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 18:14:19
User signature succeeded.	Michael Koren (b) (4)	15 Mar 2021 12:52:32
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Mar 2021 13:50:48
User entered 'No (N)'	Sheldon Warren (b) (4) (b) (4)	11 Mar 2021 20:49:48

**US3512248**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (17)**

**Generated On: 10 Jun 2021 07:56:44**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 18:14:19
User entered empty.	System	11 Mar 2021 20:49:48

**US3512248**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (17)**

**Generated On: 10 Jun 2021 07:56:44**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 18:14:19
User entered empty.	System	11 Mar 2021 20:49:48

US3512248

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 10 Jun 2021 07:56:44

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 18:14:19
User entered empty.	System	11 Mar 2021 20:49:48

US3512248

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 10 Jun 2021 07:56:44

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 18:14:38
User signature succeeded.	Michael Koren (b) (4)	15 Mar 2021 12:52:32
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Mar 2021 13:50:48
User coded data point as ATC: ANTIINFECTIVES FOR SYSTEMIC USE, ATC: ANTIBACTERIALS FOR SYSTEMIC USE, ATC: OTHER ANTIBACTERIALS, ATC: OTHER ANTIBACTERIALS, PRODUCT: LINEZOLID, PRODUCTSYNONYM: ZYVOX - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	11 Mar 2021 21:06:58
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	11 Mar 2021 21:06:58
User coded data point as ATC: ANTIINFECTIVES FOR SYSTEMIC USE, ATC: ANTIBACTERIALS FOR SYSTEMIC USE, ATC: OTHER ANTIBACTERIALS, ATC: OTHER ANTIBACTERIALS, PRODUCT: LINEZOLID, PRODUCTSYNONYM: ZYVOX - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	11 Mar 2021 20:51:53
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	11 Mar 2021 20:51:53
Data point term sent to Coder User entered 'zyvox'	System Sheldon Warren (b) (4) (b) (4)	11 Mar 2021 20:51:21 11 Mar 2021 20:50:52



US3512248

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 10 Jun 2021 07:56:44

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 18:14:38
User signature succeeded.	Michael Koren (b) (4)	15 Mar 2021 12:52:32
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Mar 2021 13:50:48
User entered 'No (N)'	Sheldon Warren (b) (4) (b) (4)	11 Mar 2021 20:50:52

US3512248

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 10 Jun 2021 07:56:44

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 18:14:38
User signature succeeded.	Michael Koren (b) (4)	15 Mar 2021 12:52:32
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Mar 2021 13:50:48
User entered 'Left elbow Septic Arthritis'	Sheldon Warren (b) (4) (b) (4)	11 Mar 2021 20:50:52

US3512248

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 10 Jun 2021 07:56:44

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 18:14:38
User signature succeeded.	Michael Koren (b) (4)	15 Mar 2021 12:52:32
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Mar 2021 13:50:48
User entered '600'	Sheldon Warren (b) (4) (b) (4)	11 Mar 2021 20:50:52

US3512248

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 10 Jun 2021 07:56:44

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 18:14:38
User signature succeeded.	Michael Koren (b) (4)	15 Mar 2021 12:52:32
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Mar 2021 13:50:48
User entered 'mg (mg)'	Sheldon Warren (b) (4) (b) (4)	11 Mar 2021 20:50:52

US3512248

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 10 Jun 2021 07:56:44

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 18:14:38
User signature succeeded.	Michael Koren (b) (4)	15 Mar 2021 12:52:32
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Mar 2021 13:50:48
User entered empty.	Sheldon Warren (b) (4) (b) (4)	11 Mar 2021 20:50:52

US3512248

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 10 Jun 2021 07:56:44

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 18:14:38
User signature succeeded.	Michael Koren (b) (4)	15 Mar 2021 12:52:32
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Mar 2021 13:50:48
User entered 'twice daily (BID)'	Sheldon Warren (b) (4) (b) (4)	11 Mar 2021 20:50:52

US3512248

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 10 Jun 2021 07:56:44

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 18:14:38
User signature succeeded.	Michael Koren (b) (4)	15 Mar 2021 12:52:32
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Mar 2021 13:50:48
User entered empty.	Sheldon Warren (b) (4) (b) (4)	11 Mar 2021 20:50:52

**US3512248**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (18)**

**Generated On: 10 Jun 2021 07:56:44**

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 18:14:38
User signature succeeded.	Michael Koren (b) (4)	15 Mar 2021 12:52:32
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Mar 2021 13:50:48
User entered 'Oral (ORAL)'	Sheldon Warren (b) (4) (b) (4)	11 Mar 2021 20:50:52



