

**Header Text:** c4591001

**Visit:** COHORT\_SELECTION

**Form:** COHORT SELECTION

**Form Version:** 30-Jul-2020 21:29

**Form Status:** Data Complete, Locked, Frozen, Verified

**Site No:** 1125

**Site Name:** (1125) Meridian Clinical Research

**Subject No:** 11251154

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 11:09

[eCRF Audit Trail History](#)

**Cohort Selection**

DO NOT USE THE OPTIONS STAGE 1 NONSENTINEL and STAGE 2 from this CRF. As per protocol amendment 5, STAGE 3 option is equivalent to PHASE 2/3.

1.	Select appropriate response - Protocol version	24 JUL 2020
2.	Select appropriate response - What cohort does the subject belong to?	STAGE 3 COHORTS

**Header Text:** c4591001

**Visit:** COHORT\_SELECTION

**Form:** MAIN INFORMED CONSENT

**Form Version:** 22-Apr-2020 21:02

**Form Status:** Data Complete, Locked, Frozen, Verified

**Site No:** 1125

**Site Name:** (1125) Meridian Clinical Research

**Subject No:** 11251154

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 11:09

[eCRF Audit Trail History](#)

**Informed Consent**

1.	Consent Was:	OBTAINED Date Written Consent Obtained Sep/3/2020
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**Header Text:** c4591001

**Visit:** COHORT\_SELECTION

**Form:** DEMOGRAPHY

**Form Version:** 06-Jul-2020 21:55

**Form Status:** Data Complete, Locked, Frozen, Verified

**Site No:** 1125

**Site Name:** (1125) Meridian Clinical Research

**Subject No:** 11251154

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 11:09

[eCRF Audit Trail History](#)

**Demography**

1.	Subject ID	[11251154]
2.	Birth Date:	(b) (6) 1955
3.	Sex:	MALE
4.	Ethnicity:	NOT HISPANIC OR LATINO(A) OR OF SPANISH ORIGIN
5.	Race: (Check X all that apply):	WHITE
6.	Racial Designation:	

**Header Text:** c4591001

**Visit:** V1\_DAY1\_VAX1\_L

**Form Version:** 22-Apr-2020 21:02

**Site No:** 1125

**Subject No:** 11251154

**Generated By:** (b) (4)

**Form:** DATE OF VISIT

**Form Status:** Data Complete, Locked, Frozen, Verified

**Site Name:** (1125) Meridian Clinical Research

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 11:09

[eCRF Audit Trail History](#)

**Date of Visit**

1.	Date of Visit	Sep/3/2020
2.	Erroneous Visit	

**Header Text:** c4591001

**Visit:** V1\_DAY1\_VAX1\_L

**Form Version:** 30-Jul-2020 21:29

**Site No:** 1125

**Subject No:** 11251154

**Generated By:** (b) (4)

**Form:** INCLUSION/EXCLUSION CRITERIA

**Form Status:** Data Complete, Locked, Frozen, Verified

**Site Name:** (1125) Meridian Clinical Research

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 11:09

[Form Comments](#)

**Inclusion Criteria Not Met**

1.	Description of Inclusion Criterion Not Met	Not Applicable _____
----	--	-------------------------

**Exclusion Criteria Met**

2.	Description of Exclusion Criterion Met	Not Applicable _____
----	--	-------------------------

**Header Text:** c4591001

**Visit:** V1\_DAY1\_VAX1\_L

**Form Version:** 22-Apr-2020 21:03

**Site No:** 1125

**Subject No:** 11251154

**Generated By:** (b) (4)

**Form:** DISPOSITION - SCREENING

**Form Status:** Data Complete, Locked, Frozen, Verified

**Site Name:** (1125) Meridian Clinical Research

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 11:09

[eCRF Audit Trail History](#)

**Disposition - Screening**

1.	Date of Completion/Discontinuation /Death	Sep/3/2020
2.	Phase of Disposition:	SCREENING
3.	Status:	COMPLETED
4.	Specify Status:	[ ]

**Header Text:** c4591001

**Visit:** V1\_DAY1\_VAX1\_L

**Form Version:** 22-Apr-2020 21:03

**Site No:** 1125

**Subject No:** 11251154

**Generated By:** (b) (4)

**Form:** GENERAL MEDICAL HISTORY

**Form Status:** Data Complete, Frozen, Verified

**Site Name:** (1125) Meridian Clinical Research

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 11:09

[eCRF Audit Trail History](#)

**Medical History Details**

1.a	Line/MH Number:	[1]
	Disease/Syndrome/Surgery /Non-Drug Allergies/Drug Allergies:	[Hypertension]
	Start Date:	Feb/UNK/2000
	Ongoing:	YES
1.b	Line/MH Number:	[2]
	Disease/Syndrome/Surgery /Non-Drug Allergies/Drug Allergies:	[Hypercholesterolemia]
	Start Date:	UNK/UNK/2015
	Ongoing:	YES
1.c	Line/MH Number:	[3]
	Disease/Syndrome/Surgery /Non-Drug Allergies/Drug Allergies:	[OSteoArthritis]
	Start Date:	UNK/UNK/2018
	Ongoing:	YES
1.d	Line/MH Number:	[4]
	Disease/Syndrome/Surgery /Non-Drug Allergies/Drug Allergies:	[Angina pectoris]
	Start Date:	UNK/UNK/2015
	Ongoing:	YES

090177e196ae3d1e\Final\Final On: 01-Apr-2021 04:27 (GMT)

**Header Text:** c4591001

**Visit:** V1\_DAY1\_VAX1\_L

**Form Version:** 21-Aug-2020 02:51

**Site No:** 1125

**Subject No:** 11251154

**Generated By:** (b) (4)

**Form:** VITAL SIGNS - BASELINE

**Form Status:** Data Complete, Locked, Frozen, Verified

**Site Name:** (1125) Meridian Clinical Research

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 11:09

[eCRF Audit Trail History](#)

**Vital Signs**

1.	Date:	Sep/3/2020
2.	Weight:	[229.0]
3.	Unit:	LB
4.	Height:	[71.0]
5.	Unit:	in
6.	Body Mass Index:	[31.9]

**Vital Signs Details**

7.a	Record Identifier:	1
	Temperature:	[98.2]
	Unit:	F
	Temperature Location:	ORAL CAVITY

090177e196ae3d1e\Final\Final On: 01-Apr-2021 04:27 (GMT)

**Header Text:** c4591001

**Visit:** V1\_DAY1\_VAX1\_L

**Form Version:** 22-Apr-2020 21:03

**Site No:** 1125

**Subject No:** 11251154

**Generated By:** (b) (4)

**Form:** RANDOMIZATION

**Form Status:** Data Complete, Locked, Frozen, Verified

**Site Name:** (1125) Meridian Clinical Research

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 11:09

[eCRF Audit Trail History](#)

**Disposition**

1.	Randomization Date :	Sep/3/2020
2.	Randomization Number:	[250931]
3.	Randomization Group:	[ ]

**Header Text:** c4591001

**Visit:** V1\_DAY1\_VAX1\_L

**Form Version:** 22-Apr-2020 21:03

**Site No:** 1125

**Subject No:** 11251154

**Generated By:** (b) (4)

**Form:** ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY

**Form Status:** Data Complete, Locked, Frozen, Verified

**Site Name:** (1125) Meridian Clinical Research

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 11:09

[eCRF Audit Trail History](#)

**Electronic Sample Tracking**

1.	Data Origin	SITE
2.	Sample Type	SERUM
3.	Sample Collected?	YES Date of Collection: Sep/3/2020
4.	If no sample was collected or sample was not collected according to protocol, please provide reason:	[ ]

**Aliquot**

Please enter barcode for each aliquot.

5.a	Sample ID	[BJ38SL]
5.b	Sample ID	[BJ38SM]
5.c	Sample ID	[BP52VF]
5.d	Sample ID	[BP52VG]

090177e196ae3d1e\Final\Final On: 01-Apr-2021 04:27 (GMT)

**Header Text:** c4591001

**Visit:** V1\_DAY1\_VAX1\_L

**Form:** ELECTRONIC SAMPLE TRACKING - NASAL SWAB

**Form Version:** 22-Apr-2020 21:03

**Form Status:** Data Complete, Locked, Frozen, Verified

**Site No:** 1125

**Site Name:** (1125) Meridian Clinical Research

**Subject No:** 11251154

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 11:09

[eCRF Audit Trail History](#)

**Electronic Sample Tracking**

1.	Data Origin	SITE
2.	Sample Type	NASAL_SWAB
3.	Sample Collected?	YES Date of Collection: Sep/3/2020
4.	If no sample was collected or sample was not collected according to protocol, please provide reason:	[ ]

**Aliquot**

Please enter barcode for each aliquot.

5.a	Sample ID	[BKMKWX]
-----	-----------	----------

090177e196ae3d1e\Final\Final On: 01-Apr-2021 04:27 (GMT)

**Header Text:** c4591001

**Visit:** V1\_DAY1\_VAX1\_L

**Form Version:** 22-Apr-2020 21:04

**Site No:** 1125

**Subject No:** 11251154

**Generated By:** (b) (4)

**Form:** VACCINATION

**Form Status:** Data Complete, Locked, Frozen, Verified

**Site Name:** (1125) Meridian Clinical Research

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 11:09

[eCRF Audit Trail History](#)

**Vaccination**

1.	Was there a temporary delay of vaccination?	NO
2.	Treatment Name	[BLINDED THERAPY]
3.	Formulation:	INJECTION
4.	Dose Date Time:	Sep/3/2020 09:39
5.	Anatomical Location:	DELTOID MUSCLE
6.	Body Side:	LEFT
7.	Route:	INTRAMUSCULAR
8.	Actual Dose:	[ ]
9.	Unit:	
10.	Timeframe Subject Was Observed	THE PROTOCOL SPECIFIED OBSERVATION PERIOD
11.	Was the subject observed for at least the protocol specified observation period after investigational product administration?	YES

090177e196ae3d1e\Final\Final On: 01-Apr-2021 04:27 (GMT)

**Header Text:** c4591001

**Visit:** V1\_DAY1\_VAX1\_L

**Form Version:** 06-Jul-2020 21:53

**Site No:** 1125

**Subject No:** 11251154

**Generated By:** (b) (4)

**Form:** REACTOGENICITY DIARY

**Form Status:** Data Complete, Locked, Frozen, Verified

**Site Name:** (1125) Meridian Clinical Research

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 11:09

[eCRF Audit Trail History](#)

**Reactogenicity Diary**

1.	Select appropriate response - Reactogenicity diary collection	NO - REACTOGENICITY E-DIARY NOT COLLECTED FOR THIS SUBJECT
----	---	--

**Header Text:** c4591001

**Visit:** V2\_VAX2\_L

**Form Version:** 22-Apr-2020 21:02

**Site No:** 1125

**Subject No:** 11251154

**Generated By:** (b) (4)

**Form:** DATE OF VISIT

**Form Status:** Data Complete, Locked, Frozen, Verified

**Site Name:** (1125) Meridian Clinical Research

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 11:09

[eCRF Audit Trail History](#)

**Date of Visit**

1.	Date of Visit	Sep/22/2020
2.	Erroneous Visit	

**Header Text:** c4591001

**Visit:** V2\_VAX2\_L

**Form Version:** 15-Sep-2020 21:54

**Site No:** 1125

**Subject No:** 11251154

**Generated By:** (b) (4)

**Form:** VITAL SIGNS - TEMP

**Form Status:** Data Complete, Locked, Frozen, Verified

**Site Name:** (1125) Meridian Clinical Research

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 11:09

[eCRF Audit Trail History](#)

**Vital Signs**

1.	Date:	Sep/22/2020
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**Vital Signs Details**

2.a	Record Identifier:	1
	Temperature:	[97.5]
	Unit:	F
	Temperature Location:	ORAL CAVITY

**Header Text:** c4591001

**Visit:** V2\_VAX2\_L

**Form Version:** 22-Apr-2020 21:03

**Site No:** 1125

**Subject No:** 11251154

**Generated By:** (b) (4)

**Form:** ELECTRONIC SAMPLE TRACKING - NASAL SWAB

**Form Status:** Data Complete, Locked, Frozen, Verified

**Site Name:** (1125) Meridian Clinical Research

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 11:09

[eCRF Audit Trail History](#)

**Electronic Sample Tracking**

1.	Data Origin	SITE
2.	Sample Type	NASAL_SWAB
3.	Sample Collected?	YES Date of Collection: Sep/22/2020
4.	If no sample was collected or sample was not collected according to protocol, please provide reason:	[ ]

**Aliquot**

Please enter barcode for each aliquot.

5.a	Sample ID	[BP52XB]
-----	-----------	----------

090177e196ae3d1e\Final\Final On: 01-Apr-2021 04:27 (GMT)

**Header Text:** c4591001

**Visit:** V2\_VAX2\_L

**Form Version:** 22-Apr-2020 21:04

**Site No:** 1125

**Subject No:** 11251154

**Generated By:** (b) (4)

**Form:** VACCINATION

**Form Status:** Data Complete, Locked, Frozen, Verified

**Site Name:** (1125) Meridian Clinical Research

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 11:09

[eCRF Audit Trail History](#)

**Vaccination**

1.	Was there a temporary delay of vaccination?	NO
2.	Treatment Name	[BLINDED THERAPY]
3.	Formulation:	INJECTION
4.	Dose Date Time:	Sep/22/2020 08:51
5.	Anatomical Location:	DELTOID MUSCLE
6.	Body Side:	LEFT
7.	Route:	INTRAMUSCULAR
8.	Actual Dose:	[ ]
9.	Unit:	
10.	Timeframe Subject Was Observed	THE PROTOCOL SPECIFIED OBSERVATION PERIOD
11.	Was the subject observed for at least the protocol specified observation period after investigational product administration?	YES

090177e196ae3d1e\Final\Final On: 01-Apr-2021 04:27 (GMT)

**Header Text:** c4591001

**Visit:** V3\_MONTH1\_POSTVAX2\_L

**Form Version:** 22-Apr-2020 21:02

**Site No:** 1125

**Subject No:** 11251154

**Generated By:** (b) (4)

**Form:** DATE OF VISIT

**Form Status:** Data Complete, Locked, Frozen, Verified

**Site Name:** (1125) Meridian Clinical Research

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 11:09

[eCRF Audit Trail History](#)

**Date of Visit**

1.	Date of Visit	Oct/23/2020
2.	Erroneous Visit	

**Header Text:** c4591001

**Visit:** V3\_MONTH1\_POSTVAX2\_L

**Form Version:** 22-Apr-2020 21:03

**Site No:** 1125

**Subject No:** 11251154

**Generated By:** (b) (4)

**Form:** ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY

**Form Status:** Data Complete, Locked, Frozen, Verified

**Site Name:** (1125) Meridian Clinical Research

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 11:09

[eCRF Audit Trail History](#)

**Electronic Sample Tracking**

1.	Data Origin	SITE
2.	Sample Type	SERUM
3.	Sample Collected?	YES Date of Collection: Oct/23/2020
4.	If no sample was collected or sample was not collected according to protocol, please provide reason:	[ ]

**Aliquot**

Please enter barcode for each aliquot.

5.a	Sample ID	[BPTMV5]
5.b	Sample ID	[BPTMV6]
5.c	Sample ID	[BJ39KF]
5.d	Sample ID	[BJ39KG]

090177e196ae3d1e\Final\Final On: 01-Apr-2021 04:27 (GMT)

**Header Text:** c4591001

**Visit:** V4\_MONTH6\_L

**Form Version:** 22-Apr-2020 21:02

**Site No:** 1125

**Subject No:** 11251154

**Generated By:** (b) (4)

**Form:** DATE OF VISIT

**Form Status:** Not Started

**Site Name:** (1125) Meridian Clinical Research

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 11:09

**Date of Visit**

1.	Date of Visit	//
2.	Erroneous Visit	

**Header Text:** c4591001

**Visit:** V4\_MONTH6\_L

**Form Version:** 22-Apr-2020 21:03

**Site No:** 1125

**Subject No:** 11251154

**Generated By:** (b) (4)

**Form:** ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY

**Form Status:** Not Started

**Site Name:** (1125) Meridian Clinical Research

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 11:09

**Electronic Sample Tracking**

1.	Data Origin	
2.	Sample Type	
3.	Sample Collected?	
4.	If no sample was collected or sample was not collected according to protocol, please provide reason:	[ ]

**Aliquot**

Please enter barcode for each aliquot.

5.	Sample ID	[ ]
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090177e196ae3d1e\Final\Final On: 01-Apr-2021 04:27 (GMT)

**Header Text:** c4591001

**Visit:** V5\_MONTH12\_L

**Form Version:** 22-Apr-2020 21:02

**Site No:** 1125

**Subject No:** 11251154

**Generated By:** (b) (4)

**Form:** DATE OF VISIT

**Form Status:** Not Started

**Site Name:** (1125) Meridian Clinical Research

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 11:09

**Date of Visit**

1.	Date of Visit	//
2.	Erroneous Visit	

**Header Text:** c4591001

**Visit:** V5\_MONTH12\_L

**Form Version:** 22-Apr-2020 21:03

**Site No:** 1125

**Subject No:** 11251154

**Generated By:** (b) (4)

**Form:** ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY

**Form Status:** Not Started

**Site Name:** (1125) Meridian Clinical Research

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 11:09

**Electronic Sample Tracking**

1.	Data Origin	
2.	Sample Type	
3.	Sample Collected?	
4.	If no sample was collected or sample was not collected according to protocol, please provide reason:	[ ]

**Aliquot**

Please enter barcode for each aliquot.

5.	Sample ID	[ ]
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090177e196ae3d1e\Final\Final On: 01-Apr-2021 04:27 (GMT)

**Header Text:** c4591001

**Visit:** V6\_MONTH24\_L

**Form Version:** 22-Apr-2020 21:02

**Site No:** 1125

**Subject No:** 11251154

**Generated By:** (b) (4)

**Form:** DATE OF VISIT

**Form Status:** Not Started

**Site Name:** (1125) Meridian Clinical Research

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 11:09

**Date of Visit**

1.	Date of Visit	//
2.	Erroneous Visit	

**Header Text:** c4591001

**Visit:** V6\_MONTH24\_L

**Form Version:** 22-Apr-2020 21:03

**Site No:** 1125

**Subject No:** 11251154

**Generated By:** (b) (4)

**Form:** ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY

**Form Status:** Not Started

**Site Name:** (1125) Meridian Clinical Research

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 11:09

**Electronic Sample Tracking**

1.	Data Origin	
2.	Sample Type	
3.	Sample Collected?	
4.	If no sample was collected or sample was not collected according to protocol, please provide reason:	[ ]

**Aliquot**

Please enter barcode for each aliquot.

5.	Sample ID	[ ]
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090177e196ae3d1e\Final\Final On: 01-Apr-2021 04:27 (GMT)

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit **Form:** DATE OF VISIT - ILLNESS ONSET  
on Feb/04/2021

**Form Version:** 22-Apr-2020 21:03

**Form Status:** Data Complete, Frozen, Verified

**Site No:** 1125

**Site Name:** (1125) Meridian Clinical Research

**Subject No:** 11251154

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 11:09

[eCRF Audit Trail History](#)

**Date of Visit**

1.	Date of Visit	Feb/4/2021
2.	Erroneous Visit	

**COVID-19 Illness Visit**

3.	COVID-19 Illness Visit:	COVID_A
----	-------------------------	---------

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit **Form:** SIGNS AND SYMPTOMS OF POTENTIAL COVID-19 on Feb/04/2021

**Form Version:** 14-Jan-2021 02:23

**Form Status:** Data Complete

**Site No:** 1125

**Site Name:** (1125) Meridian Clinical Research

**Subject No:** 11251154

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 11:09

[eCRF Audit Trail History](#)

**Signs and Symptoms**

1.	Date of Assessment:	Feb/4/2021
2.	Date of First Symptom Started:	Jan/20/2021
3.	Symptoms Ongoing?	YES

**Symptoms**

4.a	Symptoms:	FEVER
	Was symptom present?	YES
4.b	Symptoms:	NEW OR INCREASED COUGH
	Was symptom present?	YES
4.c	Symptoms:	NEW OR INCREASED SHORTNESS OF BREATH
	Was symptom present?	YES
4.d	Symptoms:	CHILLS
	Was symptom present?	NO
4.e	Symptoms:	NEW OR INCREASED MUSCLE PAIN
	Was symptom present?	NO
4.f	Symptoms:	NEW LOSS OF TASTE OR SMELL
	Was symptom present?	YES
4.g	Symptoms:	NEW OR INCREASED SORE THROAT
	Was symptom present?	YES
4.h	Symptoms:	DIARRHEA
	Was symptom present?	YES
4.i	Symptoms:	VOMITING
	Was symptom present?	NO

090177e196ae3d1e\Final\Final On: 01-Apr-2021 04:27 (GMT)

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit **Form:** SIGNS AND SYMPTOMS OF POTENTIAL COVID-19 on Feb/04/2021

**Form Version:** 14-Jan-2021 02:23

**Form Status:** Data Complete

**Site No:** 1125

**Site Name:** (1125) Meridian Clinical Research

**Subject No:** 11251154

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 11:09

**Symptoms - Other**

5.a	Symptoms - Other Text:	[Headache]
5.b	Symptoms - Other Text:	[fatigue]
5.c	Symptoms - Other Text:	[New or increased nasal discharge]
5.d	Symptoms - Other Text:	[New or increased nasal congestion]

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1

**Form:** MICROBIOLOGY SPECIMEN

**Form Version:** 06-Jul-2020 21:54

**Site No:** 1125

**Site Name:** (1125) Meridian Clinical Research

**Subject No:** 11251154

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 11:09

#	Date of Collection	Specimen Type	Specimen Collection Location	Assay Code and Description	Device Type	Form Instance
1.	Not Done	Not Done	Not Done	Not Done	Not Done	<a href="#">Repeating Pages</a>

090177e196ae3d1e\Final\Final On: 01-Apr-2021 04:27 (GMT)

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit **Form:** MICROBIOLOGY SPECIMEN  
on Feb/04/2021

**Form Version:** 06-Jul-2020 21:54

**Form Status:** Data Complete, Frozen

**Site No:** 1125

**Site Name:** (1125) Meridian Clinical Research

**Subject No:** 11251154

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 11:09

[Back to Form](#)

[Form Comments](#)

[eCRF Audit Trail History](#)

**Microbiology Specimen**

1.	Actual Date of Collection:	Not Done _____ //	<a href="#">Comments</a>
2.	Specimen Type:	Not Done _____	<a href="#">Comments</a>
3.	Specimen Collection Location:	Not Done _____	<a href="#">Comments</a>
4.	Assay Code and Description:	Not Done _____	<a href="#">Comments</a>
5.	Device Type:	Not Done _____	<a href="#">Comments</a>
6.	Trade Name:	Not Done _____	<a href="#">Comments</a>
7.	Test Result:	Not Done _____	<a href="#">Comments</a>
8.	Comments/Findings/Details:	Not Done _____ [ ]	<a href="#">Comments</a>
9.	Trade Name Other, Specify:	Not Done _____ [ ]	<a href="#">Comments</a>

090177e196ae3d1e\Final\Final On: 01-Apr-2021 04:27 (GMT)

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit **Form:** ELECTRONIC SAMPLE TRACKING - NASAL SWAB SELF on Feb/04/2021

**Form Version:** 22-Apr-2020 21:03

**Form Status:** Data Complete, Frozen, Verified

**Site No:** 1125

**Site Name:** (1125) Meridian Clinical Research

**Subject No:** 11251154

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 11:09

[eCRF Audit Trail History](#)

**Electronic Sample Tracking**

1.	Data Origin	SITE
2.	Sample Type	NASAL_SWAB_SELF
3.	Sample Collected?	YES Date of Collection: Feb/27/2021
4.	If no sample was collected or sample was not collected according to protocol, please provide reason:	[ ]

**Aliquot**

Please enter barcode for each aliquot.

5.a	Sample ID	[AA03141]
-----	-----------	-----------

090177e196ae3d1e\Final\Final On: 01-Apr-2021 04:27 (GMT)

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit **Form:** ELECTRONIC SAMPLE TRACKING - NASAL SWAB  
on Feb/04/2021

**Form Version:** 22-Apr-2020 21:03

**Form Status:** Data Complete, Frozen, Verified

**Site No:** 1125

**Site Name:** (1125) Meridian Clinical Research

**Subject No:** 11251154

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 11:09

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**Electronic Sample Tracking**

1.	Data Origin	SITE
2.	Sample Type	NASAL_SWAB
3.	Sample Collected?	NO
4.	If no sample was collected or sample was not collected according to protocol, please provide reason:	[Telehealth visit]

**Aliquot**

Please enter barcode for each aliquot.

5.	Sample ID	[ ]
----	-----------	-----

090177e196ae3d1e\Final\Final On: 01-Apr-2021 04:27 (GMT)

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit **Form:** HEALTH CARE UTILIZATION  
on Feb/04/2021

**Form Version:** 14-Jan-2021 02:24

**Form Status:** Data Complete

**Site No:** 1125

**Site Name:** (1125) Meridian Clinical Research

**Subject No:** 11251154

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 11:09

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**Health Care Utilization**

1.a	Physician or Healthcare Professional:	SPECIALIST
	Occurrence of Visits or Contacts:	NO
1.b	Physician or Healthcare Professional:	EMERGENCY ROOM
	Occurrence of Visits or Contacts:	YES Number of Visits or Contacts: [1]
1.c	Physician or Healthcare Professional:	PRIMARY CARE PHYSICIAN
	Occurrence of Visits or Contacts:	YES Number of Visits or Contacts: [1]
1.d	Physician or Healthcare Professional:	URGENT CARE
	Occurrence of Visits or Contacts:	NO
1.e	Physician or Healthcare Professional:	TELEPHONE CONSULTATION
	Occurrence of Visits or Contacts:	NO
1.f	Physician or Healthcare Professional:	OTHER
	Occurrence of Visits or Contacts:	YES Number of Visits or Contacts: [1]

**Health Care Utilization Other**

090177e196ae3d1e\Final\Final On: 01-Apr-2021 04:27 (GMT)

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit **Form:** HEALTH CARE UTILIZATION  
on Feb/04/2021

**Form Version:** 14-Jan-2021 02:24

**Form Status:** Data Complete

**Site No:** 1125

**Site Name:** (1125) Meridian Clinical Research

**Subject No:** 11251154

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 11:09

2.	Other Type of Practitioner Specify:	[Outpatient BAM infusion]
----	--	---------------------------

**Health Care Utilization**

3.	Has the subject been hospitalized due to potential COVID-19 illness?	YES Has the subject been in intensive care due to potential COVID-19 illness? NO
----	--	--

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1

**Form:** HOSPITALIZATION DETAILS

**Form Version:** 22-Apr-2020 21:02

**Site No:** 1125

**Site Name:** (1125) Meridian Clinical Research

**Subject No:** 11251154

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 11:09

#	Hospitalization Category	Hospitalization Term	Admission Date	Ongoing	Form Instance
1.	HOSPITALIZATION STATUS	HOSPITAL	Jan/28/2021	NO Discharge Date: Feb/1/2021	<a href="#">Repeating Pages</a>

090177e196ae3d1e\Final\Final On: 01-Apr-2021 04:27 (GMT)

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit **Form:** HOSPITALIZATION DETAILS  
on Feb/04/2021

**Form Version:** 22-Apr-2020 21:02

**Form Status:** Data Complete

**Site No:** 1125

**Site Name:** (1125) Meridian Clinical Research

**Subject No:** 11251154

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 11:09

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**Hospitalization Details**

1.	Hospitalization Category:	HOSPITALIZATION STATUS
2.	Hospitalization Term:	HOSPITAL
3.	Admission Date:	Jan/28/2021
4.	Ongoing?	NO Discharge Date: Feb/1/2021

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1

**Form:** RESPIRATORY TREATMENT

**Form Version:** 06-Jul-2020 21:53

**Site No:** 1125

**Site Name:** (1125) Meridian Clinical Research

**Subject No:** 11251154

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 11:09

#	Treatment Identifier	Con Non-Drug Treatments Pre-specified	Treatment	Treatment	Start Date	Form Instance
1.	Not Applicable	Not Applicable	Not Applicable	Not Applicable	Not Applicable	<a href="#">Repeating Pages</a>

090177e196ae3d1e\Final\Final On: 01-Apr-2021 04:27 (GMT)

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit **Form:** RESPIRATORY TREATMENT  
on Feb/04/2021

**Form Version:** 06-Jul-2020 21:53

**Form Status:** Data Complete, Frozen

**Site No:** 1125

**Site Name:** (1125) Meridian Clinical Research

**Subject No:** 11251154

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 11:09

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**Respiratory Treatment**

1.	What is the treatment Identifier?	Not Applicable _____ [ ]	<a href="#">Comments</a>
2.	Concomitant Non-drug Treatment Pre-specified:	Not Applicable _____	<a href="#">Comments</a>
3.	Treatment:	Not Applicable _____	<a href="#">Comments</a>
4.	Treatment:	Not Applicable _____ [ ]	<a href="#">Comments</a>
5.	Start Date:	Not Applicable _____ //	<a href="#">Comments</a>
6.	Ongoing?	Not Applicable _____	<a href="#">Comments</a>

090177e196ae3d1e\Final\Final On: 01-Apr-2021 04:27 (GMT)

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit **Form:** ILLNESS DETAILS  
on Feb/04/2021

**Form Version:** 06-Jul-2020 21:52

**Form Status:** Data Complete

**Site No:** 1125

**Site Name:** (1125) Meridian Clinical Research

**Subject No:** 11251154

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 11:09

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**Illness Details**

1.	Category of Clinical Event:	POTENTIAL COVID-19 ILLNESS
2.	Was a diagnosis obtained for Potential COVID-19 Illness?	YES Respiratory Illness Diagnosis: [Covid-19]  Date of Diagnosis: Jan/26/2021
3.	Toxicity Grade:	3

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**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1

**Form:** ILLNESS DETAILS - SEVERE

**Form Version:** 17-Jul-2020 21:55

**Site No:** 1125

**Site Name:** (1125) Meridian Clinical Research

**Subject No:** 11251154

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 11:09

#	Category of Clinical Event:	Subcategory of Clinical Event	Diagnosis Obtained	Toxicity Grade	Form Instance
1.	Not Applicable	Not Applicable	Not Applicable	Not Applicable	<a href="#">Repeating Pages</a>

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit **Form:** ILLNESS DETAILS - SEVERE  
on Feb/04/2021

**Form Version:** 17-Jul-2020 21:55

**Form Status:** Data Complete, Frozen

**Site No:** 1125

**Site Name:** (1125) Meridian Clinical Research

**Subject No:** 11251154

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 11:09

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**Illness Details**

1.	Category of Clinical Event:	Not Applicable _____	<a href="#">Comments</a>
2.	Subcategory of Clinical Event:	Not Applicable _____	<a href="#">Comments</a>
3.	Was a diagnosis obtained?	Not Applicable _____	<a href="#">Comments</a>
4.	Toxicity Grade:	Not Applicable _____	<a href="#">Comments</a>

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Header Text: c4591001

Visit: POT\_COVID\_ILL 1

Form: LOCAL LABORATORY DATA - REPEATING CHEMISTRY

Form Version: 21-Aug-2020 02:49

Site No: 1125

Site Name: (1125) Meridian Clinical Research

Subject No: 11251154

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:09

#	Category for Lab Test	Vendor Name	Collection Date:	Specimen Type	Lab Result			Form Instance
1.	Not Applicable	Not Applicable	Not Applicable	Not Applicable	<b>Sponsor-Defined Identifier</b>	<b>Test:</b>	<b>Result:</b>	<a href="#">Repeating Pages</a>
					Not Applicable	Not Applicable	Not Applicable	
					Not Applicable	Not Applicable	Not Applicable	
					Not Applicable	Not Applicable	Not Applicable	
					Not Applicable	Not Applicable	Not Applicable	
					Not Applicable	Not Applicable	Not Applicable	
					Not Applicable	Not Applicable	Not Applicable	
					Not Applicable	Not Applicable	Not Applicable	

090177e196ae3d1e\Final\Final On: 01-Apr-2021 04:27 (GMT)

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit **Form:** LOCAL LABORATORY DATA - REPEATING CHEMISTRY  
on Feb/04/2021

**Form Version:** 21-Aug-2020 02:49

**Form Status:** Data Complete, Frozen

**Site No:** 1125

**Site Name:** (1125) Meridian Clinical Research

**Subject No:** 11251154

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 11:09

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**Lab Chemistry Details**

1.	Lab Panel:	Not Applicable _____	<a href="#">Comments</a>
2.	Laboratory Name and Address	Not Applicable _____ [ ]	<a href="#">Comments</a>
3.	Collection Date:	Not Applicable _____ //	<a href="#">Comments</a>
4.	Specimen Type:	Not Applicable _____	<a href="#">Comments</a>

**Lab Result**

5.a	Sponsor ID:	Not Applicable _____ [ ]	<a href="#">Comments</a>
	Test:	C Reactive Protein_PX329	
	Result:	Not Applicable _____ [ ]	<a href="#">Comments</a>
	Not Done:	Not Applicable _____	<a href="#">Comments</a>
	LNMT	Not Applicable _____ Low [ ] High [ ] Unit	<a href="#">Comments</a>

090177e196ae3d1e\Final\Final On: 01-Apr-2021 04:27 (GMT)

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit **Form:** LOCAL LABORATORY DATA - REPEATING CHEMISTRY on Feb/04/2021

**Form Version:** 21-Aug-2020 02:49

**Form Status:** Data Complete, Frozen

**Site No:** 1125

**Site Name:** (1125) Meridian Clinical Research

**Subject No:** 11251154

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 11:09

5.b	Sponsor ID:	Not Applicable _____ [ ]	<a href="#">Comments</a>
	Test:	Alanine Aminotransferase_PX30	
	Result:	Not Applicable _____ [ ]	<a href="#">Comments</a>
	Not Done:	Not Applicable _____ [ ]	<a href="#">Comments</a>
	LNMT	Not Applicable _____ Low [ ] High [ ] Unit	<a href="#">Comments</a>
5.c	Sponsor ID:	Not Applicable _____ [ ]	<a href="#">Comments</a>
	Test:	Aspartate Aminotransferase_PX28	
	Result:	Not Applicable _____ [ ]	<a href="#">Comments</a>
	Not Done:	Not Applicable _____ [ ]	<a href="#">Comments</a>
	LNMT	Not Applicable _____ Low [ ] High [ ] Unit	<a href="#">Comments</a>

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**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit **Form:** LOCAL LABORATORY DATA - REPEATING CHEMISTRY on Feb/04/2021

**Form Version:** 21-Aug-2020 02:49

**Form Status:** Data Complete, Frozen

**Site No:** 1125

**Site Name:** (1125) Meridian Clinical Research

**Subject No:** 11251154

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 11:09

5.d	Sponsor ID:	Not Applicable _____ [ ]	<a href="#">Comments</a>
	Test:	Alkaline Phosphatase_PX35	
	Result:	Not Applicable _____ [ ]	<a href="#">Comments</a>
	Not Done:	Not Applicable _____ [ ]	<a href="#">Comments</a>
	LNMT	Not Applicable _____ Low [ ] High [ ] Unit	<a href="#">Comments</a>
5.e	Sponsor ID:	Not Applicable _____ [ ]	<a href="#">Comments</a>
	Test:	Bilirubin_PX21	
	Result:	Not Applicable _____ [ ]	<a href="#">Comments</a>
	Not Done:	Not Applicable _____ [ ]	<a href="#">Comments</a>
	LNMT	Not Applicable _____ Low [ ] High [ ] Unit	<a href="#">Comments</a>

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**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit **Form:** LOCAL LABORATORY DATA - REPEATING CHEMISTRY on Feb/04/2021

**Form Version:** 21-Aug-2020 02:49

**Form Status:** Data Complete, Frozen

**Site No:** 1125

**Site Name:** (1125) Meridian Clinical Research

**Subject No:** 11251154

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 11:09

5 f	Sponsor ID:	Not Applicable _____ [ ]	<a href="#">Comments</a>
	Test:	Blood Urea Nitrogen_PX47	
	Result:	Not Applicable _____ [ ]	<a href="#">Comments</a>
	Not Done:	Not Applicable _____ [ ]	<a href="#">Comments</a>
	LNMT	Not Applicable _____ Low [ ] High [ ] Unit	<a href="#">Comments</a>
5.g	Sponsor ID:	Not Applicable _____ [ ]	<a href="#">Comments</a>
	Test:	Creatinine_PX48	
	Result:	Not Applicable _____ [ ]	<a href="#">Comments</a>
	Not Done:	Not Applicable _____ [ ]	<a href="#">Comments</a>
	LNMT	Not Applicable _____ Low [ ] High [ ] Unit	<a href="#">Comments</a>

090177e196ae3d1e\Final\Final On: 01-Apr-2021 04:27 (GMT)

Header Text: c4591001

Visit: POT\_COVID\_ILL 1

Form: LOCAL LABORATORY DATA - REPEATING Hematology

Form Version: 21-Aug-2020 02:51

Site No: 1125

Site Name: (1125) Meridian Clinical Research

Subject No: 11251154

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:09

#	Category for Lab Test	Vendor Name ( DERIVED)	Collection Date:	Specimen Type	Lab Result			Form Instance
1.	Not Applicable	Not Applicable	Not Applicable	Not Applicable	<b>Sponsor-Defined Identifier</b>	<b>Test:</b>	<b>Result:</b>	<a href="#">Repeating Pages</a>
					Not Applicable	Not Applicable	Not Applicable	
					Not Applicable	Not Applicable	Not Applicable	
					Not Applicable	Not Applicable	Not Applicable	
					Not Applicable	Not Applicable	Not Applicable	
					Not Applicable	Not Applicable	Not Applicable	
					Not Applicable	Not Applicable	Not Applicable	
					Not Applicable	Not Applicable	Not Applicable	
					Not Applicable	Not Applicable	Not Applicable	
					Not Applicable	Not Applicable	Not Applicable	
					Not Applicable	Not Applicable	Not Applicable	

090177e196ae3d1e\Final\Final On: 01-Apr-2021 04:27 (GMT)

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit **Form:** LOCAL LABORATORY DATA - REPEATING Hematology on Feb/04/2021

**Form Version:** 21-Aug-2020 02:51

**Form Status:** Data Complete, Frozen

**Site No:** 1125

**Site Name:** (1125) Meridian Clinical Research

**Subject No:** 11251154

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 11:09

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**Laboratory Data Hematology**

1.	Lab Panel:	Not Applicable _____	<a href="#">Comments</a>
2.	Laboratory Name and Address	Not Applicable _____ [ ]	<a href="#">Comments</a>
3.	Collection Date:	Not Applicable _____ //	<a href="#">Comments</a>
4.	Specimen Type:	Not Applicable _____	<a href="#">Comments</a>

**Lab Result**

5.a	Sponsor ID:	Not Applicable _____ [ ]	<a href="#">Comments</a>
	Test:	Hemoglobin_PX1	
	Result:	Not Applicable _____ [ ]	<a href="#">Comments</a>
	Not Done:	Not Applicable _____	<a href="#">Comments</a>
	LNMT	Not Applicable _____ Low [ ] High [ ] Unit	<a href="#">Comments</a>

090177e196ae3d1e\Final\Final On: 01-Apr-2021 04:27 (GMT)

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit **Form:** LOCAL LABORATORY DATA - REPEATING Hematology on Feb/04/2021

**Form Version:** 21-Aug-2020 02:51

**Form Status:** Data Complete, Frozen

**Site No:** 1125

**Site Name:** (1125) Meridian Clinical Research

**Subject No:** 11251154

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 11:09

5.b	Sponsor ID:	Not Applicable _____ [ ]	<a href="#">Comments</a>
	Test:	Hematocrit_PX2	
	Result:	Not Applicable _____ [ ]	<a href="#">Comments</a>
	Not Done:	Not Applicable _____ [ ]	<a href="#">Comments</a>
	LNMT	Not Applicable _____ Low [ ] High [ ] Unit	<a href="#">Comments</a>
5.c	Sponsor ID:	Not Applicable _____ [ ]	<a href="#">Comments</a>
	Test:	Erythrocytes_PX3	
	Result:	Not Applicable _____ [ ]	<a href="#">Comments</a>
	Not Done:	Not Applicable _____ [ ]	<a href="#">Comments</a>
	LNMT	Not Applicable _____ Low [ ] High [ ] Unit	<a href="#">Comments</a>

090177e196ae3d1e\Final\Final On: 01-Apr-2021 04:27 (GMT)

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit **Form:** LOCAL LABORATORY DATA - REPEATING Hematology on Feb/04/2021

**Form Version:** 21-Aug-2020 02:51

**Form Status:** Data Complete, Frozen

**Site No:** 1125

**Site Name:** (1125) Meridian Clinical Research

**Subject No:** 11251154

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 11:09

5.d	Sponsor ID:	Not Applicable _____ [ ]	<a href="#">Comments</a>
	Test:	Platelets_PX5	
	Result:	Not Applicable _____ [ ]	<a href="#">Comments</a>
	Not Done:	Not Applicable _____ [ ]	<a href="#">Comments</a>
	LNMT	Not Applicable _____ Low [ ] High [ ] Unit	<a href="#">Comments</a>
5.e	Sponsor ID:	Not Applicable _____ [ ]	<a href="#">Comments</a>
	Test:	Leukocytes_PX7	
	Result:	Not Applicable _____ [ ]	<a href="#">Comments</a>
	Not Done:	Not Applicable _____ [ ]	<a href="#">Comments</a>
	LNMT	Not Applicable _____ Low [ ] High [ ] Unit	<a href="#">Comments</a>

090177e196ae3d1e\Final\Final On: 01-Apr-2021 04:27 (GMT)

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit **Form:** LOCAL LABORATORY DATA - REPEATING Hematology on Feb/04/2021

**Form Version:** 21-Aug-2020 02:51

**Form Status:** Data Complete, Frozen

**Site No:** 1125

**Site Name:** (1125) Meridian Clinical Research

**Subject No:** 11251154

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 11:09

5 f	Sponsor ID:	Not Applicable _____ [ ]	<a href="#">Comments</a>
	Test:	Neutrophils_PX608	
	Result:	Not Applicable _____ [ ]	<a href="#">Comments</a>
	Not Done:	Not Applicable _____ [ ]	<a href="#">Comments</a>
	LNMT	Not Applicable _____ Low [ ] High [ ] Unit	<a href="#">Comments</a>
5.g	Sponsor ID:	Not Applicable _____ [ ]	<a href="#">Comments</a>
	Test:	Eosinophils_PX609	
	Result:	Not Applicable _____ [ ]	<a href="#">Comments</a>
	Not Done:	Not Applicable _____ [ ]	<a href="#">Comments</a>
	LNMT	Not Applicable _____ Low [ ] High [ ] Unit	<a href="#">Comments</a>

090177e196ae3d1e\Final\Final On: 01-Apr-2021 04:27 (GMT)

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit **Form:** LOCAL LABORATORY DATA - REPEATING Hematology on Feb/04/2021

**Form Version:** 21-Aug-2020 02:51

**Form Status:** Data Complete, Frozen

**Site No:** 1125

**Site Name:** (1125) Meridian Clinical Research

**Subject No:** 11251154

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 11:09

5 h	Sponsor ID:	Not Applicable _____ [ ]	<a href="#">Comments</a>
	Test:	Monocytes_PX612	
	Result:	Not Applicable _____ [ ]	<a href="#">Comments</a>
	Not Done:	Not Applicable _____ [ ]	<a href="#">Comments</a>
	LNMT	Not Applicable _____ Low [ ] High [ ] Unit	<a href="#">Comments</a>
5.i	Sponsor ID:	Not Applicable _____ [ ]	<a href="#">Comments</a>
	Test:	Basophils_PX610	
	Result:	Not Applicable _____ [ ]	<a href="#">Comments</a>
	Not Done:	Not Applicable _____ [ ]	<a href="#">Comments</a>
	LNMT	Not Applicable _____ Low [ ] High [ ] Unit	<a href="#">Comments</a>

090177e196ae3d1e\Final\Final On: 01-Apr-2021 04:27 (GMT)

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit **Form:** LOCAL LABORATORY DATA - REPEATING Hematology on Feb/04/2021