US3512248

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 10 Jun 2021 07:56:44

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 18:14:38
User signature succeeded.	Michael Koren (b) (4)	15 Mar 2021 12:52:32
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Mar 2021 13:50:48
User entered empty.	Sheldon Warren (b) (4) (b) (4)	11 Mar 2021 20:50:52

US3512248

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 10 Jun 2021 07:56:44

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 18:14:38
User signature succeeded.	Michael Koren (b) (4)	15 Mar 2021 12:52:32
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Mar 2021 13:50:48
User entered '26 Feb 2021'	Sheldon Warren (b) (4) (b) (4)	11 Mar 2021 20:50:52

**US3512248**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (18)**

**Generated On: 10 Jun 2021 07:56:44**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 18:14:38
User signature succeeded.	Michael Koren (b) (4)	15 Mar 2021 12:52:32
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Mar 2021 13:50:48
User entered '0'	Sheldon Warren (b) (4) (b) (4)	11 Mar 2021 20:50:52

**US3512248**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (18)**

**Generated On: 10 Jun 2021 07:56:44**

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 18:14:38
User signature succeeded.	Michael Koren (b) (4)	15 Mar 2021 12:52:32
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Mar 2021 13:50:48
User entered 'No (N)'	Sheldon Warren (b) (4) (b) (4)	11 Mar 2021 20:50:52

**US3512248**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (18)**

**Generated On: 10 Jun 2021 07:56:44**

*If not Ongoing, End date (dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 18:14:38
User signature succeeded.	Michael Koren (b) (4)	15 Mar 2021 12:52:32
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Mar 2021 13:50:48
User entered '5 Mar 2021'	Sheldon Warren (b) (4) (b) (4)	11 Mar 2021 20:50:52

US3512248

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 10 Jun 2021 07:56:44

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 18:14:38
User signature succeeded.	Michael Koren (b) (4)	15 Mar 2021 12:52:32
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Mar 2021 13:50:48
User entered 'No (N)'	Sheldon Warren (b) (4) (b) (4)	11 Mar 2021 20:50:52

**US3512248**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (18)**

**Generated On: 10 Jun 2021 07:56:44**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 18:14:38
User entered '2'	System	11 Mar 2021 20:50:52

US3512248

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 10 Jun 2021 07:56:44

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 18:14:38
User entered '1'	System	11 Mar 2021 20:50:52



**US3512248**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (18)**

**Generated On: 10 Jun 2021 07:56:44**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 18:14:38
User entered '804 (804)'	System	11 Mar 2021 20:50:52

US3512248

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 10 Jun 2021 07:56:44

[Name of Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 19:47:41
User signature succeeded.	Michael Koren (b) (4)	31 Mar 2021 17:34:59
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: VITAMINS, ATC: OTHER PLAIN VITAMIN PREPARATIONS, ATC: OTHER PLAIN VITAMIN PREPARATIONS, PRODUCT: PYRIDOXINE HYDROCHLORIDE, PRODUCTSYNONYM: VITAMIN B6 - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	30 Mar 2021 00:30:19
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 00:30:19
Data point term sent to Coder	System	29 Mar 2021 17:33:00
User entered 'B6 vitamin'	Brenda Anderson (b) (4)	29 Mar 2021 17:32:16

US3512248

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 10 Jun 2021 07:56:44

[Prophylaxis](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 19:47:41
User signature succeeded.	Michael Koren (b) (4)	31 Mar 2021 17:34:59
User entered 'Yes (Y)'	Brenda Anderson (b) (4)	29 Mar 2021 17:32:16

US3512248

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 10 Jun 2021 07:56:44

[Indication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 19:47:41
User signature succeeded.	Michael Koren (b) (4)	31 Mar 2021 17:34:59
User entered 'dietary supplement'	Brenda Anderson (b) (4)	29 Mar 2021 17:32:16

US3512248

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 10 Jun 2021 07:56:44

[Dose per administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 19:47:41
User signature succeeded.	Michael Koren (b) (4)	31 Mar 2021 17:34:59
User entered 'I'	Brenda Anderson (b) (4)	29 Mar 2021 17:32:16

US3512248

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 10 Jun 2021 07:56:44

[Dose unit](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 19:47:41
User signature succeeded.	Michael Koren (b) (4)	31 Mar 2021 17:34:59
User entered 'tablet (TABLET)'	Brenda Anderson (b) (4)	29 Mar 2021 17:32:16