**Form Version:** 21-Aug-2020 02:51

**Form Status:** Data Complete, Frozen

**Site No:** 1125

**Site Name:** (1125) Meridian Clinical Research

**Subject No:** 11251154

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 11:09

5.j	Sponsor ID:	Not Applicable _____ [ ]	<a href="#">Comments</a>
	Test:	Lymphocytes_PX611	
	Result:	Not Applicable _____ [ ]	<a href="#">Comments</a>
	Not Done:	Not Applicable _____ [ ]	<a href="#">Comments</a>
	LNMT	Not Applicable _____ Low [ ] High [ ] Unit	<a href="#">Comments</a>

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**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1

**Form:** VITAL SIGNS - COVID

**Form Version:** 21-Aug-2020 02:50

**Site No:** 1125

**Site Name:** (1125) Meridian Clinical Research

**Subject No:** 11251154

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 11:09

#	Date:	Vital Signs Details			Form Instance
1.	Not Applicable	<b>Record Identifier:</b>	<b>Systolic:</b>	<b>Diastolic:</b>	<a href="#">Repeating Pages</a>
		Not Applicable	Not Applicable	Not Applicable	

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit **Form:** VITAL SIGNS - COVID  
on Feb/04/2021

**Form Version:** 21-Aug-2020 02:50

**Form Status:** Data Complete, Frozen

**Site No:** 1125

**Site Name:** (1125) Meridian Clinical Research

**Subject No:** 11251154

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 11:09

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**Vital Signs**

1.	Date:	Not Applicable _____ //	<a href="#">Comments</a>
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**Vital Signs Details**

2.a	Record Identifier:	Not Applicable _____ 1	
	Systolic:	Not Applicable _____ [ ]	<a href="#">Comments</a>
	Diastolic:	Not Applicable _____ [ ]	<a href="#">Comments</a>
	Respiratory Rate in respirations/minute:	Not Applicable _____ [ ]	<a href="#">Comments</a>
	Heart Rate in beats/minute:	Not Applicable _____ [ ]	<a href="#">Comments</a>

090177e196ae3d1e\Final\Final On: 01-Apr-2021 04:27 (GMT)

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1

**Form:** VITAL SIGNS - PULSE OX ROOM AIR

**Form Version:** 21-Aug-2020 02:51

**Site No:** 1125

**Site Name:** (1125) Meridian Clinical Research

**Subject No:** 11251154

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 11:09

#	Date:	Vital Signs Details		Form Instance
1.	Not Applicable	<b>Record Identifier:</b>	<b>Oxygen Saturation</b>	<a href="#">Repeating Pages</a>
		Not Applicable	Not Applicable	

090177e196ae3d1e\Final\Final On: 01-Apr-2021 04:27 (GMT)

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit **Form:** VITAL SIGNS - PULSE OX ROOM AIR  
on Feb/04/2021

**Form Version:** 21-Aug-2020 02:51

**Form Status:** Data Complete, Frozen

**Site No:** 1125

**Site Name:** (1125) Meridian Clinical Research

**Subject No:** 11251154

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 11:09

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**Vital Signs**

1.	Date:	Not Applicable _____ //	<a href="#">Comments</a>
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**Vital Signs Details**

2.a	Record Identifier:	Not Applicable _____ 1	
	SPO2 Pulse Oximetry %	Not Applicable _____ [ ]	<a href="#">Comments</a>

090177e196ae3d1e\Final\Final On: 01-Apr-2021 04:27 (GMT)

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1

**Form:** OXYGENATION PARAMETERS

**Form Version:** 06-Jul-2020 21:52

**Site No:** 1125

**Site Name:** (1125) Meridian Clinical Research

**Subject No:** 11251154

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 11:09

#	Date Time of Assessment	Arterial Blood Gases PaO2	FiO2 (Fraction of Inhaled Oxygen)	Form Instance
1.	Not Applicable	Not Applicable	Not Applicable	<a href="#">Repeating Pages</a>

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit **Form:** OXYGENATION PARAMETERS  
on Feb/04/2021

**Form Version:** 06-Jul-2020 21:52

**Form Status:** Data Complete, Frozen

**Site No:** 1125

**Site Name:** (1125) Meridian Clinical Research

**Subject No:** 11251154

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 11:09

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**Oxygenation Parameters**

1.	Date Time of Assessment:	Not Applicable _____ //	<a href="#">Comments</a>
2.	Arterial Blood Gases PaO2 (mmHg):	Not Applicable _____ [ ]	<a href="#">Comments</a>
3.	FiO2 (Fraction of Inhaled Oxygen):	Not Applicable _____ [ ]	<a href="#">Comments</a>

090177e196ae3d1e\Final\Final On: 01-Apr-2021 04:27 (GMT)

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1

**Form:** CONCOMITANT MEDICATIONS - VASOPRESSORS

**Form Version:** 06-Jul-2020 21:55

**Site No:** 1125

**Site Name:** (1125) Meridian Clinical Research

**Subject No:** 11251154

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 11:09

#	Sponsor-Defined Identifier	Category for Medication	Concomitant Medications Pre-specified	Name of Medication	Start Date	Form Instance
1.	Not Applicable	Not Applicable	Not Applicable	Not Applicable	Not Applicable	<a href="#">Repeating Pages</a>

090177e196ae3d1e\Final\Final On: 01-Apr-2021 04:27 (GMT)

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit **Form:** CONCOMITANT MEDICATIONS - VASOPRESSORS  
on Feb/04/2021

**Form Version:** 06-Jul-2020 21:55

**Form Status:** Data Complete, Frozen

**Site No:** 1125

**Site Name:** (1125) Meridian Clinical Research

**Subject No:** 11251154

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 11:09

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**Concomitant Medications**

1.	What is the medication identifier?	Not Applicable _____ [ ]	<a href="#">Comments</a>
2.	Category:	Not Applicable _____	<a href="#">Comments</a>
3.	Concomitant Medications Pre-specified:	Not Applicable _____	<a href="#">Comments</a>
4.	Medication:  Provide the complete generic drug name (including salt form, where applicable). Where generic name is unknown, enter the full trade or proprietary name. Include clarifying information in the Medication text (e.g., Ingredient(s), route, use, formulation).	Not Applicable _____ [ ]	<a href="#">Comments</a>
5.	Start Date:	Not Applicable _____ //	<a href="#">Comments</a>
6.	Ongoing?	Not Applicable _____	<a href="#">Comments</a>

090177e196ae3d1e\Final\Final On: 01-Apr-2021 04:27 (GMT)

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1

**Form:** IMAGING

**Form Version:** 06-Jul-2020 21:53

**Site No:** 1125

**Site Name:** (1125) Meridian Clinical Research

**Subject No:** 11251154

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 11:09

#	Date of Assessment	Location of Assessment	Imaging Method	Overall Assessment	Form Instance
1.	Not Applicable	Not Applicable	Not Applicable	Not Applicable	<a href="#">Repeating Pages</a>

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit **Form:** IMAGING

on Feb/04/2021

**Form Version:** 06-Jul-2020 21:53

**Form Status:** Data Complete, Frozen

**Site No:** 1125

**Site Name:** (1125) Meridian Clinical Research

**Subject No:** 11251154

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 11:09

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**Imaging**

1.	Date of Assessment:	Not Applicable _____ //	<a href="#">Comments</a>
2.	Location of Assessment:	Not Applicable _____	<a href="#">Comments</a>
3.	Type of Imaging Exam:	Not Applicable _____	<a href="#">Comments</a>
4.	Assessment:	Not Applicable _____	<a href="#">Comments</a>

090177e196ae3d1e\Final\Final On: 01-Apr-2021 04:27 (GMT)

**Header Text:** c4591001

**Visit:** POT\_COVID\_CONVA 1 - Unscheduled **Form:** DATE OF VISIT - ILLNESS CONVALESCENT  
Visit on Feb/27/2021

**Form Version:** 22-Apr-2020 21:04

**Form Status:** Data Complete, Frozen, Verified

**Site No:** 1125

**Site Name:** (1125) Meridian Clinical Research

**Subject No:** 11251154

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 11:09

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**Date of Visit**

1.	Date of Visit	Feb/27/2021
2.	Erroneous Visit	

**COVID-19 Illness Visit**

3.	COVID-19 Illness Visit:	COVID_A1
----	-------------------------	----------

**Header Text:** c4591001

**Visit:** POT\_COVID\_CONVA 1 - Unscheduled **Form:** ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY  
Visit on Feb/27/2021

**Form Version:** 22-Apr-2020 21:03

**Form Status:** Data Complete, Frozen, Verified

**Site No:** 1125

**Site Name:** (1125) Meridian Clinical Research

**Subject No:** 11251154

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 11:09

[eCRF Audit Trail History](#)

**Electronic Sample Tracking**

1.	Data Origin	SITE
2.	Sample Type	SERUM
3.	Sample Collected?	YES Date of Collection: Feb/27/2021
4.	If no sample was collected or sample was not collected according to protocol, please provide reason:	[ ]

**Aliquot**

Please enter barcode for each aliquot.

5.a	Sample ID	[BRHFYK]
5.b	Sample ID	[BMPGV7]
5.c	Sample ID	[BS5H6C]

090177e196ae3d1e\Final\Final On: 01-Apr-2021 04:27 (GMT)

**Header Text:** c4591001

**Visit:** Unplanned - New Unscheduled Visit

**Form:** DATE OF VISIT

**Form Version:** 22-Apr-2020 21:02

**Form Status:** Not Started

**Site No:** 1125

**Site Name:** (1125) Meridian Clinical Research

**Subject No:** 11251154

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 11:09

**Date of Visit**

1.	Date of Visit	//
2.	Erroneous Visit	

**Header Text:** c4591001

**Visit:** Unplanned - New Unscheduled Visit

**Form:** UNPLANNED VISIT

**Form Version:** 22-Apr-2020 21:04

**Form Status:** Not Started

**Site No:** 1125

**Site Name:** (1125) Meridian Clinical Research

**Subject No:** 11251154

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 11:09

**Unplanned Assessments**

1.	Assessments	
----	-------------	--

090177e196ae3d1e\Final\Final On: 01-Apr-2021 04:27 (GMT)

**Header Text:** c4591001

**Visit:** End of Treatment - Unscheduled

**Form:** DISPOSITION - TREATMENT

**Form Version:** 15-Sep-2020 21:55

**Form Status:** Data Complete, Locked, Frozen, Verified

**Site No:** 1125

**Site Name:** (1125) Meridian Clinical Research

**Subject No:** 11251154

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 11:09

[eCRF Audit Trail History](#)

**Disposition - Treatment**

1.	Date of Completion/Discontinuation /Death :	Oct/23/2020
2.	Phase of Disposition:	VACCINATION
3.	Status:	COMPLETED
4.	Specify Status:	[ ]

**Header Text:** c4591001

**Visit:** Follow-Up - Unscheduled

**Form Version:** 15-Sep-2020 21:53

**Site No:** 1125

**Subject No:** 11251154

**Generated By:** (b) (4)

**Form:** DISPOSITION - FOLLOW-UP

**Form Status:** Not Started

**Site Name:** (1125) Meridian Clinical Research

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 11:09

**Disposition - Follow-Up**

1.	Date of Completion/Discontinuation /Death :	//
2.	Phase of Disposition:	
3.	Status:	
4.	Specify Status:	[ ]

**Header Text:** c4591001

**Visit:** POT\_COVID\_REPEAT\_SWAB - New **Form:** DATE OF VISIT - REPEAT SWAB  
Unscheduled Visit

**Form Version:** 10-Oct-2020 15:57

**Form Status:** Not Started

**Site No:** 1125

**Site Name:** (1125) Meridian Clinical Research

**Subject No:** 11251154

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 11:09

**Date of Visit**

1.	Date of Visit	//
2.	Erroneous Visit	

**COVID-19 Repeat Swab**

3.	COVID-19 Repeat Swab:	
----	-----------------------	--

**Header Text:** c4591001

**Visit:** POT\_COVID\_REPEAT\_SWAB - New **Form:** ELECTRONIC SAMPLE TRACKING - REPEAT SWAB  
Unscheduled Visit

**Form Version:** 10-Oct-2020 15:57

**Form Status:** Not Started

**Site No:** 1125

**Site Name:** (1125) Meridian Clinical Research

**Subject No:** 11251154

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 11:09

**Electronic Sample Tracking**

1.	Data Origin	
2.	Sample Type	
3.	Sample Collected?	
4.	If no sample was collected or sample was not collected according to protocol, please provide reason:	[ ]

**Aliquot**

Please enter barcode for each aliquot.

5.	Sample ID	[ ]
----	-----------	-----

090177e196ae3d1e\Final\Final On: 01-Apr-2021 04:27 (GMT)

**Header Text:** c4591001

**Visit:** Logs

**Form:** ADVERSE EVENT REPORT

**Form Version:** 22-Apr-2020 21:02

**Site No:** 1125

**Site Name:** (1125) Meridian Clinical Research

**Subject No:** 11251154

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 11:09

#	Category	AE Identifier	Adverse Event	Start Date	Is the Adverse Event Still Ongoing	Form Instance
1.	ADVERSE EVENT	1	Covid-19	Jan/20/2021 UNK: UNK	NO End Date Time:  Feb/14/2021 UNK:UNK	<a href="#">Repeating Pages</a>

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1125

Subject No: 11251154

Generated By: (b) (4)

Form: ADVERSE EVENT REPORT

Form Status: Data Complete, Answered Queries, Verified

Site Name: (1125) Meridian Clinical Research

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 11:09

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**Adverse Event Report**

1.	Category:	ADVERSE EVENT
2.	AE ID:	[1]
3.	Adverse Event: (If possible specify diagnosis, not individual symptoms)	[Covid-19]
4.	Start Date Time:	Jan/20/2021 UNK:UNK
5.	Is the adverse event still ongoing?	NO End Date Time: Feb/14/2021 UNK:UNK
6.	Toxicity Grade:	3
7.	Is the adverse event serious?  If Yes, NOTIFY PFIZER IMMEDIATELY.  Fatal; Life-threatening; Inpatient hospitalization or prolongation of existing hospitalization; Persistent or significant disability/incapacity; Congenital anomaly/birth defect; Important medical event (i.e. may jeopardize subject and may require medical/surgical intervention to prevent above outcomes).	YES  Is this serious event associated with congenital anomaly or birth defect? NO  Did this serious event result in death? NO  Did this serious event require or prolong hospitalization? YES  Did this serious event result in persistent or significant disability/incapacity? NO  Is this serious event life threatening? NO  Other medically important serious event NO
8.	Is this adverse event the result of a study Medication Error? If Yes, record the type of medication error on the Medication Error Log.	NO

090177e196ae3d1e\Final\Final On: 01-Apr-2021 04:27 (GMT)

**Header Text:** c4591001

**Visit:** Logs - Unscheduled

**Form Version:** 22-Apr-2020 21:02

**Site No:** 1125

**Subject No:** 11251154

**Generated By:** (b) (4)

**Form:** ADVERSE EVENT REPORT

**Form Status:** Data Complete, Answered Queries, Verified

**Site Name:** (1125) Meridian Clinical Research

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 11:09

9.	Is this event related to study treatment:	NOT RELATED If Not Related to study treatment(s), this event is due to: OTHER If Other, specify: [infection]
10.	Latest Action Taken with Study Treatment:	NOT APPLICABLE
11.	Was a Concomitant Medication given?	YES
12.	Was a Non-Drug Treatment given?	NO
13.	What was the outcome of this adverse event?:	RECOVERED/RESOLVED
14.	Did the adverse event cause the subject to be discontinued from the study?	NO
15.	Serious Adverse Event Number: For Pfizer Use Only	[2021123725]

090177e196ae3d1e\Final\Final On: 01-Apr-2021 04:27 (GMT)

**Header Text:** c4591001

**Visit:** Logs

**Form:** MEDICATION ERROR

**Form Version:** 17-Jul-2020 21:54

**Site No:** 1125

**Site Name:** (1125) Meridian Clinical Research

**Subject No:** 11251154

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 11:09

#	Category	Medication Error	Start Date	Is the medication error Still Ongoing	Study Medication Errors Action	Form Instance
1.						<a href="#">Repeating Pages</a>

090177e196ae3d1e\Final\Final On: 01-Apr-2021 04:27 (GMT)

**Header Text:** c4591001

**Visit:** Logs - Unscheduled

**Form Version:** 17-Jul-2020 21:54

**Site No:** 1125

**Subject No:** 11251154

**Generated By:** (b) (4)

**Form:** MEDICATION ERROR

**Form Status:** Not Started

**Site Name:** (1125) Meridian Clinical Research

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 11:09

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**Medication Error**

1.	Category:	
2.	Medication Error (Type of Medication Error):	[ ]
3.	Start Date:	//
4.	Is the medication error still ongoing?	
5.	Latest Action Taken with Study Treatment:	
6.	Was a Concomitant Medication given?	
7.	Was a Non-Drug Treatment given?	
8.	Did the Medication Error cause the subject to be discontinued from the study?	
9.	Was this medication error associated with any adverse events?	
10.	Serious Adverse Event Number: For Pfizer Use Only	[ ]

090177e196ae3d1e\Final\Final On: 01-Apr-2021 04:27 (GMT)

**Header Text:** c4591001

**Visit:** Logs

**Form:** CONCOMITANT MEDICATIONS - NON STUDY  
VACCINATIONS

**Form Version:** 22-Apr-2020 21:03

**Site No:** 1125

**Site Name:** (1125) Meridian Clinical Research

**Subject No:** 11251154

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 11:09

#	Sponsor-Defined Identifier	Category for Medication	Concomitant Medications Pre-specified	Name of Medication	Start Date	Form Instance
1.						<a href="#">Repeating Pages</a>

090177e196ae3d1e\Final\Final On: 01-Apr-2021 04:27 (GMT)

**Header Text:** c4591001

**Visit:** Logs - Unscheduled

**Form:** CONCOMITANT MEDICATIONS - NON STUDY VACCINATIONS

**Form Version:** 22-Apr-2020 21:03

**Form Status:** Not Started

**Site No:** 1125

**Site Name:** (1125) Meridian Clinical Research

**Subject No:** 11251154

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 11:09

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**Concomitant Medications**

1.	What is the medication identifier?	[ ]
2.	Category:	
3.	Concomitant Medications Pre-specified:	
4.	Medication:  Provide the complete generic drug name (including salt form, where applicable). Where generic name is unknown, enter the full trade or proprietary name. Include clarifying information in the Medication text (e.g., Ingredient(s), route, use, formulation).	[ ]
5.	Date:	//

090177e196ae3d1e\Final\Final On: 01-Apr-2021 04:27 (GMT)

**Header Text:** c4591001

**Visit:** Logs

**Form:** CONCOMITANT MEDICATIONS - PROHIBITED

**Form Version:** 22-Apr-2020 21:03

**Site No:** 1125

**Site Name:** (1125) Meridian Clinical Research

**Subject No:** 11251154

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 11:09

#	Sponsor-Defined Identifier	Category for Medication	Concomitant Medications Pre-specified	Name of Medication	Dose Description	Form Instance
1.	1	IMMUNOGLOBULINS	NO	bamlanivimab	750	<a href="#">Repeating Pages</a>

090177e196ae3d1e\Final\Final On: 01-Apr-2021 04:27 (GMT)

**Header Text:** c4591001

**Visit:** Logs - Unscheduled

**Form Version:** 22-Apr-2020 21:03

**Site No:** 1125

**Subject No:** 11251154

**Generated By:** (b) (4)

**Form:** CONCOMITANT MEDICATIONS - PROHIBITED

**Form Status:** Data Complete, Frozen, Verified

**Site Name:** (1125) Meridian Clinical Research

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 11:09

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**Concomitant Medications**

1.	What is the medication identifier?	[1]
2.	Category:	IMMUNOGLOBULINS
3.	Concomitant Medications Pre-specified:	NO
4.	Medication:  Provide the complete generic drug name (including salt form, where applicable). Where generic name is unknown, enter the full trade or proprietary name. Include clarifying information in the Medication text (e.g., Ingredient(s), route, use, formulation).	[bamlanivimab]
5.	Dose:	[750]
6.	Dose Unit:	mg
7.	Dose Frequency:	ONCE
8.	Route:	INTRAVENOUS
9.	Start Date:	Jan/24/2021
10.	Ongoing?	NO End Date: Jan/24/2021

090177e196ae3d1e\Final\Final On: 01-Apr-2021 04:27 (GMT)

**Header Text:** c4591001

**Visit:** Logs

**Form:** RADIATION TREATMENT

**Form Version:** 22-Apr-2020 21:02

**Site No:** 1125

**Site Name:** (1125) Meridian Clinical Research

**Subject No:** 11251154

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 11:09

#	Category	Treatment Identifier	Con Non-Drug Treatments Pre-specified	Treatment	Start Date	Form Instance
1.						<a href="#">Repeating Pages</a>

090177e196ae3d1e\Final\Final On: 01-Apr-2021 04:27 (GMT)

**Header Text:** c4591001

**Visit:** Logs - Unscheduled

**Form Version:** 22-Apr-2020 21:02

**Site No:** 1125

**Subject No:** 11251154

**Generated By:** (b) (4)

**Form:** RADIATION TREATMENT

**Form Status:** Not Started

**Site Name:** (1125) Meridian Clinical Research

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 11:09

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**Radiation Treatment**

1.	Category:	
2.	What is the treatment Identifier?	[ ]
3.	Concomitant Non-drug Treatment Pre-specified:	
4.	Treatment:	[ ]
5.	Start Date:	//
6.	Ongoing?	

**Header Text:** c4591001

**Visit:** Logs

**Form:** TRANSFUSIONS

**Form Version:** 22-Apr-2020 21:03

**Site No:** 1125

**Site Name:** (1125) Meridian Clinical Research

**Subject No:** 11251154

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 11:09

#	Transfusion Type	Date of Transfusion	Form Instance
1.			<a href="#">Repeating Pages</a>

090177e196ae3d1e\Final\Final On: 01-Apr-2021 04:27 (GMT)

**Header Text:** c4591001

**Visit:** Logs - Unscheduled

**Form Version:** 22-Apr-2020 21:03

**Site No:** 1125

**Subject No:** 11251154

**Generated By:** (b) (4)

**Form:** TRANSFUSIONS

**Form Status:** Not Started

**Site Name:** (1125) Meridian Clinical Research

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 11:09

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1.	Transfusion Type:	
2.	Date of Transfusion:	//

**Header Text:** c4591001

**Visit:** Unplanned Vaccination - Unscheduled

**Form:** DATE OF VISIT

**Form Version:** 22-Apr-2020 21:02

**Form Status:** Not Started

**Site No:** 1125

**Site Name:** (1125) Meridian Clinical Research

**Subject No:** 11251154

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 11:09

**Date of Visit**

1.	Date of Visit	//
2.	Erroneous Visit	

**Header Text:** c4591001

**Visit:** Unplanned Vaccination - Unscheduled

**Form:** VITAL SIGNS - TEMP

**Form Version:** 20-Feb-2021 02:16

**Form Status:** Not Started

**Site No:** 1125

**Site Name:** (1125) Meridian Clinical Research

**Subject No:** 11251154

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 11:09

**Vital Signs**

1.	Date:	//
----	-------	----

**Vital Signs Details**

2.	Record Identifier:	
	Temperature:	[ ]
	Unit:	
	Temperature Location:	

**Header Text:** c4591001

**Visit:** Unplanned Vaccination - Unscheduled

**Form:** VACCINATION

**Form Version:** 10-Dec-2020 02:26

**Form Status:** Not Started

**Site No:** 1125

**Site Name:** (1125) Meridian Clinical Research

**Subject No:** 11251154

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 11:09

**Vaccination**

1.	Was there a temporary delay of vaccination?	
2.	Treatment Name	[ ]
3.	Formulation:	
4.	Dose Date Time:	//
5.	Anatomical Location:	
6.	Body Side:	
7.	Route:	
8.	Actual Dose:	[ ]
9.	Unit:	
10.	Timeframe Subject Was Observed	
11.	Was the subject observed for at least the protocol specified observation period after investigational product administration?	

090177e196ae3d1e\Final\Final On: 01-Apr-2021 04:27 (GMT)

**Header Text:** c4591001

**Visit:** Unplanned Vaccination - Unscheduled

**Form:** CONTACT OUTCOME - MONTH 1

**Form Version:** 10-Oct-2020 15:57

**Form Status:** Not Started

**Site No:** 1125

**Site Name:** (1125) Meridian Clinical Research

**Subject No:** 11251154

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 11:09

**Contact Outcome**

1.	Contact Type:	
2.	Was contact made?	
3.	Comments:	[ ]

**Header Text:** c4591001

**Visit:** Unplanned Vaccination - Unscheduled

**Form:** CONTACT OUTCOME - MONTH 6

**Form Version:** 10-Oct-2020 16:01

**Form Status:** Not Started

**Site No:** 1125

**Site Name:** (1125) Meridian Clinical Research

**Subject No:** 11251154

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 11:09

**Contact Outcome**

1.	Contact Type:	
2.	Was contact made?	
3.	Comments:	[ ]

**Header Text:** c4591001

**Visit:** V201\_SURVEIL\_CONSENT -  
Unscheduled

**Form:** DATE OF VISIT

**Form Version:** 22-Apr-2020 21:02

**Form Status:** Not Started

**Site No:** 1125

**Site Name:** (1125) Meridian Clinical Research

**Subject No:** 11251154

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 11:09

**Date of Visit**

1.	Date of Visit	//
2.	Erroneous Visit	

**Header Text:** c4591001

**Visit:** V201\_SURVEIL\_CONSENT -  
Unscheduled

**Form:** INFORMED CONSENT - ASYMPTOMATIC  
SURVEILLANCE

**Form Version:** 14-Jan-2021 02:29

**Form Status:** Not Started

**Site No:** 1125

**Site Name:** (1125) Meridian Clinical Research

**Subject No:** 11251154

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 11:09

**Informed Consent - Asymptomatic Surveillance**

1.	Consent Was:	
----	--------------	--

090177e196ae3d1e\Final\Final On: 01-Apr-2021 04:27 (GMT)

**Header Text:** c4591001

**Visit:** V201\_SURVEIL\_CONSENT -  
Unscheduled

**Form:** ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY

**Form Version:** 22-Apr-2020 21:03

**Form Status:** Not Started

**Site No:** 1125

**Site Name:** (1125) Meridian Clinical Research

**Subject No:** 11251154

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 11:09

**Electronic Sample Tracking**

1.	Data Origin	
2.	Sample Type	
3.	Sample Collected?	
4.	If no sample was collected or sample was not collected according to protocol, please provide reason:	[ ]

**Aliquot**

Please enter barcode for each aliquot.

5.	Sample ID	[ ]
----	-----------	-----

090177e196ae3d1e\Final\Final On: 01-Apr-2021 04:27 (GMT)

**Header Text:** c4591001

**Visit:** V201\_SURVEIL\_CONSENT -  
Unscheduled

**Form:** ELECTRONIC SAMPLE TRACKING - NASAL SWAB

**Form Version:** 22-Apr-2020 21:03

**Form Status:** Not Started

**Site No:** 1125

**Site Name:** (1125) Meridian Clinical Research

**Subject No:** 11251154

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 11:09

**Electronic Sample Tracking**

1.	Data Origin	
2.	Sample Type	
3.	Sample Collected?	
4.	If no sample was collected or sample was not collected according to protocol, please provide reason:	[ ]

**Aliquot**

Please enter barcode for each aliquot.

5.	Sample ID	[ ]
----	-----------	-----

090177e196ae3d1e\Final\Final On: 01-Apr-2021 04:27 (GMT)

**Header Text:** c4591001

**Visit:** Potential ReVax Initial Contact -  
Unscheduled

**Form:** DATE OF VISIT

**Form Version:** 22-Apr-2020 21:02

**Form Status:** Data Complete, Frozen, Verified

**Site No:** 1125

**Site Name:** (1125) Meridian Clinical Research

**Subject No:** 11251154

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 11:09

[eCRF Audit Trail History](#)

**Date of Visit**

1.	Date of Visit	Feb/25/2021
2.	Erroneous Visit	

**Header Text:** c4591001

**Visit:** Potential ReVax Initial Contact -  
Unscheduled

**Form:** FURTHER VACCINATION CONFIRMATION

**Form Version:** 10-Dec-2020 02:25

**Form Status:** Data Complete, Frozen

**Site No:** 1125

**Site Name:** (1125) Meridian Clinical Research

**Subject No:** 11251154

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 11:09

[eCRF Audit Trail History](#)

**Further Vaccination Confirmation**

1.	Select appropriate response - Is participant willing to return for Vaccination 3?	Participant is willing to return for Vaccination 3 Participant is: eligible per other protocol allowance(s) and confirmed to have received only placebo at Vaccination 1/2
----	---	--

090177e196ae3d1e\Final\Final On: 01-Apr-2021 04:27 (GMT)

**Header Text:** c4591001

**Visit:** Disposition - Unscheduled

**Form Version:** 22-Apr-2020 21:03

**Site No:** 1125

**Subject No:** 11251154

**Generated By:** (b) (4)

**Form:** TREATMENT UNBLINDED

**Form Status:** Data Complete, Frozen, Verified

**Site Name:** (1125) Meridian Clinical Research

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 11:09

[eCRF Audit Trail History](#)

**Treatment Unblinded**

1.	Date Treatment Unblinded :	Feb/25/2021
2.	Primary Reason for Unblinding:	ASSESS ELIGIBILITY FOR ADDITIONAL VACCINATION

**Header Text:** c4591001

**Visit:** Disposition - Unscheduled

**Form:** WITHDRAWAL OF CONSENT

**Form Version:** 22-Apr-2020 21:03

**Form Status:** Not Started

**Site No:** 1125

**Site Name:** (1125) Meridian Clinical Research

**Subject No:** 11251154

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 11:09

**Withdrawal Of Consent**

1.	Withdrawal of Consent Date :	//
----	------------------------------	----

**Header Text:** c4591001

**Visit:** Disposition - Unscheduled

**Form:** DEATH DETAILS CODED

**Form Version:** 22-Apr-2020 21:03

**Form Status:** Not Started

**Site No:** 1125

**Site Name:** (1125) Meridian Clinical Research

**Subject No:** 11251154

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 11:09

**Death Details**

1.	Date of Collection / Notification of Death:	//
----	---	----

**Cause of Death**

2.	Cause of Death Status:	
	Cause of Death:	[ ]

**Header Text:** c4591001

**Visit:** V101\_VAX3

**Form Version:** 22-Apr-2020 21:02

**Site No:** 1125

**Subject No:** 11251154

**Generated By:** (b) (4)

**Form:** DATE OF VISIT

**Form Status:** Data Complete, Frozen, Verified

**Site Name:** (1125) Meridian Clinical Research

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 11:09

[eCRF Audit Trail History](#)

**Date of Visit**

1.	Date of Visit	Feb/27/2021
2.	Erroneous Visit	ERRONEOUS VISIT

090177e196ae3d1e\Final\Final On: 01-Apr-2021 04:27 (GMT)

**Header Text:** c4591001

**Visit:** V101\_VAX3

**Form Version:** 10-Dec-2020 02:31

**Site No:** 1125

**Subject No:** 11251154

**Generated By:** (b) (4)

**Form:** INFORMED CONSENT - FURTHER VACCINATION

**Form Status:** Data Complete, Frozen, Verified

**Site Name:** (1125) Meridian Clinical Research

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 11:09

[Form Comments](#)

[eCRF Audit Trail History](#)

**Informed Consent - Further Vaccination**

			<a href="#">Comments</a>
1.	Consent Was:	Not Applicable	

**Header Text:** c4591001

**Visit:** V101\_VAX3

**Form:** INCLUSION/EXCLUSION CRITERIA - FURTHER VACCINATION

**Form Version:** 10-Dec-2020 02:30

**Form Status:** Data Complete, Frozen, Verified

**Site No:** 1125

**Site Name:** (1125) Meridian Clinical Research

**Subject No:** 11251154

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 11:09

**Form Comments**

**Inclusion Criteria Not Met**

1.	Description of Inclusion Criterion Not Met	Not Applicable _____
----	--	-------------------------

**Exclusion Criteria Met**

2.	Description of Exclusion Criterion Met	Not Applicable _____
----	--	-------------------------

**Header Text:** c4591001

**Visit:** V101\_VAX3

**Form:** DISPOSITION - SCREENING FOR FURTHER VACCINATION

**Form Version:** 10-Dec-2020 02:31

**Form Status:** Data Complete, Frozen, Verified

**Site No:** 1125

**Site Name:** (1125) Meridian Clinical Research

**Subject No:** 11251154

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 11:09

[Form Comments](#)

[eCRF Audit Trail History](#)

**Disposition - Screening for Further Vaccination**

1.	Date of Completion/Discontinuation /Death :	Not Applicable _____ //	<a href="#">Comments</a>
2.	Phase of Disposition:	Not Applicable _____	<a href="#">Comments</a>
3.	Status:	Not Applicable _____	<a href="#">Comments</a>
4.	Specify Status:	Not Applicable _____ [ ]	<a href="#">Comments</a>

090177e196ae3d1e\Final\Final On: 01-Apr-2021 04:27 (GMT)

**Header Text:** c4591001

**Visit:** V101\_VAX3

**Form Version:** 22-Apr-2020 21:03

**Site No:** 1125

**Subject No:** 11251154

**Generated By:** (b) (4)

**Form:** ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY

**Form Status:** Data Complete, Frozen, Verified

**Site Name:** (1125) Meridian Clinical Research

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 11:09

[Form Comments](#)

[eCRF Audit Trail History](#)

**Electronic Sample Tracking**

1.	Data Origin	Not Applicable _____	<a href="#">Comments</a>
2.	Sample Type	Not Applicable _____	<a href="#">Comments</a>
3.	Sample Collected?	Not Applicable _____	<a href="#">Comments</a>
4.	If no sample was collected or sample was not collected according to protocol, please provide reason:	Not Applicable _____ [ ]	<a href="#">Comments</a>

**Aliquot**

Please enter barcode for each aliquot.

5.	Sample ID	Not Applicable _____ [ ]
----	-----------	--------------------------------

090177e196ae3d1e\Final\Final On: 01-Apr-2021 04:27 (GMT)

**Header Text:** c4591001

**Visit:** V101\_VAX3

**Form Version:** 22-Apr-2020 21:03

**Site No:** 1125

**Subject No:** 11251154

**Generated By:** (b) (4)

**Form:** ELECTRONIC SAMPLE TRACKING - NASAL SWAB

**Form Status:** Data Complete, Frozen, Verified

**Site Name:** (1125) Meridian Clinical Research

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 11:09

[Form Comments](#)

[eCRF Audit Trail History](#)

**Electronic Sample Tracking**

1.	Data Origin	Not Applicable _____	<a href="#">Comments</a>
2.	Sample Type	Not Applicable _____	<a href="#">Comments</a>
3.	Sample Collected?	Not Applicable _____	<a href="#">Comments</a>
4.	If no sample was collected or sample was not collected according to protocol, please provide reason:	Not Applicable _____ [ ]	<a href="#">Comments</a>

**Aliquot**

Please enter barcode for each aliquot.

5.	Sample ID	Not Applicable _____ [ ]
----	-----------	--------------------------------

090177e196ae3d1e\Final\Final On: 01-Apr-2021 04:27 (GMT)

**Header Text:** c4591001

**Visit:** Subject Status - Unscheduled

**Form Version:** 22-Apr-2020 21:03

**Site No:** 1125

**Subject No:** 11251154

**Generated By:** (b) (4)

**Form:** SUBJECT STATUS

**Form Status:** Data Complete, Verified

**Site Name:** (1125) Meridian Clinical Research

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 11:09

[eCRF Audit Trail History](#)

**Subject Status**

1.	Subject Status	FOLLOW-UP
2.	Subject Status Date	Oct/23/2020

**Header Text:** c4591001

**Visit:** Investigator Signature - Unscheduled

**Form:** CASEBOOK SIGNATURE FORM

**Form Version:** 22-Apr-2020 21:04

**Form Status:** Data Complete, Signed, Verified

**Site No:** 1125

**Site Name:** (1125) Meridian Clinical Research

**Subject No:** 11251154

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 11:09

[eCRF Audit Trail History](#)

**Casebook Signature Form**

1.	Casebook Signature	Click Here to Enable
----	--------------------	----------------------

**Header Text:** c4591001

**Visit:** Investigator Signature - Unscheduled

**Form:** CASEBOOK SIGNATURE FORM

**Form Version:** 22-Apr-2020 21:04

**Form Status:** Data Complete, Signed, Verified

**Site No:** 1125

**Site Name:** (1125) Meridian Clinical Research

**Subject No:** 11251154

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 11:09

[Audit Trail](#)

This form requires signing by a member of each of the following signature groups:

- CRF\_Sign

Name	Signature Meaning	Date	Type	Action
Charles Harper	Approved	Mar-12-2021 00:09:56 (UTC-06:00) Central Time (US & Canada)	BOOK	Signed

**Affidavit:**

By my dated signature below, I, CharlesHarper, verify that all case report form pages accurately display the results of the examinations, tests, evaluations and treatments performed on this subject.

Pursuant to Section 11.100 of Title 21 of the Code of Federal Regulations, this is to certify that I intend that this electronic signature is to be the legally binding equivalent of my handwritten signature.

To this I do attest by supplying my user name and password and clicking the button marked Submit below.

090177e196ae3d1e\Final\Final On: 01-Apr-2021 04:27 (GMT)

**Header Text:** c4591001

**Visit:** V1\_DAY1\_VAX1\_L

**Form Version:** 30-Jul-2020 21:29

**Site No:** 1125

**Subject No:** 11251154

**Generated By:** (b) (4)

**Form:** INCLUSION/EXCLUSION CRITERIA - Comments

**Form Status:** Data Complete, Locked, Frozen, Verified

**Site Name:** (1125) Meridian Clinical Research

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 11:09

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Item	Date	User	Comment
Form	Sep-03-2020 10:36:15 (UTC-06:00) Central Time (US & Canada)	(b) (4), (b) (6) [REDACTED]	patient met criteria for study <hr/> Not Applicable

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit **Form:** MICROBIOLOGY SPECIMEN - Comments on Feb/04/2021

**Form Version:** 06-Jul-2020 21:54

**Form Status:** Data Complete, Frozen

**Site No:** 1125

**Site Name:** (1125) Meridian Clinical Research

**Subject No:** 11251154

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 11:09

[Back to Form](#)

Item	Date	User	Comment
Form	Feb-04-2021 11:50:47 (UTC-06:00) Central Time (US & Canada)	(b) (4), (b) (6) [Redacted]	Awaiting medical records. _____ Not Done

090177e196ae3d1e\Final\Final On: 01-Apr-2021 04:27 (GMT)

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit **Form:** MICROBIOLOGY SPECIMEN - Comments on Feb/04/2021

**Form Version:** 06-Jul-2020 21:54

**Form Status:** Data Complete, Frozen

**Site No:** 1125

**Site Name:** (1125) Meridian Clinical Research

**Subject No:** 11251154

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 11:09

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Item	Date	User	Comment
1	Feb-04-2021 11:50:47 (UTC-06:00) Central Time (US & Canada)	(b) (4), (b) (6) [Redacted]	Awaiting medical records. _____ Not Done

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit **Form:** MICROBIOLOGY SPECIMEN - Comments on Feb/04/2021

**Form Version:** 06-Jul-2020 21:54

**Form Status:** Data Complete, Frozen

**Site No:** 1125

**Site Name:** (1125) Meridian Clinical Research

**Subject No:** 11251154

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 11:09

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Item	Date	User	Comment
2	Feb-04-2021 11:50:47 (UTC-06:00) Central Time (US & Canada)	(b) (4), (b) (6) [Redacted]	Awaiting medical records. _____ Not Done

090177e196ae3d1e\Final\Final On: 01-Apr-2021 04:27 (GMT)

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit **Form:** MICROBIOLOGY SPECIMEN - Comments on Feb/04/2021

**Form Version:** 06-Jul-2020 21:54

**Form Status:** Data Complete, Frozen

**Site No:** 1125

**Site Name:** (1125) Meridian Clinical Research

**Subject No:** 11251154

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 11:09

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Item	Date	User	Comment
3	Feb-04-2021 11:50:47 (UTC-06:00) Central Time (US & Canada)	(b) (4), (b) (6) [Redacted]	Awaiting medical records. ----- Not Done

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit **Form:** MICROBIOLOGY SPECIMEN - Comments on Feb/04/2021

**Form Version:** 06-Jul-2020 21:54

**Form Status:** Data Complete, Frozen

**Site No:** 1125

**Site Name:** (1125) Meridian Clinical Research

**Subject No:** 11251154

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 11:09

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Item	Date	User	Comment
4	Feb-04-2021 11:50:47 (UTC-06:00) Central Time (US & Canada)	(b) (4), (b) (6) ( )	Awaiting medical records. Not Done

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit **Form:** MICROBIOLOGY SPECIMEN - Comments on Feb/04/2021

**Form Version:** 06-Jul-2020 21:54

**Form Status:** Data Complete, Frozen

**Site No:** 1125

**Site Name:** (1125) Meridian Clinical Research

**Subject No:** 11251154

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 11:09

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Item	Date	User	Comment
5	Feb-04-2021 11:50:47 (UTC-06:00) Central Time (US & Canada)	(b) (4), (b) (6) [REDACTED]	Awaiting medical records. _____ Not Done

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit **Form:** MICROBIOLOGY SPECIMEN - Comments on Feb/04/2021

**Form Version:** 06-Jul-2020 21:54

**Form Status:** Data Complete, Frozen

**Site No:** 1125

**Site Name:** (1125) Meridian Clinical Research

**Subject No:** 11251154

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 11:09

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Item	Date	User	Comment
6	Feb-04-2021 11:50:47 (UTC-06:00) Central Time (US & Canada)	(b) (4), (b) (6) [Redacted]	Awaiting medical records. _____ Not Done

090177e196ae3d1e\Final\Final On: 01-Apr-2021 04:27 (GMT)

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit **Form:** MICROBIOLOGY SPECIMEN - Comments on Feb/04/2021

**Form Version:** 06-Jul-2020 21:54

**Form Status:** Data Complete, Frozen

**Site No:** 1125

**Site Name:** (1125) Meridian Clinical Research

**Subject No:** 11251154

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 11:09

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Item	Date	User	Comment
7	Feb-04-2021 11:50:47 (UTC-06:00) Central Time (US & Canada)	(b) (4), (b) (6)	Awaiting medical records. Not Done

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit **Form:** MICROBIOLOGY SPECIMEN - Comments on Feb/04/2021

**Form Version:** 06-Jul-2020 21:54

**Form Status:** Data Complete, Frozen

**Site No:** 1125

**Site Name:** (1125) Meridian Clinical Research

**Subject No:** 11251154

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 11:09

[Back to Form](#)

Item	Date	User	Comment
8	Feb-04-2021 11:50:47 (UTC-06:00) Central Time (US & Canada)	(b) (4), (b) (6) [Redacted]	Awaiting medical records. ----- Not Done

090177e196ae3d1e\Final\Final On: 01-Apr-2021 04:27 (GMT)

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit **Form:** MICROBIOLOGY SPECIMEN - Comments on Feb/04/2021

**Form Version:** 06-Jul-2020 21:54

**Form Status:** Data Complete, Frozen

**Site No:** 1125

**Site Name:** (1125) Meridian Clinical Research

**Subject No:** 11251154

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 11:09

[Back to Form](#)

Item	Date	User	Comment
9	Feb-04-2021 11:50:47 (UTC-06:00) Central Time (US & Canada)	(b) (4), (b) (6) [Redacted]	Awaiting medical records. ----- Not Done

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit **Form:** RESPIRATORY TREATMENT - Comments on Feb/04/2021

**Form Version:** 06-Jul-2020 21:53

**Form Status:** Data Complete, Frozen

**Site No:** 1125

**Site Name:** (1125) Meridian Clinical Research

**Subject No:** 11251154

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 11:09

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Item	Date	User	Comment
Form	Mar-04-2021 14:15:05 (UTC-06:00) Central Time (US & Canada)	(b) (4), (b) (6) [REDACTED]	Not Applicable

090177e196ae3d1e\Final\Final On: 01-Apr-2021 04:27 (GMT)

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit **Form:** RESPIRATORY TREATMENT - Comments on Feb/04/2021

**Form Version:** 06-Jul-2020 21:53

**Form Status:** Data Complete, Frozen

**Site No:** 1125

**Site Name:** (1125) Meridian Clinical Research

**Subject No:** 11251154

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 11:09

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Item	Date	User	Comment
1	Mar-04-2021 14:15:05 (UTC-06:00) Central Time (US & Canada)	(b) (4), (b) (6)	Not Applicable