US3512248

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 10 Jun 2021 07:56:44

If dose unit is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 19:47:41
User signature succeeded.	Michael Koren (b) (4)	31 Mar 2021 17:34:59
User entered empty.	Brenda Anderson (b) (4)	29 Mar 2021 17:32:16

US3512248

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 10 Jun 2021 07:56:44

[Frequency](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 19:47:41
User signature succeeded.	Michael Koren (b) (4)	31 Mar 2021 17:34:59
User entered 'once daily (QD)'	Brenda Anderson (b) (4)	29 Mar 2021 17:32:16



US3512248

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 10 Jun 2021 07:56:44

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 19:47:41
User signature succeeded.	Michael Koren (b) (4)	31 Mar 2021 17:34:59
User entered empty.	Brenda Anderson (b) (4)	29 Mar 2021 17:32:16

US3512248

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 10 Jun 2021 07:56:44

[Route of administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 19:47:41
User signature succeeded.	Michael Koren (b) (4)	31 Mar 2021 17:34:59
User entered 'Oral (ORAL)'	Brenda Anderson (b) (4)	29 Mar 2021 17:32:16

US3512248

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 10 Jun 2021 07:56:44

If route of administration is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 19:47:41
User signature succeeded.	Michael Koren (b) (4)	31 Mar 2021 17:34:59
User entered empty.	Brenda Anderson (b) (4)	29 Mar 2021 17:32:16

US3512248

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 10 Jun 2021 07:56:44

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 19:47:41
User signature succeeded.	Michael Koren (b) (4)	31 Mar 2021 17:34:59
User entered '3 Mar 2021'	Brenda Anderson (b) (4)	29 Mar 2021 17:32:16

US3512248

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 10 Jun 2021 07:56:44

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 19:47:41
User signature succeeded.	Michael Koren (b) (4)	31 Mar 2021 17:34:59
User entered '0'	Brenda Anderson (b) (4)	29 Mar 2021 17:32:16

**US3512248**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (19)**

**Generated On: 10 Jun 2021 07:56:44**

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 19:47:41
User signature succeeded.	Michael Koren (b) (4)	31 Mar 2021 17:34:59
User entered 'Yes (Y)'	Brenda Anderson (b) (4)	29 Mar 2021 17:32:16

US3512248

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 10 Jun 2021 07:56:44

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 19:47:41
User signature succeeded.	Michael Koren (b) (4)	31 Mar 2021 17:34:59
User entered empty.	Brenda Anderson (b) (4)	29 Mar 2021 17:32:16

US3512248

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 10 Jun 2021 07:56:44

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 19:47:41
User signature succeeded.	Michael Koren (b) (4)	31 Mar 2021 17:34:59
User entered 'No (N)'	Brenda Anderson (b) (4)	29 Mar 2021 17:32:16



**US3512248**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (19)**

**Generated On: 10 Jun 2021 07:56:44**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	29 Mar 2021 17:32:16

**US3512248**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (19)**

**Generated On: 10 Jun 2021 07:56:44**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered 'I'	System	29 Mar 2021 17:32:16

**US3512248**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (19)**

**Generated On: 10 Jun 2021 07:56:44**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	29 Mar 2021 17:32:16

**US3512248**

**Folder: Concomitant Procedures (1)**

**Form: Concomitant Procedures Summary**

**Generated On: 10 Jun 2021 07:56:44**

[Were any concomitant procedures performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 07:34:28
DataPoint Verified.	(b) (4), (b) (6)	12 Mar 2021 13:50:11
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 22:12:02
User entered 'Yes (Y)'	(b) (4) Sheldon Warren (b) (4) (b) (4)	03 Feb 2021 20:10:07

US3512248

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 10 Jun 2021 07:56:44

Procedure/Surgery date (*dd MMM yyyy*)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Mar 2021 13:50:33
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 22:12:02
User entered '03 Feb 2021'	Sheldon Warren (b) (4)	03 Feb 2021 20:11:05

US3512248

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 10 Jun 2021 07:56:44

[Procedure/Surgery](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Mar 2021 13:50:33
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 22:12:02
User entered 'cryotherapy'	Sheldon Warren (b) (4)	03 Feb 2021 20:11:05

US3512248

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 10 Jun 2021 07:56:44

[Indication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 19:47:56
User signature succeeded.	Michael Koren (b) (4)	15 Mar 2021 12:52:32
User closed query 'Per DM CLR: Indication = OTHER, however, please confirm if the procedure was done for a medical condition. If yes, please record the condition in the appropriate eCRF page (i.e. AE/MedHistory) and update indication as applicable. Reconcile as appropriate, otherwise clarify. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	15 Mar 2021 02:44:28
Query 'Per DM CLR: Indication = OTHER, however, please confirm if the procedure was done for a medical condition. If yes, please record the condition in the appropriate eCRF page (i.e. AE/MedHistory) and update indication as applicable. Reconcile as appropriate, otherwise clarify. ' answered with 'AE' (Site from DM).	(b) (4), (b) (6)	12 Mar 2021 18:25:29
User closed query 'Indication is not Other, however specify has been provided. Please correct.' (Site from System).	System	12 Mar 2021 18:25:24
User opened query 'Indication is not Other, however specify has been provided. Please correct.' (Site from System).	System	12 Mar 2021 18:25:17
DataPoint Un-verified.	(b) (4), (b) (6)	12 Mar 2021 18:25:17
Signature has been broken.	(b) (4), (b) (6)	12 Mar 2021 18:25:17
User entered 'Adverse Event (AE)' reason for change: Data Entry Error	(b) (4), (b) (6)	12 Mar 2021 18:25:17
DataPoint Verified.	(b) (4), (b) (6)	12 Mar 2021 13:50:33
User opened query 'Per DM CLR: Indication = OTHER, however, please confirm if the procedure was done for a medical condition. If yes, please record the condition in the appropriate eCRF page (i.e. AE/MedHistory) and update indication as applicable. Reconcile as appropriate, otherwise clarify. ' (Site from DM).	(b) (4), (b) (6)	25 Feb 2021 09:50:29
User signature succeeded.	Michael Koren (b) (4) (b) (4)	12 Feb 2021 22:12:02

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EAB) (1725)

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Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

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[Indication](#)

Audit	User	Time (GMT)
User entered 'Other (OTHER)'	Sheldon Warren (b) (4) (b) (4)	03 Feb 2021 20:11:05



US3512248

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 10 Jun 2021 07:56:44

If indication is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 19:47:56
User signature succeeded.	Michael Koren (b) (4)	15 Mar 2021 12:52:32
DataPoint Un-verified.	(b) (4), (b) (6)	12 Mar 2021 18:25:24
Signature has been broken.	(b) (4), (b) (6)	12 Mar 2021 18:25:24
User entered empty; reason for change Data Entry Error	(b) (4), (b) (6)	12 Mar 2021 18:25:24
DataPoint Verified.	(b) (4), (b) (6)	12 Mar 2021 13:50:33
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 22:12:02
User entered 'treatment'	Sheldon Warren (b) (4)	03 Feb 2021 20:11:05

**US3512248**

**Folder: SAE USA-US065-2021-MRNA-1273-P301000005**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 07:56:44**

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	15 Mar 2021 12:52:32
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Mar 2021 13:40:46
Reviewed for Safety.	(b) (4), (b) (6)	12 Mar 2021 13:31:59
User entered 'USA-US065-2021-MRNA-1273-P301000005'	System	12 Mar 2021 13:31:37

**US3512248**

**Folder: SAE USA-US065-2021-MRNA-1273-P301000005**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 07:56:44**

**Serious**

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	15 Mar 2021 12:52:32
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	12 Mar 2021 13:40:46
Reviewed for Safety.	(b) (4), (b) (6)	12 Mar 2021 13:31:59
User entered 'Yes (Y)'	System	12 Mar 2021 13:31:37

**US3512248**

**Folder: SAE USA-US065-2021-MRNA-1273-P301000005**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 07:56:44**

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	15 Mar 2021 12:52:32
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Mar 2021 13:40:46
Reviewed for Safety.	(b) (4), (b) (6)	12 Mar 2021 13:31:59
User entered 'No (N)'	System	12 Mar 2021 13:31:37

**US3512248**

**Folder: SAE USA-US065-2021-MRNA-1273-P301000005**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 07:56:44**

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	15 Mar 2021 12:52:32
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Mar 2021 13:40:46
Reviewed for Safety.	(b) (4), (b) (6)	12 Mar 2021 13:31:59
User entered 'No (N)'	System	12 Mar 2021 13:31:37

**US3512248**

**Folder: SAE USA-US065-2021-MRNA-1273-P301000005**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 07:56:44**

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	15 Mar 2021 12:52:32
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	12 Mar 2021 13:40:46
Reviewed for Safety.	(b) (4), (b) (6)	12 Mar 2021 13:31:59
User entered 'Yes (Y)'	System	12 Mar 2021 13:31:37