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit **Form:** RESPIRATORY TREATMENT - Comments on Feb/04/2021

**Form Version:** 06-Jul-2020 21:53

**Form Status:** Data Complete, Frozen

**Site No:** 1125

**Site Name:** (1125) Meridian Clinical Research

**Subject No:** 11251154

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 11:09

[Back to Form](#)

Item	Date	User	Comment
2	Mar-04-2021 14:15:05 (UTC-06:00) Central Time (US & Canada)	(b) (4), (b) (6)	Not Applicable

090177e196ae3d1e\Final\Final On: 01-Apr-2021 04:27 (GMT)

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit **Form:** RESPIRATORY TREATMENT - Comments on Feb/04/2021

**Form Version:** 06-Jul-2020 21:53

**Form Status:** Data Complete, Frozen

**Site No:** 1125

**Site Name:** (1125) Meridian Clinical Research

**Subject No:** 11251154

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 11:09

[Back to Form](#)

Item	Date	User	Comment
3	Mar-04-2021 14:15:05 (UTC-06:00) Central Time (US & Canada)	(b) (4), (b) (6) [REDACTED]	Not Applicable

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit **Form:** RESPIRATORY TREATMENT - Comments on Feb/04/2021

**Form Version:** 06-Jul-2020 21:53

**Form Status:** Data Complete, Frozen

**Site No:** 1125

**Site Name:** (1125) Meridian Clinical Research

**Subject No:** 11251154

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 11:09

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Item	Date	User	Comment
4	Mar-04-2021 14:15:05 (UTC-06:00) Central Time (US & Canada)	(b) (4), (b) (6)	Not Applicable

090177e196ae3d1e\Final\Final On: 01-Apr-2021 04:27 (GMT)

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit **Form:** RESPIRATORY TREATMENT - Comments on Feb/04/2021

**Form Version:** 06-Jul-2020 21:53

**Form Status:** Data Complete, Frozen

**Site No:** 1125

**Site Name:** (1125) Meridian Clinical Research

**Subject No:** 11251154

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 11:09

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Item	Date	User	Comment
5	Mar-04-2021 14:15:05 (UTC-06:00) Central Time (US & Canada)	(b) (4), (b) (6)	Not Applicable

**Header Text:** c4591001

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**Form Version:** 06-Jul-2020 21:53

**Form Status:** Data Complete, Frozen

**Site No:** 1125

**Site Name:** (1125) Meridian Clinical Research

**Subject No:** 11251154

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 11:09

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090177e196ae3d1e\Final\Final On: 01-Apr-2021 04:27 (GMT)

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit **Form:** ILLNESS DETAILS - SEVERE - Comments on Feb/04/2021

**Form Version:** 17-Jul-2020 21:55

**Form Status:** Data Complete, Frozen

**Site No:** 1125

**Site Name:** (1125) Meridian Clinical Research

**Subject No:** 11251154

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 11:09

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Item	Date	User	Comment
Form	Mar-04-2021 14:16:15 (UTC-06:00) Central Time (US & Canada)	(b) (4), (b) (6) [REDACTED]	Not Applicable

090177e196ae3d1e\Final\Final On: 01-Apr-2021 04:27 (GMT)

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**Form Version:** 17-Jul-2020 21:55

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**Subject No:** 11251154

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 11:09

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Item	Date	User	Comment
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**Header Text:** c4591001

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Item	Date	User	Comment
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Item	Date	User	Comment
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Item	Date	User	Comment
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**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit **Form:** LOCAL LABORATORY DATA - REPEATING CHEMISTRY  
on Feb/04/2021 - Comments

**Form Version:** 21-Aug-2020 02:49

**Form Status:** Data Complete, Frozen

**Site No:** 1125

**Site Name:** (1125) Meridian Clinical Research

**Subject No:** 11251154

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 11:09

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Item	Date	User	Comment
Form	Mar-04-2021 14:16:40 (UTC-06:00) Central Time (US & Canada)	(b) (4), (b) (6) [REDACTED]	Not Applicable

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Item	Date	User	Comment
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Item	Date	User	Comment
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Item	Date	User	Comment
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Item	Date	User	Comment
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Item	Date	User	Comment
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Item	Date	User	Comment
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Item	Date	User	Comment
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Item	Date	User	Comment
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Item	Date	User	Comment
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Item	Date	User	Comment
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Item	Date	User	Comment
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Item	Date	User	Comment
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Item	Date	User	Comment
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5.g	Mar-04-2021 14:16:40 (UTC-06:00) Central Time (US & Canada)	(b) (4), (b) (6) [REDACTED]	Not Applicable

**Header Text:** c4591001

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**Form Version:** 21-Aug-2020 02:49

**Form Status:** Data Complete, Frozen

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**Site Name:** (1125) Meridian Clinical Research

**Subject No:** 11251154

**Subject Initials:** ---

**Generated By:** (b) (4)

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**Subject Initials:** ---

**Generated By:** (b) (4)

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5.g	Mar-04-2021 14:17:35 (UTC-06:00) Central Time (US & Canada)	(b) (4), (b) (6) [REDACTED]	Not Applicable

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Comments

**Form Version:** 21-Aug-2020 02:51

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**Generated Time (GMT):** 29-Mar-2021 11:09

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Item	Date	User	Comment
3	Mar-04-2021 14:19:57 (UTC-06:00) Central Time (US & Canada)	(b) (4), (b) (6) [REDACTED]	Not Applicable

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit **Form:** IMAGING - Comments  
on Feb/04/2021

**Form Version:** 06-Jul-2020 21:53

**Form Status:** Data Complete, Frozen

**Site No:** 1125

**Site Name:** (1125) Meridian Clinical Research

**Subject No:** 11251154

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 11:09

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Item	Date	User	Comment
4	Mar-04-2021 14:19:57 (UTC-06:00) Central Time (US & Canada)	(b) (4), (b) (6) [REDACTED]	Not Applicable

090177e196ae3d1e\Final\Final On: 01-Apr-2021 04:27 (GMT)

**Header Text:** c4591001

**Visit:** V101\_VAX3

**Form:** INFORMED CONSENT - FURTHER VACCINATION -  
Comments

**Form Version:** 10-Dec-2020 02:31

**Form Status:** Data Complete, Frozen, Verified

**Site No:** 1125

**Site Name:** (1125) Meridian Clinical Research

**Subject No:** 11251154

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 11:09

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Item	Date	User	Comment
Form	Mar-01-2021 11:21:59 (UTC-06:00) Central Time (US & Canada)	(b) (4), (b) (6) [Redacted]	Not Applicable

**Header Text:** c4591001

**Visit:** V101\_VAX3

**Form Version:** 10-Dec-2020 02:31

**Site No:** 1125

**Subject No:** 11251154

**Generated By:** (b) (4)

**Form:** INFORMED CONSENT - FURTHER VACCINATION -  
Comments

**Form Status:** Data Complete, Frozen, Verified

**Site Name:** (1125) Meridian Clinical Research

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 11:09

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Item	Date	User	Comment
1	Mar-01-2021 11:21:59 (UTC-06:00) Central Time (US & Canada)	(b) (4), (b) (6) [REDACTED]	Not Applicable

**Header Text:** c4591001

**Visit:** V101\_VAX3

**Form:** INCLUSION/EXCLUSION CRITERIA - FURTHER  
VACCINATION - Comments

**Form Version:** 10-Dec-2020 02:30

**Form Status:** Data Complete, Frozen, Verified

**Site No:** 1125

**Site Name:** (1125) Meridian Clinical Research

**Subject No:** 11251154

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 11:09

[Back to Form](#)

Item	Date	User	Comment
Form	Feb-27-2021 10:38:49 (UTC-06:00) Central Time (US & Canada)	(b) (4), (b) (6) [Redacted]	Not Applicable

**Header Text:** c4591001

**Visit:** V101\_VAX3

**Form:** DISPOSITION - SCREENING FOR FURTHER  
VACCINATION - Comments

**Form Version:** 10-Dec-2020 02:31

**Form Status:** Data Complete, Frozen, Verified

**Site No:** 1125

**Site Name:** (1125) Meridian Clinical Research

**Subject No:** 11251154

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 11:09

[Back to Form](#)

Item	Date	User	Comment
Form	Mar-01-2021 11:22:36 (UTC-06:00) Central Time (US & Canada)	(b) (4), (b) (6) [REDACTED]	Not Applicable

090177e196ae3d1e\Final\Final On: 01-Apr-2021 04:27 (GMT)

**Header Text:** c4591001

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**Form:** DISPOSITION - SCREENING FOR FURTHER  
VACCINATION - Comments

**Form Version:** 10-Dec-2020 02:31

**Form Status:** Data Complete, Frozen, Verified

**Site No:** 1125

**Site Name:** (1125) Meridian Clinical Research

**Subject No:** 11251154

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 11:09

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Item	Date	User	Comment
1	Mar-01-2021 11:22:36 (UTC-06:00) Central Time (US & Canada)	(b) (4), (b) (6) [REDACTED]	Not Applicable

**Header Text:** c4591001

**Visit:** V101\_VAX3

**Form:** DISPOSITION - SCREENING FOR FURTHER  
VACCINATION - Comments

**Form Version:** 10-Dec-2020 02:31

**Form Status:** Data Complete, Frozen, Verified

**Site No:** 1125

**Site Name:** (1125) Meridian Clinical Research

**Subject No:** 11251154

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 11:09

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Item	Date	User	Comment
2	Mar-01-2021 11:22:36 (UTC-06:00) Central Time (US & Canada)	(b) (4), (b) (6) [REDACTED]	Not Applicable

**Header Text:** c4591001

**Visit:** V101\_VAX3

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VACCINATION - Comments

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**Site Name:** (1125) Meridian Clinical Research

**Subject No:** 11251154

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 11:09

[Back to Form](#)

Item	Date	User	Comment
3	Mar-01-2021 11:22:36 (UTC-06:00) Central Time (US & Canada)	(b) (4), (b) (6) [REDACTED]	Not Applicable

**Header Text:** c4591001

**Visit:** V101\_VAX3

**Form:** DISPOSITION - SCREENING FOR FURTHER  
VACCINATION - Comments

**Form Version:** 10-Dec-2020 02:31

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**Site No:** 1125

**Site Name:** (1125) Meridian Clinical Research

**Subject No:** 11251154

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 11:09

[Back to Form](#)

Item	Date	User	Comment
4	Mar-01-2021 11:22:36 (UTC-06:00) Central Time (US & Canada)	(b) (4), (b) (6) [REDACTED]	Not Applicable

**Header Text:** c4591001

**Visit:** V101\_VAX3

**Form:** ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY  
- Comments

**Form Version:** 22-Apr-2020 21:03

**Form Status:** Data Complete, Frozen, Verified

**Site No:** 1125

**Site Name:** (1125) Meridian Clinical Research

**Subject No:** 11251154

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 11:09

[Back to Form](#)

Item	Date	User	Comment
Form	Mar-01-2021 11:22:52 (UTC-06:00) Central Time (US & Canada)	(b) (4), (b) (6) [Redacted]	Not Applicable

**Header Text:** c4591001

**Visit:** V101\_VAX3

**Form:** ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY  
- Comments

**Form Version:** 22-Apr-2020 21:03

**Form Status:** Data Complete, Frozen, Verified

**Site No:** 1125

**Site Name:** (1125) Meridian Clinical Research

**Subject No:** 11251154

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 11:09

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Item	Date	User	Comment
1	Mar-01-2021 11:22:52 (UTC-06:00) Central Time (US & Canada)	(b) (4), (b) (6) [REDACTED]	Not Applicable

090177e196ae3d1e\Final\Final On: 01-Apr-2021 04:27 (GMT)

**Header Text:** c4591001

**Visit:** V101\_VAX3

**Form:** ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY  
- Comments

**Form Version:** 22-Apr-2020 21:03

**Form Status:** Data Complete, Frozen, Verified

**Site No:** 1125

**Site Name:** (1125) Meridian Clinical Research

**Subject No:** 11251154

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 11:09

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Item	Date	User	Comment
2	Mar-01-2021 11:22:52 (UTC-06:00) Central Time (US & Canada)	(b) (4), (b) (6) [REDACTED]	Not Applicable

**Header Text:** c4591001

**Visit:** V101\_VAX3

**Form:** ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY  
- Comments

**Form Version:** 22-Apr-2020 21:03

**Form Status:** Data Complete, Frozen, Verified

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**Subject No:** 11251154

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 11:09

[Back to Form](#)

Item	Date	User	Comment
3	Mar-01-2021 11:22:52 (UTC-06:00) Central Time (US & Canada)	(b) (4), (b) (6) [REDACTED]	Not Applicable

090177e196ae3d1e\Final\Final On: 01-Apr-2021 04:27 (GMT)

**Header Text:** c4591001

**Visit:** V101\_VAX3

**Form:** ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY  
- Comments

**Form Version:** 22-Apr-2020 21:03

**Form Status:** Data Complete, Frozen, Verified

**Site No:** 1125

**Site Name:** (1125) Meridian Clinical Research

**Subject No:** 11251154

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 11:09

[Back to Form](#)

Item	Date	User	Comment
4	Mar-01-2021 11:22:52 (UTC-06:00) Central Time (US & Canada)	(b) (4), (b) (6) [REDACTED]	Not Applicable

**Header Text:** c4591001

**Visit:** V101\_VAX3

**Form:** ELECTRONIC SAMPLE TRACKING - NASAL SWAB -  
Comments

**Form Version:** 22-Apr-2020 21:03

**Form Status:** Data Complete, Frozen, Verified

**Site No:** 1125

**Site Name:** (1125) Meridian Clinical Research

**Subject No:** 11251154

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 11:09

[Back to Form](#)

Item	Date	User	Comment
Form	Mar-01-2021 11:23:13 (UTC-06:00) Central Time (US & Canada)	(b) (4), (b) (6) [REDACTED]	Not Applicable

090177e196ae3d1e\Final\Final On: 01-Apr-2021 04:27 (GMT)

**Header Text:** c4591001

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**Form:** ELECTRONIC SAMPLE TRACKING - NASAL SWAB -  
Comments

**Form Version:** 22-Apr-2020 21:03

**Form Status:** Data Complete, Frozen, Verified

**Site No:** 1125

**Site Name:** (1125) Meridian Clinical Research

**Subject No:** 11251154

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 11:09

[Back to Form](#)

Item	Date	User	Comment
1	Mar-01-2021 11:23:13 (UTC-06:00) Central Time (US & Canada)	(b) (4), (b) (6) [REDACTED]	Not Applicable

**Header Text:** c4591001

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**Form:** ELECTRONIC SAMPLE TRACKING - NASAL SWAB -  
Comments

**Form Version:** 22-Apr-2020 21:03

**Form Status:** Data Complete, Frozen, Verified

**Site No:** 1125

**Site Name:** (1125) Meridian Clinical Research

**Subject No:** 11251154

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 11:09

[Back to Form](#)

Item	Date	User	Comment
2	Mar-01-2021 11:23:13 (UTC-06:00) Central Time (US & Canada)	(b) (4), (b) (6) [REDACTED]	Not Applicable

**Header Text:** c4591001

**Visit:** V101\_VAX3

**Form Version:** 22-Apr-2020 21:03

**Site No:** 1125

**Subject No:** 11251154

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**Form:** ELECTRONIC SAMPLE TRACKING - NASAL SWAB -  
Comments

**Form Status:** Data Complete, Frozen, Verified

**Site Name:** (1125) Meridian Clinical Research

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 11:09

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Item	Date	User	Comment
3	Mar-01-2021 11:23:13 (UTC-06:00) Central Time (US & Canada)	(b) (4), (b) (6) [REDACTED]	Not Applicable

**Header Text:** c4591001

**Visit:** V101\_VAX3

**Form:** ELECTRONIC SAMPLE TRACKING - NASAL SWAB -  
Comments

**Form Version:** 22-Apr-2020 21:03

**Form Status:** Data Complete, Frozen, Verified

**Site No:** 1125

**Site Name:** (1125) Meridian Clinical Research

**Subject No:** 11251154

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 11:09

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Item	Date	User	Comment
4	Mar-01-2021 11:23:13 (UTC-06:00) Central Time (US & Canada)	(b) (4), (b) (6) [REDACTED]	Not Applicable

**Header Text:** c4591001

**Visit:** Investigator Signature - Unscheduled

**Form:** CASEBOOK SIGNATURE FORM - Signature History

**Form Version:** 22-Apr-2020 21:04

**Form Status:** Data Complete, Signed, Verified

**Site No:** 1125

**Site Name:** (1125) Meridian Clinical Research

**Subject No:** 11251154

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 11:09

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This form requires signing by a member of each of the following signature groups:

- CRF\_Sign

Name	Signature Meaning	Date	Type	Action
Charles Harper	Approved	Mar-12-2021 00:09:56 (UTC-06:00) Central Time (US & Canada)	BOOK	Signed

**Affidavit:**

By my dated signature below, I, CharlesHarper, verify that all case report form pages accurately display the results of the examinations, tests, evaluations and treatments performed on this subject.

Pursuant to Section 11.100 of Title 21 of the Code of Federal Regulations, this is to certify that I intend that this electronic signature is to be the legally binding equivalent of my handwritten signature.

To this I do attest by supplying my user name and password and clicking the button marked Submit below.

(b) (6)	N/A	Mar-10-2021 10:25:46 (UTC-06:00) Central Time (US & Canada)		Edit - All signatures invalidated
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**Affidavit:**

N/A

Charles Harper	Approved	Mar-09-2021 00:23:23 (UTC-06:00) Central Time (US & Canada)	BOOK	Signed
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**Affidavit:**

By my dated signature below, I, CharlesHarper, verify that all case report form pages accurately display the results of the examinations, tests, evaluations and treatments performed on this subject.

Pursuant to Section 11.100 of Title 21 of the Code of Federal Regulations, this is to certify that I intend that this electronic signature is to be the legally binding equivalent of my handwritten signature.

To this I do attest by supplying my user name and password and clicking the button marked Submit below.

(b) (6)	N/A	Mar-04-2021 11:15:30 (UTC-06:00) Central Time (US & Canada)		Edit - All signatures invalidated
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**Affidavit:**

N/A

090177e196ae3d1e\Final\Final On: 01-Apr-2021 04:27 (GMT)

**Header Text:** c4591001

**Visit:** Investigator Signature - Unscheduled

**Form:** CASEBOOK SIGNATURE FORM - Signature History

**Form Version:** 22-Apr-2020 21:04

**Form Status:** Data Complete, Signed, Verified

**Site No:** 1125

**Site Name:** (1125) Meridian Clinical Research

**Subject No:** 11251154

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 11:09

Charles Harper	Approved	Mar-03-2021 23:15:27 (UTC-06:00) Central Time (US & Canada)	BOOK	Signed
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**Affidavit:**

By my dated signature below, I, CharlesHarper, verify that all case report form pages accurately display the results of the examinations, tests, evaluations and treatments performed on this subject.

Pursuant to Section 11.100 of Title 21 of the Code of Federal Regulations, this is to certify that I intend that this electronic signature is to be the legally binding equivalent of my handwritten signature.

To this I do attest by supplying my user name and password and clicking the button marked Submit below.

(b) (6)	N/A	Mar-01-2021 11:21:59 (UTC-06:00) Central Time (US & Canada)		Edit - All signatures invalidated
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**Affidavit:**

N/A

Charles Harper	Approved	Feb-28-2021 19:11:26 (UTC-06:00) Central Time (US & Canada)	BOOK	Signed
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**Affidavit:**

By my dated signature below, I, CharlesHarper, verify that all case report form pages accurately display the results of the examinations, tests, evaluations and treatments performed on this subject.

Pursuant to Section 11.100 of Title 21 of the Code of Federal Regulations, this is to certify that I intend that this electronic signature is to be the legally binding equivalent of my handwritten signature.

To this I do attest by supplying my user name and password and clicking the button marked Submit below.

(b) (6)	N/A	Feb-25-2021 11:50:59 (UTC-06:00) Central Time (US & Canada)		Edit - All signatures invalidated
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**Affidavit:**

N/A

Charles Harper	Approved	Feb-24-2021 08:15:51 (UTC-06:00) Central Time (US & Canada)	BOOK	Signed
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090177e196ae3d1e\Final\Final On: 01-Apr-2021 04:27 (GMT)

**Header Text:** c4591001**Visit:** Investigator Signature - Unscheduled**Form:** CASEBOOK SIGNATURE FORM - Signature History**Form Version:** 22-Apr-2020 21:04**Form Status:** Data Complete, Signed, Verified**Site No:** 1125**Site Name:** (1125) Meridian Clinical Research**Subject No:** 11251154**Subject Initials:** ---**Generated By:** (b) (4)**Generated Time (GMT):** 29-Mar-2021 11:09**Affidavit:**

By my dated signature below, I, CharlesHarper, verify that all case report form pages accurately display the results of the examinations, tests, evaluations and treatments performed on this subject.

Pursuant to Section 11.100 of Title 21 of the Code of Federal Regulations, this is to certify that I intend that this electronic signature is to be the legally binding equivalent of my handwritten signature.

To this I do attest by supplying my user name and password and clicking the button marked Submit below.

(b) (6)	N/A	Feb-15-2021 17:45:38 (UTC-06:00) Central Time (US & Canada)		Edit - All signatures invalidated
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**Affidavit:**

N/A

Charles Harper	Approved	Feb-09-2021 22:24:40 (UTC-06:00) Central Time (US & Canada)	BOOK	Signed
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**Affidavit:**

By my dated signature below, I, CharlesHarper, verify that all case report form pages accurately display the results of the examinations, tests, evaluations and treatments performed on this subject.

Pursuant to Section 11.100 of Title 21 of the Code of Federal Regulations, this is to certify that I intend that this electronic signature is to be the legally binding equivalent of my handwritten signature.

To this I do attest by supplying my user name and password and clicking the button marked Submit below.

(b) (6)	N/A	Feb-04-2021 11:43:44 (UTC-06:00) Central Time (US & Canada)		Edit - All signatures invalidated
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**Affidavit:**

N/A

Charles Harper	Approved	Oct-28-2020 22:31:52 (UTC-06:00) Central Time (US & Canada)	BOOK	Signed
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**Header Text:** c4591001

**Visit:** Investigator Signature - Unscheduled

**Form:** CASEBOOK SIGNATURE FORM - Signature History

**Form Version:** 22-Apr-2020 21:04

**Form Status:** Data Complete, Signed, Verified

**Site No:** 1125

**Site Name:** (1125) Meridian Clinical Research

**Subject No:** 11251154

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 11:09

**Affidavit:**

By my dated signature below, I, CharlesHarper, verify that all case report form pages accurately display the results of the examinations, tests, evaluations and treatments performed on this subject.