**US3512248**

**Folder: SAE USA-US065-2021-MRNA-1273-P301000005**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 07:56:44**

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	15 Mar 2021 12:52:32
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Mar 2021 13:40:46
Reviewed for Safety.	(b) (4), (b) (6)	12 Mar 2021 13:31:59
User entered 'No (N)'	System	12 Mar 2021 13:31:37

**US3512248**

**Folder: SAE USA-US065-2021-MRNA-1273-P301000005**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 07:56:44**

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	15 Mar 2021 12:52:32
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Mar 2021 13:40:46
Reviewed for Safety.	(b) (4), (b) (6)	12 Mar 2021 13:31:59
User entered 'No (N)'	System	12 Mar 2021 13:31:37



**US3512248**

**Folder: SAE USA-US065-2021-MRNA-1273-P301000005**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 07:56:44**

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	15 Mar 2021 12:52:32
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Mar 2021 13:40:46
Reviewed for Safety.	(b) (4), (b) (6)	12 Mar 2021 13:31:59
User entered 'No (N)'	System	12 Mar 2021 13:31:37

**US3512248**

**Folder: SAE USA-US065-2021-MRNA-1273-P301000005**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 07:56:44**

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	15 Mar 2021 12:52:32
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Mar 2021 13:40:46
Reviewed for Safety.	(b) (4), (b) (6)	12 Mar 2021 13:31:59
User entered 'Michael'	System	12 Mar 2021 13:31:37

**US3512248**

**Folder: SAE USA-US065-2021-MRNA-1273-P301000005**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 07:56:44**

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	15 Mar 2021 12:52:32
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Mar 2021 13:40:46
Reviewed for Safety.	(b) (4), (b) (6)	12 Mar 2021 13:31:59
User entered 'Koren'	System	12 Mar 2021 13:31:37

**US3512248**

**Folder: SAE USA-US065-2021-MRNA-1273-P301000005**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 07:56:44**

[Investigator Country](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	30 Mar 2021 15:02:43
User signature succeeded.	Michael Koren (b) (4)	15 Mar 2021 12:52:32
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Mar 2021 13:40:46
User entered 'US'	System	12 Mar 2021 13:32:04

**US3512248**

**Folder: SAE USA-US065-2021-MRNA-1273-P301000005**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 07:56:44**

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '3'	System	13 Apr 2021 13:00:34
User entered '2'	System	30 Mar 2021 15:03:00
User entered '1'	System	12 Mar 2021 13:32:04

**US3512248**

**Folder: SAE USA-US065-2021-MRNA-1273-P301000005**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 07:56:44**

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	15 Mar 2021 12:52:32
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Mar 2021 13:40:46
Reviewed for Safety.	(b) (4), (b) (6)	12 Mar 2021 13:31:59
User entered 'USA-US065-2021-MRNA-1273-P301000005'	System	12 Mar 2021 13:31:37

**US3512248**

**Folder: SAE USA-US065-2021-MRNA-1273-P301000005**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 07:56:44**

**Serious**

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	15 Mar 2021 12:52:32
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Mar 2021 13:40:46
Reviewed for Safety.	(b) (4), (b) (6)	12 Mar 2021 13:31:59
User entered 'Yes (Y)'	System	12 Mar 2021 13:31:37

**US3512248**

**Folder: SAE USA-US065-2021-MRNA-1273-P301000005**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 07:56:44**

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	15 Mar 2021 12:52:32
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	12 Mar 2021 13:40:46
Reviewed for Safety.	(b) (4), (b) (6)	12 Mar 2021 13:31:59
User entered 'No (N)'	System	12 Mar 2021 13:31:37



**US3512248**

**Folder: SAE USA-US065-2021-MRNA-1273-P301000005**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 07:56:44**

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	15 Mar 2021 12:52:32
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Mar 2021 13:40:46
Reviewed for Safety.	(b) (4), (b) (6)	12 Mar 2021 13:31:59
User entered 'No (N)'	System	12 Mar 2021 13:31:37

**US3512248**

**Folder: SAE USA-US065-2021-MRNA-1273-P301000005**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 07:56:44**

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	15 Mar 2021 12:52:32
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	12 Mar 2021 13:40:46
Reviewed for Safety.	(b) (4), (b) (6)	12 Mar 2021 13:31:59
User entered 'Yes (Y)'	System	12 Mar 2021 13:31:37

**US3512248**

**Folder: SAE USA-US065-2021-MRNA-1273-P301000005**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 07:56:44**

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	15 Mar 2021 12:52:32
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Mar 2021 13:40:46
Reviewed for Safety.	(b) (4), (b) (6)	12 Mar 2021 13:31:59
User entered 'No (N)'	System	12 Mar 2021 13:31:37

**US3512248**

**Folder: SAE USA-US065-2021-MRNA-1273-P301000005**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 07:56:44**

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	15 Mar 2021 12:52:32
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Mar 2021 13:40:46
Reviewed for Safety.	(b) (4), (b) (6)	12 Mar 2021 13:31:59
User entered 'No (N)'	System	12 Mar 2021 13:31:37

**US3512248**

**Folder: SAE USA-US065-2021-MRNA-1273-P301000005**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 07:56:44**

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	15 Mar 2021 12:52:32
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Mar 2021 13:40:46
Reviewed for Safety.	(b) (4), (b) (6)	12 Mar 2021 13:31:59
User entered 'No (N)'	System	12 Mar 2021 13:31:37

**US3512248**

**Folder: SAE USA-US065-2021-MRNA-1273-P301000005**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 07:56:44**

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	15 Mar 2021 12:52:32
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Mar 2021 13:40:46
Reviewed for Safety.	(b) (4), (b) (6)	12 Mar 2021 13:31:59
User entered 'Michael'	System	12 Mar 2021 13:31:37

**US3512248**

**Folder: SAE USA-US065-2021-MRNA-1273-P301000005**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 07:56:44**

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	15 Mar 2021 12:52:32
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Mar 2021 13:40:46
Reviewed for Safety.	(b) (4), (b) (6)	12 Mar 2021 13:31:59
User entered 'Koren'	System	12 Mar 2021 13:31:37

**US3512248**

**Folder: SAE USA-US065-2021-MRNA-1273-P301000005**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 07:56:44**

[Investigator Country](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	30 Mar 2021 15:02:43
User signature succeeded.	Michael Koren (b) (4)	15 Mar 2021 12:52:32
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Mar 2021 13:40:46
User entered 'US'	System	12 Mar 2021 13:32:04



**US3512248**

**Folder: SAE USA-US065-2021-MRNA-1273-P301000005**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 07:56:44**

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '3'	System	13 Apr 2021 13:00:34
User entered '2'	System	30 Mar 2021 15:03:00
User entered '1'	System	12 Mar 2021 13:32:04

**US3512248**

**Folder: SAE USA-US065-2021-MRNA-1273-P301000005**

**Form: Safety Report Form (1)**

**Generated On: 10 Jun 2021 07:56:44**

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	15 Mar 2021 12:52:32
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Mar 2021 13:40:46
User entered '12/Mar/2021 13:32'	System	12 Mar 2021 13:32:04

US3512248

Folder: SAE USA-US065-2021-MRNA-1273-P301000005

Form: Safety Report Form (1)

Generated On: 10 Jun 2021 07:56:44

**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)	30 Mar 2021 15:02:43
User signature succeeded.	Michael Koren (b) (4)	15 Mar 2021 12:52:32
DataPoint Verified.	(b) (4), (b) (6)	12 Mar 2021 13:40:46
User entered '1'	(b) (4), (b) (6)	12 Mar 2021 13:32:04

**US3512248**

**Folder: SAE USA-US065-2021-MRNA-1273-P301000005**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 07:56:44**

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	15 Mar 2021 12:52:32
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Mar 2021 13:40:46
Reviewed for Safety.	(b) (4), (b) (6)	12 Mar 2021 13:31:59
User entered 'USA-US065-2021-MRNA-1273-P301000005'	System	12 Mar 2021 13:31:37

**US3512248**

**Folder: SAE USA-US065-2021-MRNA-1273-P301000005**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 07:56:44**

**Serious**

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	15 Mar 2021 12:52:32
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Mar 2021 13:40:46
Reviewed for Safety.	(b) (4), (b) (6)	12 Mar 2021 13:31:59
User entered 'Yes (Y)'	System	12 Mar 2021 13:31:37

**US3512248**

**Folder: SAE USA-US065-2021-MRNA-1273-P301000005**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 07:56:44**

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	15 Mar 2021 12:52:32
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	12 Mar 2021 13:40:46
Reviewed for Safety.	(b) (4), (b) (6)	12 Mar 2021 13:31:59
User entered 'No (N)'	System	12 Mar 2021 13:31:37