Pursuant to Section 11.100 of Title 21 of the Code of Federal Regulations, this is to certify that I intend that this electronic signature is to be the legally binding equivalent of my handwritten signature.

To this I do attest by supplying my user name and password and clicking the button marked Submit below.

090177e196ae3d1e\Final\Final On: 01-Apr-2021 04:27 (GMT)

**Header Text:** c4591001

**Visit:** COHORT\_SELECTION

**Form:** COHORT SELECTION - eCRF Audit Trail History

**Form Version:** 30-Jul-2020 21:29

**Form Status:** Data Complete, Locked, Frozen, Verified

**Site No:** 1125

**Site Name:** (1125) Meridian Clinical Research

**Subject No:** 11251154

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 11:09

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**1. Select appropriate response - Protocol version**

Date	Location	User	Value	Reason
Sep-03-2020 10:33:43 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> 24 JUL 2020	Initial Entry

**2. Select appropriate response - What cohort does the subject belong to?**

Date	Location	User	Value	Reason
Sep-03-2020 10:33:43 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> STAGE 3 COHORTS	Initial Entry

**Header Text:** c4591001

**Visit:** COHORT\_SELECTION

**Form Version:** 22-Apr-2020 21:02

**Site No:** 1125

**Subject No:** 11251154

**Generated By:** (b) (4)

**Form:** MAIN INFORMED CONSENT - eCRF Audit Trail History

**Form Status:** Data Complete, Locked, Frozen, Verified

**Site Name:** (1125) Meridian Clinical Research

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 11:09

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**I. Consent Was:**

Date	Location	User	Value	Reason
Sep-03-2020 10:33:56 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> OBTAINED Date Written Consent Obtained  Sep/3/2020	Initial Entry

090177e196ae3d1e\Final\Final On: 01-Apr-2021 04:27 (GMT)

Header Text: c4591001

Visit: COHORT\_SELECTION

Form: DEMOGRAPHY - eCRF Audit Trail History

Form Version: 06-Jul-2020 21:55

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1125

Site Name: (1125) Meridian Clinical Research

Subject No: 11251154

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:09

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**1. Subject ID**

Date	Location	User	Value	Reason
Sep-03-2020 10:31:11 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> 11251154	Item copied from previous form

**2. Birth Date:**

Date	Location	User	Value	Reason
Sep-03-2020 10:31:08 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> (b) (6) 1955	Enrollment Entry

**3. Sex:**

Date	Location	User	Value	Reason
Sep-03-2020 10:34:51 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> MALE	Initial Entry

**4. Ethnicity:**

Date	Location	User	Value	Reason
Sep-03-2020 10:34:51 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NOT HISPANIC OR LATINO(A) OR OF SPANISH ORIGIN	Initial Entry

**5. Race: (Check X all that apply):**

Date	Location	User	Value	Reason
Sep-03-2020 10:34:51 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> WHITE	Initial Entry

090177e196ae3d1e\Final\Final On: 01-Apr-2021 04:27 (GMT)

**Header Text:** c4591001

**Visit:** V1\_DAY1\_VAX1\_L

**Form Version:** 22-Apr-2020 21:02

**Site No:** 1125

**Subject No:** 11251154

**Generated By:** (b) (4)

**Form:** DATE OF VISIT - eCRF Audit Trail History

**Form Status:** Data Complete, Locked, Frozen, Verified

**Site Name:** (1125) Meridian Clinical Research

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 11:09

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*1. Date of Visit*

Date	Location	User	Value	Reason
Sep-03-2020 10:35:52 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Sep/3/2020	Initial Entry

090177e196ae3d1e\Final\Final On: 01-Apr-2021 04:27 (GMT)

**Header Text:** c4591001

**Visit:** V1\_DAY1\_VAX1\_L

**Form Version:** 22-Apr-2020 21:03

**Site No:** 1125

**Subject No:** 11251154

**Generated By:** (b) (4)

**Form:** DISPOSITION - SCREENING - eCRF Audit Trail History

**Form Status:** Data Complete, Locked, Frozen, Verified

**Site Name:** (1125) Meridian Clinical Research

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 11:09

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**1. Date of Completion/Discontinuation/Death**

Date	Location	User	Value	Reason
Sep-03-2020 10:36:30 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Sep/3/2020	Initial Entry

**2. Phase of Disposition:**

Date	Location	User	Value	Reason
Sep-03-2020 10:36:30 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> SCREENING	Initial Entry

**3. Status:**

Date	Location	User	Value	Reason
Sep-03-2020 10:36:30 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> COMPLETED	Initial Entry

090177e196ae3d1e\Final\Final On: 01-Apr-2021 04:27 (GMT)

Header Text: c4591001

Visit: V1\_DAY1\_VAX1\_L

Form Version: 22-Apr-2020 21:03

Site No: 1125

Subject No: 11251154

Generated By: (b) (4)

Form: GENERAL MEDICAL HISTORY - eCRF Audit Trail History

Form Status: Data Complete, Frozen, Verified

Site Name: (1125) Meridian Clinical Research

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 11:09

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*I.a*

Date	Location	User	Value	Reason
Sep-03-2020 10:37:42 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> <b>Line/MH Number</b> 1 : <b>Medical History T</b> Hypertensio <b>erm:</b> n <b>Start Date:</b> Feb/UNK/2 000 <b>Ongoing:</b> YES	Initial Entry

*I.a Line/MH Number:*

Date	Location	User	Value	Reason
Sep-03-2020 10:37:42 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> 1	Initial Entry

*I.a Disease/Syndrome/Surgery/Non-Drug Allergies/Drug Allergies:*

Date	Location	User	Value	Reason
Sep-03-2020 10:37:42 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Hypertension	Initial Entry

*I.a Start Date:*

Date	Location	User	Value	Reason
Sep-03-2020 10:37:42 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Feb/UNK/2000	Initial Entry

*I.a Ongoing:*

Date	Location	User	Value	Reason
Sep-03-2020 10:37:42 (UTC-06:00) Central	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> YES	Initial Entry

090177e196ae3d1e\Final\Final On: 01-Apr-2021 04:27 (GMT)

**Header Text:** c4591001

**Visit:** V1\_DAY1\_VAX1\_L

**Form Version:** 22-Apr-2020 21:03

**Site No:** 1125

**Subject No:** 11251154

**Generated By:** (b) (4)

**Form:** GENERAL MEDICAL HISTORY - eCRF Audit Trail History

**Form Status:** Data Complete, Frozen, Verified

**Site Name:** (1125) Meridian Clinical Research

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 11:09

Time (US & Canada)

(b) (4), (b) (6)

*1.b*

Date	Location	User	Value	Reason
Sep-03-2020 10:38:19 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> <b>Line/MH Num</b> 2 <b>ber:</b> <b>Medical Histor</b> Hypercholester <b>y Term:</b> olemia <b>Start Date:</b> UNK/UNK/20 15 <b>Ongoing:</b> YES	Initial Entry

090177e196ae3d1e\Final\Final On: 01-Apr-2021 04:27 (GMT)

Header Text: c4591001

Visit: V1\_DAY1\_VAX1\_L

Form Version: 22-Apr-2020 21:03

Site No: 1125

Subject No: 11251154

Generated By: (b) (4)

Form: GENERAL MEDICAL HISTORY - eCRF Audit Trail History

Form Status: Data Complete, Frozen, Verified

Site Name: (1125) Meridian Clinical Research

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 11:09

**1.b Line/MH Number:**

Date	Location	User	Value	Reason
Sep-03-2020 10:38:19 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> 2	Initial Entry

**1.b Disease/Syndrome/Surgery/Non-Drug Allergies/Drug Allergies:**

Date	Location	User	Value	Reason
Sep-03-2020 10:38:19 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Hypercholesterolemia	Initial Entry

**1.b Start Date:**

Date	Location	User	Value	Reason
Sep-03-2020 10:38:19 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> UNK/UNK/2015	Initial Entry

**1.b Ongoing:**

Date	Location	User	Value	Reason
Sep-03-2020 10:38:19 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> YES	Initial Entry

**1.c**

Date	Location	User	Value	Reason
Sep-04-2020 18:40:55 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Line/MH Number:</b> 3 <b>Medical History</b> OSteoArthri <b>Term:</b> tis <b>Start Date:</b> UNK/UNK/ 2018 <b>Ongoing:</b> YES	Transcription Error

090177e196ae3d1e\Final\Final On: 01-Apr-2021 04:27 (GMT)

**Header Text:** c4591001

**Visit:** V1\_DAY1\_VAX1\_L

**Form Version:** 22-Apr-2020 21:03

**Site No:** 1125

**Subject No:** 11251154

**Generated By:** (b) (4)

**Form:** GENERAL MEDICAL HISTORY - eCRF Audit Trail History

**Form Status:** Data Complete, Frozen, Verified

**Site Name:** (1125) Meridian Clinical Research

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 11:09

Sep-03-2020 10:38:30 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> <b>Line/MH Number:</b> 3 <b>Medical History Term:</b> Arthritis <b>Start Date:</b> UNK/UNK/ 2018 <b>Ongoing:</b> YES	Initial Entry
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090177e196ae3d1e\Final\Final On: 01-Apr-2021 04:27 (GMT)

Header Text: c4591001

Visit: V1\_DAY1\_VAX1\_L

Form Version: 22-Apr-2020 21:03

Site No: 1125

Subject No: 11251154

Generated By: (b) (4)

Form: GENERAL MEDICAL HISTORY - eCRF Audit Trail History

Form Status: Data Complete, Frozen, Verified

Site Name: (1125) Meridian Clinical Research

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 11:09

**I.c Line/MH Number:**

Date	Location	User	Value	Reason
Sep-03-2020 10:38:30 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> 3	Initial Entry

**I.c Disease/Syndrome/Surgery/Non-Drug Allergies/Drug Allergies:**

Date	Location	User	Value	Reason
Sep-08-2020 11:54:47 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Closed	Response satisfies query
Sep-04-2020 18:40:55 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Answered	Transcription Error
Sep-04-2020 18:40:55 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> OSteoArthritis	Transcription Error
Sep-04-2020 12:28:21 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Opened	CLINQUERY - Please specify if ARTHRITIS is OSTEO or RHEUMATOID. Update as appropriate.
Sep-03-2020 10:38:30 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Arthritis	Initial Entry

**I.c Start Date:**

Date	Location	User	Value	Reason
Sep-03-2020 10:38:30 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> UNK/UNK/2018	Initial Entry

**I.c Ongoing:**

Date	Location	User	Value	Reason
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090177e196ae3d1e\Final\Final On: 01-Apr-2021 04:27 (GMT)

**Header Text:** c4591001

**Visit:** V1\_DAY1\_VAX1\_L

**Form Version:** 22-Apr-2020 21:03

**Site No:** 1125

**Subject No:** 11251154

**Generated By:** (b) (4)

**Form:** GENERAL MEDICAL HISTORY - eCRF Audit Trail History

**Form Status:** Data Complete, Frozen, Verified

**Site Name:** (1125) Meridian Clinical Research

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 11:09

Sep-03-2020 10:38:30 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> YES	Initial Entry
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*1.d*

Date	Location	User	Value	Reason
Mar-04-2021 11:15:30 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> <b>Line/MH Number:</b> 4 <b>Medical History Term:</b> Angina pectoris <b>Start Date:</b> UNK/UNK/ 2015 <b>Ongoing:</b> YES	Initial Entry

090177e196ae3d1e\Final\Final On: 01-Apr-2021 04:27 (GMT)

Header Text: c4591001

Visit: V1\_DAY1\_VAX1\_L

Form Version: 22-Apr-2020 21:03

Site No: 1125

Subject No: 11251154

Generated By: (b) (4)

Form: GENERAL MEDICAL HISTORY - eCRF Audit Trail History

Form Status: Data Complete, Frozen, Verified

Site Name: (1125) Meridian Clinical Research

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 11:09

***1.d Line/MH Number:***

Date	Location	User	Value	Reason
Mar-04-2021 11:15:30 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> 4	Initial Entry

***1.d Disease/Syndrome/Surgery/Non-Drug Allergies/Drug Allergies:***

Date	Location	User	Value	Reason
Mar-04-2021 11:15:30 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Angina pectoris	Initial Entry

***1.d Start Date:***

Date	Location	User	Value	Reason
Mar-04-2021 11:15:30 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> UNK/UNK/2015	Initial Entry

***1.d Ongoing:***

Date	Location	User	Value	Reason
Mar-04-2021 11:15:30 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> YES	Initial Entry

090177e196ae3d1e\Final\Final On: 01-Apr-2021 04:27 (GMT)

Header Text: c4591001

Visit: V1\_DAY1\_VAX1\_L

Form Version: 21-Aug-2020 02:51

Site No: 1125

Subject No: 11251154

Generated By: (b) (4)

Form: VITAL SIGNS - BASELINE - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1125) Meridian Clinical Research

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 11:09

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**1. Date:**

Date	Location	User	Value	Reason
Sep-03-2020 10:40:57 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> Sep/3/2020	Initial Entry

**2. Weight:**

Date	Location	User	Value	Reason
Sep-03-2020 10:40:57 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> 229.0	Initial Entry

**3. Unit:**

Date	Location	User	Value	Reason
Sep-03-2020 10:40:57 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> LB	Initial Entry

**4. Height:**

Date	Location	User	Value	Reason
Sep-03-2020 10:40:57 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> 71.0	Initial Entry

**5. Unit:**

Date	Location	User	Value	Reason
Sep-03-2020 10:40:57 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> in	Initial Entry

**6. Body Mass Index:**

Date	Location	User	Value	Reason
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090177e196ae3d1e\Final\Final On: 01-Apr-2021 04:27 (GMT)

Header Text: c4591001

Visit: V1\_DAY1\_VAX1\_L

Form Version: 21-Aug-2020 02:51

Site No: 1125

Subject No: 11251154

Generated By: (b) (4)

Form: VITAL SIGNS - BASELINE - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1125) Meridian Clinical Research

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 11:09

Sep-03-2020 10:40:57 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> 31.9	Initial Entry
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7.a

Date	Location	User	Value	Reason
Sep-03-2020 10:40:57 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Record Identifier 1</b> :: <b>Temperature:</b> 98.2 <b>Temperature Uni F</b> <b>t:</b> <b>Temperature Loc ORAL CA</b> <b>ation::</b> VITY	Initial Entry

7.a Record Identifier:

Date	Location	User	Value	Reason
Sep-03-2020 10:40:57 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> 1	Initial Entry

7.a Temperature:

Date	Location	User	Value	Reason
Sep-03-2020 10:40:57 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> 98.2	Initial Entry

7.a Unit:

Date	Location	User	Value	Reason
Sep-03-2020 10:40:57 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> F	Initial Entry

7.a Temperature Location:

Date	Location	User	Value	Reason
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090177e196ae3d1e\Final\Final On: 01-Apr-2021 04:27 (GMT)

**Header Text:** c4591001

**Visit:** V1\_DAY1\_VAX1\_L

**Form Version:** 21-Aug-2020 02:51

**Site No:** 1125

**Subject No:** 11251154

**Generated By:** (b) (4)

**Form:** VITAL SIGNS - BASELINE - eCRF Audit Trail History

**Form Status:** Data Complete, Locked, Frozen, Verified

**Site Name:** (1125) Meridian Clinical Research

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 11:09

Sep-03-2020 10:40:57 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> ORAL CAVITY	Initial Entry
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**Header Text:** c4591001

**Visit:** V1\_DAY1\_VAX1\_L

**Form Version:** 22-Apr-2020 21:03

**Site No:** 1125

**Subject No:** 11251154

**Generated By:** (b) (4)

**Form:** RANDOMIZATION - eCRF Audit Trail History

**Form Status:** Data Complete, Locked, Frozen, Verified

**Site Name:** (1125) Meridian Clinical Research

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 11:09

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**1. Randomization Date :**

Date	Location	User	Value	Reason
Sep-03-2020 10:44:37 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> Sep/3/2020	Initial Entry

**2. Randomization Number:**

Date	Location	User	Value	Reason
Sep-03-2020 10:44:37 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> 250931	Initial Entry

090177e196ae3d1e\Final\Final On: 01-Apr-2021 04:27 (GMT)

**Header Text:** c4591001**Visit:** V1\_DAY1\_VAX1\_L**Form:** ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY  
- eCRF Audit Trail History**Form Version:** 22-Apr-2020 21:03**Form Status:** Data Complete, Locked, Frozen, Verified**Site No:** 1125**Site Name:** (1125) Meridian Clinical Research**Subject No:** 11251154**Subject Initials:** ---**Generated By:** (b) (4)**Generated Time (GMT):** 29-Mar-2021 11:09[Back to Form](#)**1. Data Origin**

Date	Location	User	Value	Reason
Sep-03-2020 10:45:08 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> SITE	Initial Entry

**2. Sample Type**

Date	Location	User	Value	Reason
Sep-03-2020 10:45:08 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> SERUM	Initial Entry

**3. Sample Collected?**

Date	Location	User	Value	Reason
Sep-03-2020 18:21:52 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Sep-03-2020 10:45:08 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Candidate	'Sample Collected?' is Yes, however no barcodes are entered. Please review and correct as appropriate.
Sep-03-2020 10:45:08 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> YES Date of Collection:  Sep/3/2020	Initial Entry

**5.a**

Date	Location	User	Value	Reason
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Header Text: c4591001

Visit: V1\_DAY1\_VAX1\_L

Form: ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY  
- eCRF Audit Trail History

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1125

Site Name: (1125) Meridian Clinical Research

Subject No: 11251154

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:09

Sep-03-2020 18:21:52 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Sample ID:</b> BJ38SL	Initial Entry
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**5.a Sample ID**

Date	Location	User	Value	Reason
Sep-03-2020 18:21:52 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> BJ38SL	Initial Entry

**5.b**

Date	Location	User	Value	Reason
Sep-03-2020 18:22:08 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Sample ID:</b> BJ38SM	Initial Entry

**5.b Sample ID**

Date	Location	User	Value	Reason
Sep-03-2020 18:22:08 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> BJ38SM	Initial Entry

**5.c**

Date	Location	User	Value	Reason
Sep-03-2020 18:22:51 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Sample ID:</b> BP52VF	Initial Entry

**5.c Sample ID**

Date	Location	User	Value	Reason
Sep-03-2020 18:22:51 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> BP52VF	Initial Entry

**5.d**

090177e196ae3d1e\Final\Final On: 01-Apr-2021 04:27 (GMT)

**Header Text:** c4591001

**Visit:** V1\_DAY1\_VAX1\_L

**Form:** ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY  
- eCRF Audit Trail History

**Form Version:** 22-Apr-2020 21:03

**Form Status:** Data Complete, Locked, Frozen, Verified

**Site No:** 1125

**Site Name:** (1125) Meridian Clinical Research

**Subject No:** 11251154

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 11:09

Date	Location	User	Value	Reason
Sep-03-2020 18:22:56 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Sample ID:</b> BP52VG	Initial Entry

**5.d Sample ID**

Date	Location	User	Value	Reason
Sep-03-2020 18:22:56 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> BP52VG	Initial Entry

Header Text: c4591001

Visit: V1\_DAY1\_VAX1\_L

Form: ELECTRONIC SAMPLE TRACKING - NASAL SWAB - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1125

Site Name: (1125) Meridian Clinical Research

Subject No: 11251154

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:09

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**1. Data Origin**

Date	Location	User	Value	Reason
Sep-03-2020 10:45:18 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> SITE	Initial Entry

**2. Sample Type**

Date	Location	User	Value	Reason
Sep-03-2020 10:45:18 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> NASAL_SWAB	Initial Entry

**3. Sample Collected?**

Date	Location	User	Value	Reason
Sep-03-2020 18:21:35 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Sep-03-2020 10:45:18 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Candidate	'Sample Collected?' is Yes, however no barcodes are entered. Please review and correct as appropriate.
Sep-03-2020 10:45:18 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> YES Date of Collection:  Sep/3/2020	Initial Entry

**5.a**

Date	Location	User	Value	Reason
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090177e196ae3d1e\Final\Final On: 01-Apr-2021 04:27 (GMT)

**Header Text:** c4591001

**Visit:** V1\_DAY1\_VAX1\_L

**Form:** ELECTRONIC SAMPLE TRACKING - NASAL SWAB - eCRF Audit Trail History

**Form Version:** 22-Apr-2020 21:03

**Form Status:** Data Complete, Locked, Frozen, Verified

**Site No:** 1125

**Site Name:** (1125) Meridian Clinical Research

**Subject No:** 11251154

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 11:09

Sep-03-2020 18:21:35 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Sample ID:</b> BKMKWX	Initial Entry
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**5.a Sample ID**

Date	Location	User	Value	Reason
Sep-03-2020 18:21:35 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> BKMKWX	Initial Entry

Header Text: c4591001

Visit: V1\_DAY1\_VAX1\_L

Form Version: 22-Apr-2020 21:04

Site No: 1125

Subject No: 11251154

Generated By: (b) (4)

Form: VACCINATION - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1125) Meridian Clinical Research

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 11:09

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**1. Was there a temporary delay of vaccination?**

Date	Location	User	Value	Reason
Sep-03-2020 10:45:32 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO	Initial Entry

**2. Treatment Name**

Date	Location	User	Value	Reason
Sep-03-2020 10:45:32 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> BLINDED THERAPY	Initial Entry

**3. Formulation:**

Date	Location	User	Value	Reason
Sep-03-2020 10:45:32 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> INJECTION	Initial Entry

**4. Dose Date Time:**

Date	Location	User	Value	Reason
Sep-03-2020 10:45:32 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Sep/3/2020 09:39	Initial Entry

**5. Anatomical Location:**

Date	Location	User	Value	Reason
Sep-03-2020 10:45:32 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> DELTOID MUSCLE	Initial Entry

**6. Body Side:**

Date	Location	User	Value	Reason
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090177e196ae3d1e\Final\Final On: 01-Apr-2021 04:27 (GMT)

Header Text: c4591001

Visit: V1\_DAY1\_VAX1\_L

Form Version: 22-Apr-2020 21:04

Site No: 1125

Subject No: 11251154

Generated By: (b) (4)

Form: VACCINATION - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1125) Meridian Clinical Research

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 11:09

Sep-03-2020 10:45:32 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> LEFT	Initial Entry
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**7. Route:**

Date	Location	User	Value	Reason
Sep-03-2020 10:45:32 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> INTRAMUSCULAR	Initial Entry

**10. Timeframe Subject Was Observed**

Date	Location	User	Value	Reason
Sep-03-2020 10:45:32 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> THE PROTOCOL SPECIFIED OBSERVATION PERIOD	Initial Entry

**11. Was the subject observed for at least the protocol specified observation period after investigational product administration?**

Date	Location	User	Value	Reason
Sep-03-2020 10:45:32 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> YES	Initial Entry

090177e196ae3d1e\Final\Final On: 01-Apr-2021 04:27 (GMT)

**Header Text:** c4591001

**Visit:** V1\_DAY1\_VAX1\_L

**Form Version:** 06-Jul-2020 21:53

**Site No:** 1125

**Subject No:** 11251154

**Generated By:** (b) (4)

**Form:** REACTOGENICITY DIARY - eCRF Audit Trail History

**Form Status:** Data Complete, Locked, Frozen, Verified

**Site Name:** (1125) Meridian Clinical Research

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 11:09

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*1. Select appropriate response - Reactogenicity diary collection*

Date	Location	User	Value	Reason
Sep-03-2020 10:46:48 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO - REACTOGENICITY E-D IARY NOT COLLECTED FOR THIS SUBJECT	Initial Entry

**Header Text:** c4591001

**Visit:** V2\_VAX2\_L

**Form Version:** 22-Apr-2020 21:02

**Site No:** 1125

**Subject No:** 11251154

**Generated By:** (b) (4)

**Form:** DATE OF VISIT - eCRF Audit Trail History

**Form Status:** Data Complete, Locked, Frozen, Verified

**Site Name:** (1125) Meridian Clinical Research

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 11:09

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*1. Date of Visit*

Date	Location	User	Value	Reason
Sep-22-2020 09:44:48 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Sep/22/2020	Initial Entry

Header Text: c4591001

Visit: V2\_VAX2\_L

Form Version: 15-Sep-2020 21:54

Site No: 1125

Subject No: 11251154

Generated By: (b) (4)

Form: VITAL SIGNS - TEMP - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1125) Meridian Clinical Research

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 11:09

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**1. Date:**

Date	Location	User	Value	Reason
Sep-22-2020 09:45:21 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> Sep/22/2020	Initial Entry

**2.a**

Date	Location	User	Value	Reason
Sep-22-2020 09:45:21 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> <b>Record Identifier 1</b> :: <b>Temperature: 97.5</b> <b>Temperature Unit:</b> <b>Temperature Location:</b> ORAL CAVITY	Initial Entry

**2.a Record Identifier:**

Date	Location	User	Value	Reason
Sep-22-2020 09:45:21 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> 1	Initial Entry

**2.a Temperature:**

Date	Location	User	Value	Reason
Sep-22-2020 09:45:21 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> 97.5	Initial Entry

**2.a Unit:**

Date	Location	User	Value	Reason
Sep-22-2020 09:45:21 (UTC-06:00) Central	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> F	Initial Entry

090177e196ae3d1e\Final\Final On: 01-Apr-2021 04:27 (GMT)

**Header Text:** c4591001

**Visit:** V2\_VAX2\_L

**Form Version:** 15-Sep-2020 21:54

**Site No:** 1125

**Subject No:** 11251154

**Generated By:** (b) (4)

**Form:** VITAL SIGNS - TEMP - eCRF Audit Trail History

**Form Status:** Data Complete, Locked, Frozen, Verified

**Site Name:** (1125) Meridian Clinical Research

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 11:09

Time (US & Canada)	(b) (4), (b) (6)
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**2.a Temperature Location:**

Date	Location	User	Value	Reason
Sep-22-2020 09:45:21 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> ORAL CAVITY	Initial Entry

Header Text: c4591001

Visit: V2\_VAX2\_L

Form: ELECTRONIC SAMPLE TRACKING - NASAL SWAB - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1125

Site Name: (1125) Meridian Clinical Research

Subject No: 11251154

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:09

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**1. Data Origin**

Date	Location	User	Value	Reason
Sep-22-2020 09:45:32 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> SITE	Initial Entry

**2. Sample Type**

Date	Location	User	Value	Reason
Sep-22-2020 09:45:32 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> NASAL_SWAB	Initial Entry

**3. Sample Collected?**

Date	Location	User	Value	Reason
Sep-23-2020 16:39:59 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Closed	Close Auto Query
Sep-23-2020 05:15:35 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Opened	'Sample Collected?' is Yes, however no barcodes are entered. Please review and correct as appropriate.
Sep-22-2020 09:45:32 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Candidate	'Sample Collected?' is Yes, however no barcodes are entered. Please review and correct as appropriate.
Sep-22-2020 09:45:32 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> YES Date of Collection:	Initial Entry

090177e196ae3d1e\Final\Final On: 01-Apr-2021 04:27 (GMT)

**Header Text:** c4591001

**Visit:** V2\_VAX2\_L

**Form:** ELECTRONIC SAMPLE TRACKING - NASAL SWAB - eCRF Audit Trail History

**Form Version:** 22-Apr-2020 21:03

**Form Status:** Data Complete, Locked, Frozen, Verified

**Site No:** 1125

**Site Name:** (1125) Meridian Clinical Research

**Subject No:** 11251154

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 11:09

			Sep/22/2020	
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**5.a**

Date	Location	User	Value	Reason
Sep-23-2020 16:39:59 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Sample ID:</b> BP52XB	Initial Entry

**5.a Sample ID**

Date	Location	User	Value	Reason
Sep-23-2020 16:39:59 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> BP52XB	Initial Entry

090177e196ae3d1e\Final\Final On: 01-Apr-2021 04:27 (GMT)

Header Text: c4591001

Visit: V2\_VAX2\_L

Form Version: 22-Apr-2020 21:04

Site No: 1125

Subject No: 11251154

Generated By: (b) (4)

Form: VACCINATION - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1125) Meridian Clinical Research

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 11:09

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**1. Was there a temporary delay of vaccination?**

Date	Location	User	Value	Reason
Sep-22-2020 09:46:29 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO	Initial Entry

**2. Treatment Name**

Date	Location	User	Value	Reason
Sep-22-2020 09:46:29 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> BLINDED THERAPY	Initial Entry

**3. Formulation:**

Date	Location	User	Value	Reason
Sep-22-2020 09:46:29 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> INJECTION	Initial Entry

**4. Dose Date Time:**

Date	Location	User	Value	Reason
Sep-22-2020 09:46:29 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Sep/22/2020 08:51	Initial Entry

**5. Anatomical Location:**

Date	Location	User	Value	Reason
Sep-22-2020 09:46:29 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> DELTOID MUSCLE	Initial Entry

**6. Body Side:**

Date	Location	User	Value	Reason
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090177e196ae3d1e\Final\Final On: 01-Apr-2021 04:27 (GMT)

Header Text: c4591001

Visit: V2\_VAX2\_L

Form Version: 22-Apr-2020 21:04

Site No: 1125

Subject No: 11251154

Generated By: (b) (4)

Form: VACCINATION - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1125) Meridian Clinical Research

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 11:09

Sep-22-2020 09:46:29 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> LEFT	Initial Entry
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**7. Route:**

Date	Location	User	Value	Reason
Sep-22-2020 09:46:29 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> INTRAMUSCULAR	Initial Entry

**10. Timeframe Subject Was Observed**

Date	Location	User	Value	Reason
Sep-22-2020 09:46:29 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> THE PROTOCOL SPECIFIED OBSERVATION PERIOD	Initial Entry

**11. Was the subject observed for at least the protocol specified observation period after investigational product administration?**

Date	Location	User	Value	Reason
Sep-22-2020 09:46:29 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> YES	Initial Entry

090177e196ae3d1e\Final\Final On: 01-Apr-2021 04:27 (GMT)

**Header Text:** c4591001

**Visit:** V3\_MONTH1\_POSTVAX2\_L

**Form Version:** 22-Apr-2020 21:02

**Site No:** 1125

**Subject No:** 11251154

**Generated By:** (b) (4)

**Form:** DATE OF VISIT - eCRF Audit Trail History

**Form Status:** Data Complete, Locked, Frozen, Verified

**Site Name:** (1125) Meridian Clinical Research

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 11:09

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*1. Date of Visit*

Date	Location	User	Value	Reason
Oct-23-2020 08:42:43 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Oct/23/2020	Initial Entry

090177e196ae3d1e\Final\Final On: 01-Apr-2021 04:27 (GMT)

Header Text: c4591001

Visit: V3\_MONTH1\_POSTVAX2\_L

Form: ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY  
- eCRF Audit Trail History

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1125

Site Name: (1125) Meridian Clinical Research

Subject No: 11251154

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:09

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**1. Data Origin**

Date	Location	User	Value	Reason
Oct-23-2020 08:43:01 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> SITE	Initial Entry

**2. Sample Type**

Date	Location	User	Value	Reason
Oct-23-2020 08:43:01 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> SERUM	Initial Entry

**3. Sample Collected?**

Date	Location	User	Value	Reason
Oct-23-2020 14:22:47 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Oct-23-2020 08:43:01 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Candidate	'Sample Collected?' is Yes, however no barcodes are entered. Please review and correct as appropriate.
Oct-23-2020 08:43:01 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> YES Date of Collection:  Oct/23/2020	Initial Entry

**5.a**

Date	Location	User	Value	Reason
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090177e196ae3d1e\Final\Final On: 01-Apr-2021 04:27 (GMT)

Header Text: c4591001

Visit: V3\_MONTH1\_POSTVAX2\_L

Form: ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY  
- eCRF Audit Trail History

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1125

Site Name: (1125) Meridian Clinical Research

Subject No: 11251154

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:09

Oct-23-2020 14:22:47 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Sample ID: BPTMV5</b>	Initial Entry
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**5.a Sample ID**

Date	Location	User	Value	Reason
Oct-23-2020 14:22:47 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> BPTMV5	Initial Entry

**5.b**

Date	Location	User	Value	Reason
Oct-23-2020 14:23:00 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Sample ID: BPTMV6</b>	Initial Entry

**5.b Sample ID**

Date	Location	User	Value	Reason
Oct-23-2020 14:23:00 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> BPTMV6	Initial Entry

**5.c**

Date	Location	User	Value	Reason
Oct-23-2020 14:23:12 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Sample ID: BJ39KF</b>	Initial Entry

**5.c Sample ID**

Date	Location	User	Value	Reason
Oct-23-2020 14:23:12 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> BJ39KF	Initial Entry

**5.d**

090177e196ae3d1e\Final\Final On: 01-Apr-2021 04:27 (GMT)

**Header Text:** c4591001

**Visit:** V3\_MONTH1\_POSTVAX2\_L

**Form:** ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY  
- eCRF Audit Trail History

**Form Version:** 22-Apr-2020 21:03

**Form Status:** Data Complete, Locked, Frozen, Verified

**Site No:** 1125

**Site Name:** (1125) Meridian Clinical Research

**Subject No:** 11251154

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 11:09

Date	Location	User	Value	Reason
Oct-23-2020 14:23:19 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Sample ID:</b> BJ39KG	Initial Entry

**5.d Sample ID**

Date	Location	User	Value	Reason
Oct-23-2020 14:23:19 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> BJ39KG	Initial Entry

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit **Form:** DATE OF VISIT - ILLNESS ONSET - eCRF Audit Trail  
on Feb/04/2021 History

**Form Version:** 22-Apr-2020 21:03

**Form Status:** Data Complete, Frozen, Verified

**Site No:** 1125

**Site Name:** (1125) Meridian Clinical Research

**Subject No:** 11251154

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 11:09

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*1. Date of Visit*

Date	Location	User	Value	Reason
Mar-05-2021 00:08:58 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 4: Closed	Response satisfies query
Mar-04-2021 14:21:49 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 4: Answered	Changed data per query
Feb-25-2021 01:03:57 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 3: Closed	SOD entered, Not valid hence closed
Feb-21-2021 22:31:16 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 4: Reissued:Opened	DM: Please let us know tentative date by when you will be able to update the details. Thank you.
Feb-19-2021 13:48:45 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 4: Answered	waiting on med records for information
Feb-19-2021 13:48:28 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 3: Answered	waiting on med records for information
Feb-12-2021 05:09:40 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 3: Reissued:Opened	PDQ: Date of Visit is completed but Date of Assessment in the Signs and Symptoms form is missing. Please review and update as appropriate.
Feb-09-2021 04:38:23 (UTC-06:00) Central	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 3: Reissued:Candidate	PDQ: Date of Visit is completed but

090177e196ae3d1e\Final\Final On: 01-Apr-2021 04:27 (GMT)

**Header Text:** c4591001**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit **Form:** DATE OF VISIT - ILLNESS ONSET - eCRF Audit Trail  
on Feb/04/2021 History**Form Version:** 22-Apr-2020 21:03**Form Status:** Data Complete, Frozen, Verified**Site No:** 1125**Site Name:** (1125) Meridian Clinical Research**Subject No:** 11251154**Subject Initials:** ---**Generated By:** (b) (4)**Generated Time (GMT):** 29-Mar-2021 11:09

Time (US & Canada)				Date of Assessment in the Signs and Symptoms form is missing. Please review and update as appropriate.
Feb-08-2021 07:07:14 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) [REDACTED]	Query 4: Opened	DM: Kindly review and complete 'Illness Details form' at this visit. Thank you.
Feb-05-2021 17:24:08 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) [REDACTED]	Query 3: Answered	awaiting medical records for further information
Feb-05-2021 00:31:52 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) [REDACTED]	Query 3: Opened	PDQ: Date of Visit is completed but Date of Assessment in the Signs and Symptoms form is missing. Please review and update as appropriate.
Feb-05-2021 00:31:36 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) [REDACTED]	Query 1: Closed	Invalid hence closed
Feb-05-2021 00:31:10 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) [REDACTED]	Query 1: Opened	Date of Visit is completed but Date of Collection in both Nasal Swab Self and Nasal Swab are missing. Please review and update as appropriate.
Feb-04-2021 11:46:00 (UTC-06:00) Central	ACV0PFEINFP6000	auto query (autoquery)	Query 2: Deleted	Close Auto Query

**Header Text:** c4591001**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit **Form:** DATE OF VISIT - ILLNESS ONSET - eCRF Audit Trail on Feb/04/2021 History**Form Version:** 22-Apr-2020 21:03**Form Status:** Data Complete, Frozen, Verified**Site No:** 1125**Site Name:** (1125) Meridian Clinical Research**Subject No:** 11251154**Subject Initials:** ---**Generated By:** (b) (4)**Generated Time (GMT):** 29-Mar-2021 11:09

Time (US & Canada)				
Feb-04-2021 11:43:42 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 2: Candidate	Date of Visit is completed but Date of Assessment in the Signs and Symptoms form is missing. Please review and update as appropriate.
Feb-04-2021 11:43:42 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Candidate	Date of Visit is completed but Date of Collection in both Nasal Swab Self and Nasal Swab are missing. Please review and update as appropriate.
Feb-04-2021 11:43:42 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Feb/4/2021	Initial Entry

**3. COVID-19 Illness Visit:**

Date	Location	User	Value	Reason
Feb-04-2021 11:43:42 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> COVID_A	Initial Entry

**Header Text:** c4591001**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit **Form:** SIGNS AND SYMPTOMS OF POTENTIAL COVID-19 - eCRF Audit Trail History  
on Feb/04/2021**Form Version:** 14-Jan-2021 02:23**Form Status:** Data Complete**Site No:** 1125**Site Name:** (1125) Meridian Clinical Research**Subject No:** 11251154**Subject Initials:** ---**Generated By:** (b) (4)**Generated Time (GMT):** 29-Mar-2021 11:09[Back to Form](#)**1. Date of Assessment:**

Date	Location	User	Value	Reason
Feb-04-2021 11:46:00 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Feb/4/2021	Initial Entry

**2. Date of First Symptom Started:**

Date	Location	User	Value	Reason
Mar-10-2021 10:25:46 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Jan/20/2021	Transcription Error
Feb-04-2021 11:46:00 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Jan/28/2021	Initial Entry

**3. Symptoms Ongoing?**

Date	Location	User	Value	Reason
Feb-04-2021 11:46:00 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> YES	Initial Entry

**4.a**

Date	Location	User	Value	Reason
Feb-04-2021 11:46:00 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Symptoms:</b> FEVER <b>Symptom Present:</b> YES	Initial Entry

**4.a Symptoms:**

Date	Location	User	Value	Reason
Feb-04-2021 11:46:00 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> FEVER	Initial Entry

Header Text: c4591001

Visit: POT\_COVID\_ILL 1 - Unscheduled Visit Form: SIGNS AND SYMPTOMS OF POTENTIAL COVID-19 - on Feb/04/2021 eCRF Audit Trail History

Form Version: 14-Jan-2021 02:23

Form Status: Data Complete

Site No: 1125

Site Name: (1125) Meridian Clinical Research

Subject No: 11251154

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:09

4.a Was symptom present?

Date	Location	User	Value	Reason
Feb-04-2021 11:46:00 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> YES	Initial Entry

4.b

Date	Location	User	Value	Reason
Feb-04-2021 11:46:00 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Symptoms NEW OR INCRE : ASSED COUGH Symptom YES Present:	Initial Entry

4.b Symptoms:

Date	Location	User	Value	Reason
Feb-04-2021 11:46:00 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NEW OR INCREASED COUG H	Initial Entry

4.b Was symptom present?

Date	Location	User	Value	Reason
Feb-04-2021 11:46:00 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> YES	Initial Entry

4.c

Date	Location	User	Value	Reason
Feb-04-2021 11:46:00 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Sympto NEW OR INCREAS ms: ED SHORTNESS OF BREATH Sympto YES m Prese nt:	Initial Entry

090177e196ae3d1e\Final\Final On: 01-Apr-2021 04:27 (GMT)

Header Text: c4591001

Visit: POT\_COVID\_ILL 1 - Unscheduled Visit Form: SIGNS AND SYMPTOMS OF POTENTIAL COVID-19 - on Feb/04/2021 eCRF Audit Trail History

Form Version: 14-Jan-2021 02:23

Form Status: Data Complete

Site No: 1125

Site Name: (1125) Meridian Clinical Research

Subject No: 11251154

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:09

4.c Symptoms:

Date	Location	User	Value	Reason
Feb-04-2021 11:46:00 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NEW OR INCREASED SHOR TNESS OF BREATH	Initial Entry

4.c Was symptom present?

Date	Location	User	Value	Reason
Feb-04-2021 11:46:00 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> YES	Initial Entry

4.d

Date	Location	User	Value	Reason
Feb-04-2021 11:46:10 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Symptoms:</b> CHILLS <b>Symptom Present:</b> NO	Initial Entry
Feb-04-2021 11:46:00 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Symptoms:</b> CHILLS <b>Symptom Present:</b>	Initial Entry

4.d Symptoms:

Date	Location	User	Value	Reason
Feb-04-2021 11:46:00 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> CHILLS	Initial Entry

4.d Was symptom present?

Date	Location	User	Value	Reason
Feb-04-2021 11:46:10 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO	Initial Entry

4.e

090177e196ae3d1e\Final\Final On: 01-Apr-2021 04:27 (GMT)

Header Text: c4591001

Visit: POT\_COVID\_ILL 1 - Unscheduled Visit Form: SIGNS AND SYMPTOMS OF POTENTIAL COVID-19 - eCRF Audit Trail History

Form Version: 14-Jan-2021 02:23

Form Status: Data Complete

Site No: 1125

Site Name: (1125) Meridian Clinical Research

Subject No: 11251154

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:09

Date	Location	User	Value	Reason
Feb-04-2021 11:46:10 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Symptom</b> NEW OR INCREASED MUSCLE PAIN <b>Symptom</b> NO <b>Present:</b>	Initial Entry
Feb-04-2021 11:46:00 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Symptom</b> NEW OR INCREASED MUSCLE PAIN <b>Symptom</b> <b>Present:</b>	Initial Entry

4.e Symptoms:

Date	Location	User	Value	Reason
Feb-04-2021 11:46:00 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NEW OR INCREASED MUSCLE PAIN	Initial Entry

4.e Was symptom present?

Date	Location	User	Value	Reason
Feb-04-2021 11:46:10 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO	Initial Entry

4.f

Date	Location	User	Value	Reason
Feb-04-2021 11:46:00 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Symptom</b> NEW LOSS OF TASTE OR SMELL <b>Symptom</b> YES <b>Present:</b>	Initial Entry

090177e196ae3d1e\Final\Final On: 01-Apr-2021 04:27 (GMT)

Header Text: c4591001

Visit: POT\_COVID\_ILL 1 - Unscheduled Visit Form: SIGNS AND SYMPTOMS OF POTENTIAL COVID-19 - on Feb/04/2021 eCRF Audit Trail History

Form Version: 14-Jan-2021 02:23

Form Status: Data Complete

Site No: 1125

Site Name: (1125) Meridian Clinical Research

Subject No: 11251154

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:09

4.f Symptoms:

Date	Location	User	Value	Reason
Feb-04-2021 11:46:00 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NEW LOSS OF TASTE OR S MELL	Initial Entry

4.f Was symptom present?

Date	Location	User	Value	Reason
Feb-04-2021 11:46:00 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> YES	Initial Entry

4.g

Date	Location	User	Value	Reason
Feb-04-2021 11:46:00 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Sympto</b> NEW OR INCREA <b>ms:</b> SED SORE THRO AT <b>Sympto</b> YES <b>m Presen</b> <b>t:</b>	Initial Entry

4.g Symptoms:

Date	Location	User	Value	Reason
Feb-04-2021 11:46:00 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NEW OR INCREASED SORE THROAT	Initial Entry

4.g Was symptom present?