**US3512248**

**Folder: SAE USA-US065-2021-MRNA-1273-P301000005**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 07:56:44**

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	15 Mar 2021 12:52:32
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Mar 2021 13:40:46
Reviewed for Safety.	(b) (4), (b) (6)	12 Mar 2021 13:31:59
User entered 'No (N)'	System	12 Mar 2021 13:31:37

**US3512248**

**Folder: SAE USA-US065-2021-MRNA-1273-P301000005**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 07:56:44**

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	15 Mar 2021 12:52:32
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Mar 2021 13:40:46
Reviewed for Safety.	(b) (4), (b) (6)	12 Mar 2021 13:31:59
User entered 'Yes (Y)'	System	12 Mar 2021 13:31:37



**US3512248**

**Folder: SAE USA-US065-2021-MRNA-1273-P301000005**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 07:56:44**

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	15 Mar 2021 12:52:32
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	12 Mar 2021 13:40:46
Reviewed for Safety.	(b) (4), (b) (6)	12 Mar 2021 13:31:59
User entered 'No (N)'	System	12 Mar 2021 13:31:37

**US3512248**

**Folder: SAE USA-US065-2021-MRNA-1273-P301000005**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 07:56:44**

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	15 Mar 2021 12:52:32
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Mar 2021 13:40:46
Reviewed for Safety.	(b) (4), (b) (6)	12 Mar 2021 13:31:59
User entered 'No (N)'	System	12 Mar 2021 13:31:37

**US3512248**

**Folder: SAE USA-US065-2021-MRNA-1273-P301000005**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 07:56:44**

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	15 Mar 2021 12:52:32
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Mar 2021 13:40:46
Reviewed for Safety.	(b) (4), (b) (6)	12 Mar 2021 13:31:59
User entered 'No (N)'	System	12 Mar 2021 13:31:37

US3512248

Folder: SAE USA-US065-2021-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 10 Jun 2021 07:56:44

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	15 Mar 2021 12:52:32
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	12 Mar 2021 13:40:46
Reviewed for Safety.	(b) (4), (b) (6)	12 Mar 2021 13:31:59
User entered 'Michael'	System	12 Mar 2021 13:31:37

US3512248

Folder: SAE USA-US065-2021-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 10 Jun 2021 07:56:44

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	15 Mar 2021 12:52:32
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	12 Mar 2021 13:40:46
Reviewed for Safety.	(b) (4), (b) (6)	12 Mar 2021 13:31:59
User entered 'Koren'	System	12 Mar 2021 13:31:37

**US3512248**

**Folder: SAE USA-US065-2021-MRNA-1273-P301000005**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 07:56:44**

[Investigator Country](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	30 Mar 2021 15:02:43
User signature succeeded.	Michael Koren (b) (4)	15 Mar 2021 12:52:32
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Mar 2021 13:40:46
User entered 'US'	System	12 Mar 2021 13:32:04

**US3512248**

**Folder: SAE USA-US065-2021-MRNA-1273-P301000005**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 07:56:44**

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '3'	System	13 Apr 2021 13:00:34
User entered '2'	System	30 Mar 2021 15:03:00
User entered '1'	System	12 Mar 2021 13:32:04

**US3512248**

**Folder: SAE USA-US065-2021-MRNA-1273-P301000005**

**Form: Safety Report Form (2)**

**Generated On: 10 Jun 2021 07:56:44**

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 19:47:13
User signature succeeded.	Michael Koren (b) (4)	31 Mar 2021 17:34:59
User entered '30/Mar/2021 11:02'	(b) (4) System	30 Mar 2021 15:03:00



US3512248

Folder: SAE USA-US065-2021-MRNA-1273-P301000005

Form: Safety Report Form (2)

Generated On: 10 Jun 2021 07:56:44

**Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.**

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	13 Apr 2021 13:00:28
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 19:47:13
User signature succeeded.	Michael Koren (b) (4)	31 Mar 2021 17:34:59
User entered 'I'	(b) (4) (b) (4), (b) (6)	30 Mar 2021 15:03:00

**US3512248**

**Folder: SAE USA-US065-2021-MRNA-1273-P301000005**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 07:56:44**

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	15 Mar 2021 12:52:32
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Mar 2021 13:40:46
Reviewed for Safety.	(b) (4), (b) (6)	12 Mar 2021 13:31:59
User entered 'USA-US065-2021-MRNA-1273-P301000005'	System	12 Mar 2021 13:31:37

**US3512248**

**Folder: SAE USA-US065-2021-MRNA-1273-P301000005**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 07:56:44**

**Serious**

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	15 Mar 2021 12:52:32
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Mar 2021 13:40:46
Reviewed for Safety.	(b) (4), (b) (6)	12 Mar 2021 13:31:59
User entered 'Yes (Y)'	System	12 Mar 2021 13:31:37

**US3512248**

**Folder: SAE USA-US065-2021-MRNA-1273-P301000005**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 07:56:44**

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	15 Mar 2021 12:52:32
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	12 Mar 2021 13:40:46
Reviewed for Safety.	(b) (4), (b) (6)	12 Mar 2021 13:31:59
User entered 'No (N)'	System	12 Mar 2021 13:31:37

**US3512248**

**Folder: SAE USA-US065-2021-MRNA-1273-P301000005**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 07:56:44**

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	15 Mar 2021 12:52:32
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Mar 2021 13:40:46
Reviewed for Safety.	(b) (4), (b) (6)	12 Mar 2021 13:31:59
User entered 'No (N)'	System	12 Mar 2021 13:31:37

**US3512248**

**Folder: SAE USA-US065-2021-MRNA-1273-P301000005**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 07:56:44**

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	15 Mar 2021 12:52:32
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Mar 2021 13:40:46
Reviewed for Safety.	(b) (4), (b) (6)	12 Mar 2021 13:31:59
User entered 'Yes (Y)'	System	12 Mar 2021 13:31:37

**US3512248**

**Folder: SAE USA-US065-2021-MRNA-1273-P301000005**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 07:56:44**

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	15 Mar 2021 12:52:32
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Mar 2021 13:40:46
Reviewed for Safety.	(b) (4), (b) (6)	12 Mar 2021 13:31:59
User entered 'No (N)'	System	12 Mar 2021 13:31:37

**US3512248**

**Folder: SAE USA-US065-2021-MRNA-1273-P301000005**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 07:56:44**

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	15 Mar 2021 12:52:32
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Mar 2021 13:40:46
Reviewed for Safety.	(b) (4), (b) (6)	12 Mar 2021 13:31:59
User entered 'No (N)'	System	12 Mar 2021 13:31:37



**US3512248**

**Folder: SAE USA-US065-2021-MRNA-1273-P301000005**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 07:56:44**

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	15 Mar 2021 12:52:32
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Mar 2021 13:40:46
Reviewed for Safety.	(b) (4), (b) (6)	12 Mar 2021 13:31:59
User entered 'No (N)'	System	12 Mar 2021 13:31:37

**US3512248**

**Folder: SAE USA-US065-2021-MRNA-1273-P301000005**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 07:56:44**

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	15 Mar 2021 12:52:32
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Mar 2021 13:40:46
Reviewed for Safety.	(b) (4), (b) (6)	12 Mar 2021 13:31:59
User entered 'Michael'	System	12 Mar 2021 13:31:37

**US3512248**

**Folder: SAE USA-US065-2021-MRNA-1273-P301000005**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 07:56:44**

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	15 Mar 2021 12:52:32
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Mar 2021 13:40:46
Reviewed for Safety.	(b) (4), (b) (6)	12 Mar 2021 13:31:59
User entered 'Koren'	System	12 Mar 2021 13:31:37

**US3512248**

**Folder: SAE USA-US065-2021-MRNA-1273-P301000005**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 07:56:44**

[Investigator Country](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	30 Mar 2021 15:02:43
User signature succeeded.	Michael Koren (b) (4)	15 Mar 2021 12:52:32
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Mar 2021 13:40:46
User entered 'US'	System	12 Mar 2021 13:32:04

**US3512248**

**Folder: SAE USA-US065-2021-MRNA-1273-P301000005**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 07:56:44**

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '3'	System	13 Apr 2021 13:00:34
User entered '2'	System	30 Mar 2021 15:03:00
User entered '1'	System	12 Mar 2021 13:32:04

**US3512248**

**Folder: SAE USA-US065-2021-MRNA-1273-P301000005**

**Form: Safety Report Form (3)**

**Generated On: 10 Jun 2021 07:56:44**

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 12:17:30
User signature succeeded.	Michael Koren (b) (4)	14 Apr 2021 16:45:45
User entered '13/Apr/2021 08:00'	(b) (4) System	13 Apr 2021 13:00:34

US3512248

Folder: SAE USA-US065-2021-MRNA-1273-P301000005

Form: Safety Report Form (3)

Generated On: 10 Jun 2021 07:56:44

**Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.**

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 12:17:30
User signature succeeded.	Michael Koren (b) (4)	14 Apr 2021 16:45:45
User entered 'I'	(b) (4), (b) (6)	13 Apr 2021 13:00:34