Date	Location	User	Value	Reason
Feb-04-2021 11:46:00 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> YES	Initial Entry

4.h

090177e196ae3d1e\Final\Final On: 01-Apr-2021 04:27 (GMT)

Header Text: c4591001

Visit: POT\_COVID\_ILL 1 - Unscheduled Visit Form: SIGNS AND SYMPTOMS OF POTENTIAL COVID-19 - eCRF Audit Trail History on Feb/04/2021

Form Version: 14-Jan-2021 02:23

Form Status: Data Complete

Site No: 1125

Site Name: (1125) Meridian Clinical Research

Subject No: 11251154

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:09

Date	Location	User	Value	Reason
Feb-04-2021 11:46:00 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Symptoms:</b> DIARRHEA A <b>Symptom Present:</b> YES	Initial Entry

4.h Symptoms:

Date	Location	User	Value	Reason
Feb-04-2021 11:46:00 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> DIARRHEA	Initial Entry

4.h Was symptom present?

Date	Location	User	Value	Reason
Feb-04-2021 11:46:00 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> YES	Initial Entry

4.i

Date	Location	User	Value	Reason
Feb-04-2021 11:46:00 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Symptoms:</b> VOMITIN G <b>Symptom Present:</b> NO	Initial Entry

090177e196ae3d1e\Final\Final On: 01-Apr-2021 04:27 (GMT)

Header Text: c4591001

Visit: POT\_COVID\_ILL 1 - Unscheduled Visit Form: SIGNS AND SYMPTOMS OF POTENTIAL COVID-19 - eCRF Audit Trail History on Feb/04/2021

Form Version: 14-Jan-2021 02:23

Form Status: Data Complete

Site No: 1125

Site Name: (1125) Meridian Clinical Research

Subject No: 11251154

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:09

4.i Symptoms:

Date	Location	User	Value	Reason
Feb-04-2021 11:46:00 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> VOMITING	Initial Entry

4.i Was symptom present?

Date	Location	User	Value	Reason
Feb-04-2021 11:46:00 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO	Initial Entry

5.a

Date	Location	User	Value	Reason
Feb-04-2021 11:46:53 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Symptoms - Other: Headache	Initial Entry

5.a Symptoms - Other Text:

Date	Location	User	Value	Reason
Feb-04-2021 11:46:53 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Headache	Initial Entry

5.b

Date	Location	User	Value	Reason
Feb-04-2021 11:47:03 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Symptoms - Other: fatigue	Initial Entry

090177e196ae3d1e\Final\Final On: 01-Apr-2021 04:27 (GMT)

Header Text: c4591001

Visit: POT\_COVID\_ILL 1 - Unscheduled Visit Form: SIGNS AND SYMPTOMS OF POTENTIAL COVID-19 - eCRF Audit Trail History  
on Feb/04/2021

Form Version: 14-Jan-2021 02:23

Form Status: Data Complete

Site No: 1125

Site Name: (1125) Meridian Clinical Research

Subject No: 11251154

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:09

5.b Symptoms - Other Text:

Date	Location	User	Value	Reason
Feb-04-2021 11:47:03 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> fatigue	Initial Entry

5.c

Date	Location	User	Value	Reason
Feb-04-2021 11:47:33 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Symptoms</b> New or increased <b>- Other:</b> nasal discharge	Initial Entry

5.c Symptoms - Other Text:

Date	Location	User	Value	Reason
Feb-04-2021 11:47:33 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> New or increased nasal discharg e	Initial Entry

5.d

Date	Location	User	Value	Reason
Feb-04-2021 11:47:55 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Symptoms</b> New or increased <b>- Other:</b> nasal congestion	Initial Entry

5.d Symptoms - Other Text:

Date	Location	User	Value	Reason
Feb-04-2021 11:47:55 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> New or increased nasal congesti on	Initial Entry

090177e196ae3d1e\Final\Final On: 01-Apr-2021 04:27 (GMT)

**Header Text:** c4591001**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit **Form:** MICROBIOLOGY SPECIMEN - eCRF Audit Trail History on Feb/04/2021**Form Version:** 06-Jul-2020 21:54**Form Status:** Data Complete, Frozen**Site No:** 1125**Site Name:** (1125) Meridian Clinical Research**Subject No:** 11251154**Subject Initials:** ---**Generated By:** (b) (4)**Generated Time (GMT):** 29-Mar-2021 11:09[Back to Form](#)**1. Actual Date of Collection:**

Date	Location	User	Value	Reason
Feb-16-2021 00:41:23 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Closed	Response satisfies query
Feb-15-2021 17:06:09 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Answered	will complete if data collected
Feb-05-2021 02:17:45 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Opened	DM: Per comment, please update this form once data is available. Thank you.
Feb-04-2021 11:50:47 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Done	Initial Entry

**2. Specimen Type:**

Date	Location	User	Value	Reason
Feb-04-2021 11:50:47 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Done	Initial Entry

**3. Specimen Collection Location:**

Date	Location	User	Value	Reason
Feb-04-2021 11:50:47 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Done	Initial Entry

**4. Assay Code and Description:**

Date	Location	User	Value	Reason
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Header Text: c4591001

Visit: POT\_COVID\_ILL 1 - Unscheduled Visit Form: MICROBIOLOGY SPECIMEN - eCRF Audit Trail History on Feb/04/2021

Form Version: 06-Jul-2020 21:54

Form Status: Data Complete, Frozen

Site No: 1125

Site Name: (1125) Meridian Clinical Research

Subject No: 11251154

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:09

Feb-04-2021 11:50:47 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Done	Initial Entry
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**5. Device Type:**

Date	Location	User	Value	Reason
Feb-04-2021 11:50:47 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Done	Initial Entry

**6. Trade Name:**

Date	Location	User	Value	Reason
Feb-04-2021 11:50:47 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Done	Initial Entry

**7. Test Result:**

Date	Location	User	Value	Reason
Feb-04-2021 11:50:47 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Done	Initial Entry

**8. Comments/Findings/Details:**

Date	Location	User	Value	Reason
Feb-04-2021 11:50:47 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Done	Initial Entry

**9. Trade Name Other, Specify:**

Date	Location	User	Value	Reason
Feb-04-2021 11:50:47 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Done	Initial Entry

090177e196ae3d1e\Final\Final On: 01-Apr-2021 04:27 (GMT)

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit **Form:** ELECTRONIC SAMPLE TRACKING - NASAL SWAB SELF  
on Feb/04/2021 - eCRF Audit Trail History

**Form Version:** 22-Apr-2020 21:03

**Form Status:** Data Complete, Frozen, Verified

**Site No:** 1125

**Site Name:** (1125) Meridian Clinical Research

**Subject No:** 11251154

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 11:09

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**1. Data Origin**

Date	Location	User	Value	Reason
Feb-04-2021 11:51:33 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> SITE	Initial Entry

**2. Sample Type**

Date	Location	User	Value	Reason
Feb-04-2021 11:51:33 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> NASAL_SWAB_SELF	Initial Entry

**3. Sample Collected?**

Date	Location	User	Value	Reason
Mar-08-2021 09:45:59 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 2: Deleted	Close Auto Query
Mar-08-2021 09:45:41 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 2: Candidate	'Sample Collected?' is Yes, however no barcodes are entered. Please review and correct as appropriate.
Mar-08-2021 09:45:41 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Closed	Close Auto Query
Mar-08-2021 09:45:41 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> YES Date of Collection:  Feb/27/2021	New Information
Mar-08-2021 09:45:18	ACV0PFEINFP6000	auto query	Query 1: Opened	'Sample

090177e196ae3d1e\Final\Final On: 01-Apr-2021 04:27 (GMT)

Header Text: c4591001

Visit: POT\_COVID\_ILL 1 - Unscheduled Visit Form: ELECTRONIC SAMPLE TRACKING - NASAL SWAB SELF on Feb/04/2021 - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Frozen, Verified

Site No: 1125

Site Name: (1125) Meridian Clinical Research

Subject No: 11251154

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:09

(UTC-06:00) Central Time (US & Canada)		(autoquery)		Collected?' is marked as No and 'If no sample was collected or sample was not collected according to protocol, please provide reason' is missing. Please review and update as appropriate.
Feb-04-2021 11:51:33 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO	Initial Entry

**4. If no sample was collected or sample was not collected according to protocol, please provide reason:**

Date	Location	User	Value	Reason
Mar-08-2021 09:45:18 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b>	New Information
Feb-16-2021 06:22:31 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Closed	Response satisfies query
Feb-15-2021 17:04:18 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Answered	have messaged patient to contact site to collect sample
Feb-08-2021 10:58:40 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Opened	Clinical Query: Please make every effort to collect swab which may be collected at the latest 4 days after symptom resolution as per Protocol Section 8.13.

090177e196ae3d1e\Final\Final On: 01-Apr-2021 04:27 (GMT)

Header Text: c4591001

Visit: POT\_COVID\_ILL 1 - Unscheduled Visit Form: ELECTRONIC SAMPLE TRACKING - NASAL SWAB SELF - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Frozen, Verified

Site No: 1125

Site Name: (1125) Meridian Clinical Research

Subject No: 11251154

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:09

Feb-04-2021 11:51:33 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not done, subject refuses at this time, he was confirmed to have had covid.	Initial Entry
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5.a

Date	Location	User	Value	Reason
Mar-08-2021 09:45:59 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Sample ID: AA03141	Initial Entry

5.a Sample ID

Date	Location	User	Value	Reason
Mar-08-2021 14:54:25 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Closed	Response satisfies query
Mar-08-2021 09:46:33 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Answered	Data is correct
Mar-08-2021 09:45:59 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Opened	Barcode contains unexpected characters (Q, A, E, I, O, or U). Please review and correct as appropriate.
Mar-08-2021 09:45:59 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> AA03141	Initial Entry

090177e196ae3d1e\Final\Final On: 01-Apr-2021 04:27 (GMT)

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit **Form:** ELECTRONIC SAMPLE TRACKING - NASAL SWAB - eCRF Audit Trail History on Feb/04/2021

**Form Version:** 22-Apr-2020 21:03

**Form Status:** Data Complete, Frozen, Verified

**Site No:** 1125

**Site Name:** (1125) Meridian Clinical Research

**Subject No:** 11251154

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 11:09

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**1. Data Origin**

Date	Location	User	Value	Reason
Feb-04-2021 11:50:07 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> SITE	Initial Entry

**2. Sample Type**

Date	Location	User	Value	Reason
Feb-04-2021 11:50:07 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> NASAL_SWAB	Initial Entry

**3. Sample Collected?**

Date	Location	User	Value	Reason
Feb-04-2021 11:50:07 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO	Initial Entry

**4. If no sample was collected or sample was not collected according to protocol, please provide reason:**

Date	Location	User	Value	Reason
Feb-04-2021 11:50:07 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Telehealth visit	Initial Entry

090177e196ae3d1e\Final\Final On: 01-Apr-2021 04:27 (GMT)

Header Text: c4591001

Visit: POT\_COVID\_ILL 1 - Unscheduled Visit Form: HEALTH CARE UTILIZATION - eCRF Audit Trail History on Feb/04/2021

Form Version: 14-Jan-2021 02:24

Form Status: Data Complete

Site No: 1125

Site Name: (1125) Meridian Clinical Research

Subject No: 11251154

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:09

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*1.a*

Date	Location	User	Value	Reason
Feb-04-2021 11:53:22 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Type of Practitioner</b> SPECIA : LIST <b>Occurrence of Visits NO or Contacts:</b>	Initial Entry

*1.a Physician or Healthcare Professional:*

Date	Location	User	Value	Reason
Feb-04-2021 11:53:22 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> SPECIALIST	Initial Entry

*1.a Occurrence of Visits or Contacts:*

Date	Location	User	Value	Reason
Feb-04-2021 11:53:22 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO	Initial Entry

*1.b*

Date	Location	User	Value	Reason
Feb-04-2021 11:53:22 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Type of Practitioner:</b> EMERGENC Y ROOM <b>Occurrence of YES Visits or Cont</b> <i>Number of Vi sits or Conta cts:</i>  1	Initial Entry

090177e196ae3d1e\Final\Final On: 01-Apr-2021 04:27 (GMT)

Header Text: c4591001

Visit: POT\_COVID\_ILL 1 - Unscheduled Visit Form: HEALTH CARE UTILIZATION - eCRF Audit Trail History on Feb/04/2021

Form Version: 14-Jan-2021 02:24

Form Status: Data Complete

Site No: 1125

Site Name: (1125) Meridian Clinical Research

Subject No: 11251154

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:09

***1.b Physician or Healthcare Professional:***

Date	Location	User	Value	Reason
Feb-04-2021 11:53:22 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> EMERGENCY ROOM	Initial Entry

***1.b Occurrence of Visits or Contacts:***

Date	Location	User	Value	Reason
Feb-04-2021 11:53:22 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> YES <i>Number of Visits or Contacts:</i>  1	Initial Entry

***1.c***

Date	Location	User	Value	Reason
Feb-04-2021 11:53:22 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Type of Practitioner:</b> PRIMARY CARE PHYSICIAN <b>Occurrence of Visits or Contacts:</b> YES <i>Number of Visits or Contacts:</i>  1	Initial Entry

090177e196ae3d1e\Final\Final On: 01-Apr-2021 04:27 (GMT)

**Header Text:** c4591001**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit **Form:** HEALTH CARE UTILIZATION - eCRF Audit Trail History on Feb/04/2021**Form Version:** 14-Jan-2021 02:24**Form Status:** Data Complete**Site No:** 1125**Site Name:** (1125) Meridian Clinical Research**Subject No:** 11251154**Subject Initials:** ---**Generated By:** (b) (4)**Generated Time (GMT):** 29-Mar-2021 11:09***1.c Physician or Healthcare Professional:***

Date	Location	User	Value	Reason
Feb-04-2021 11:53:22 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> PRIMARY CARE PHYSICIAN	Initial Entry

***1.c Occurrence of Visits or Contacts:***

Date	Location	User	Value	Reason
Feb-04-2021 11:53:22 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> YES <i>Number of Visits or Contacts:</i>  1	Initial Entry

***1.d***

Date	Location	User	Value	Reason
Feb-04-2021 11:53:22 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Type of Practitioner:</b> URGENT CARE <b>Occurrence of Visits or Contacts:</b> NO	Initial Entry

***1.d Physician or Healthcare Professional:***

Date	Location	User	Value	Reason
Feb-04-2021 11:53:22 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> URGENT CARE	Initial Entry

***1.d Occurrence of Visits or Contacts:***

Date	Location	User	Value	Reason
Feb-04-2021 11:53:22 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO	Initial Entry

***1.e***

Header Text: c4591001

Visit: POT\_COVID\_ILL 1 - Unscheduled Visit Form: HEALTH CARE UTILIZATION - eCRF Audit Trail History on Feb/04/2021

Form Version: 14-Jan-2021 02:24

Form Status: Data Complete

Site No: 1125

Site Name: (1125) Meridian Clinical Research

Subject No: 11251154

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:09

Date	Location	User	Value	Reason
Feb-04-2021 11:53:22 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Type of Practitioner:</b> TELEPHONE CONSULTATION <b>Occurrence of Visits or Contacts:</b> NO	Initial Entry

*I.e Physician or Healthcare Professional:*

Date	Location	User	Value	Reason
Feb-04-2021 11:53:22 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> TELEPHONE CONSULTATION	Initial Entry

*I.e Occurrence of Visits or Contacts:*

Date	Location	User	Value	Reason
Feb-04-2021 11:53:22 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO	Initial Entry

*I.f*

Date	Location	User	Value	Reason
Feb-04-2021 11:53:22 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Type of Practitioner:</b> OTHER <b>Occurrence of Visits or Contacts:</b> YES <i>Number of Visits or Contacts:</i> 1	Initial Entry

090177e196ae3d1e\Final\Final On: 01-Apr-2021 04:27 (GMT)

Header Text: c4591001

Visit: POT\_COVID\_ILL 1 - Unscheduled Visit Form: HEALTH CARE UTILIZATION - eCRF Audit Trail History on Feb/04/2021

Form Version: 14-Jan-2021 02:24

Form Status: Data Complete

Site No: 1125

Site Name: (1125) Meridian Clinical Research

Subject No: 11251154

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:09

*1.f Physician or Healthcare Professional:*

Date	Location	User	Value	Reason
Feb-04-2021 11:53:22 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> OTHER	Initial Entry

*1.f Occurrence of Visits or Contacts:*

Date	Location	User	Value	Reason
Feb-04-2021 11:53:22 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> YES <i>Number of Visits or Contacts:</i>  1	Initial Entry

*2. Other Type of Practitioner Specify:*

Date	Location	User	Value	Reason
Feb-22-2021 10:35:09 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Closed	Response satisfies query
Feb-19-2021 13:45:51 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Answered	Original value is correct
Feb-08-2021 11:04:14 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Opened	Clin: Please record bamlanivimab on Concomitant Medications - Prohibited CRF under immunoglobulins.
Feb-04-2021 11:53:22 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Outpatient BAM infusion	Initial Entry

*3. Has the subject been hospitalized due to potential COVID-19 illness?*

Date	Location	User	Value	Reason
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090177e196ae3d1e\Final\Final On: 01-Apr-2021 04:27 (GMT)

Header Text: c4591001

Visit: POT\_COVID\_ILL 1 - Unscheduled Visit Form: HEALTH CARE UTILIZATION - eCRF Audit Trail History on Feb/04/2021

Form Version: 14-Jan-2021 02:24

Form Status: Data Complete

Site No: 1125

Site Name: (1125) Meridian Clinical Research

Subject No: 11251154

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:09

Mar-10-2021 11:13:04 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 2: Closed	Response satisfies query
Mar-10-2021 10:26:18 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 2: Answered	requesting information
Mar-09-2021 20:29:46 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 2: Reissued:Opened	Clin: Please make every effort to obtain and record this information.
Mar-09-2021 17:03:12 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 2: Answered	Medical records received so far do not have the info requested
Mar-05-2021 14:24:40 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 2: Reissued:Opened	Clin: As subject was hospitalized, data expected in RESP TX, LAB CHEM, LAB HEM, VITALS COV, PULSE OX, and IMAGING. However, these are all completed as Not Applicable. Please clarify.
Mar-05-2021 12:37:47 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 2: Answered	Forms updated by CRC
Mar-04-2021 14:39:59 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 2: Reissued:Opened	Clin: No data recorded in CRFs, please confirm.
Mar-04-2021 14:21:37 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 2: Answered	Changed data per query

090177e196ae3d1e\Final\Final On: 01-Apr-2021 04:27 (GMT)

**Header Text:** c4591001**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit **Form:** HEALTH CARE UTILIZATION - eCRF Audit Trail History on Feb/04/2021**Form Version:** 14-Jan-2021 02:24**Form Status:** Data Complete**Site No:** 1125**Site Name:** (1125) Meridian Clinical Research**Subject No:** 11251154**Subject Initials:** ---**Generated By:** (b) (4)**Generated Time (GMT):** 29-Mar-2021 11:09

Mar-03-2021 15:59:43 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 2: Opened	Clin: As subject was hospitalized, please complete RESP TX, ILL SEVERE, LAB CHEM, LAB HEM, VITALS COV, PULSE OX, OXYGEN, VASOPRESS, and IMAGING CRFs, as applicable.
Feb-16-2021 06:21:59 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Closed	Response satisfies query
Feb-15-2021 17:03:44 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Answered	Will complete when records available
Feb-08-2021 11:07:04 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Opened	Clin: As subject was hospitalized, please complete RESP TX, ILL SEVERE, LAB CHEM, LAB HEM, VITALS COV, PULSE OX, OXYGEN, VASOPRESS, and IMAGING CRFs, as applicable.
Feb-04-2021 11:53:22 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> YES Has the subject been in intensive care due to potential COVID-19 illness?  NO	Initial Entry

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit **Form:** HOSPITALIZATION DETAILS - Audit Trail  
on Feb/04/2021

**Form Version:** 22-Apr-2020 21:02

**Form Status:**

**Site No:** 1125

**Site Name:** (1125) Meridian Clinical Research

**Subject No:** 11251154

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 11:09

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Date	Location	User	Value	Reason
Feb-04-2021 11:53:45 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Form Created	

090177e196ae3d1e\Final\Final On: 01-Apr-2021 04:27 (GMT)

Header Text: c4591001

Visit: POT\_COVID\_ILL 1 - Unscheduled Visit Form: HOSPITALIZATION DETAILS - eCRF Audit Trail History on Feb/04/2021

Form Version: 22-Apr-2020 21:02

Form Status: Data Complete

Site No: 1125

Site Name: (1125) Meridian Clinical Research

Subject No: 11251154

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:09

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**1. Hospitalization Category:**

Date	Location	User	Value	Reason
Feb-04-2021 11:53:45 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> HOSPITALIZATION STATUS	Initial Entry

**2. Hospitalization Term:**

Date	Location	User	Value	Reason
Feb-04-2021 11:53:45 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> HOSPITAL	Initial Entry

**3. Admission Date:**

Date	Location	User	Value	Reason
Feb-04-2021 11:53:45 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Jan/28/2021	Initial Entry

**4. Ongoing?**

Date	Location	User	Value	Reason
Feb-04-2021 11:53:45 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO Discharge Date:  Feb/1/2021	Initial Entry

090177e196ae3d1e\Final\Final On: 01-Apr-2021 04:27 (GMT)

Header Text: c4591001

Visit: POT\_COVID\_ILL 1 - Unscheduled Visit Form: RESPIRATORY TREATMENT - eCRF Audit Trail History on Feb/04/2021

Form Version: 06-Jul-2020 21:53

Form Status: Data Complete, Frozen

Site No: 1125

Site Name: (1125) Meridian Clinical Research

Subject No: 11251154

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:09

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**1. What is the treatment Identifier?**

Date	Location	User	Value	Reason
Mar-04-2021 14:15:05 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Applicable	Initial Entry

**2. Concomitant Non-drug Treatment Pre-specified:**

Date	Location	User	Value	Reason
Mar-04-2021 14:15:05 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Applicable	Initial Entry

**3. Treatment:**

Date	Location	User	Value	Reason
Mar-04-2021 14:15:05 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Applicable	Initial Entry

**4. Treatment:**

Date	Location	User	Value	Reason
Mar-04-2021 14:15:05 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Applicable	Initial Entry

**5. Start Date:**

Date	Location	User	Value	Reason
Mar-04-2021 14:15:05 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Applicable	Initial Entry

**6. Ongoing?**

Date	Location	User	Value	Reason
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090177e196ae3d1e\Final\Final On: 01-Apr-2021 04:27 (GMT)

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit **Form:** RESPIRATORY TREATMENT - eCRF Audit Trail History on Feb/04/2021

**Form Version:** 06-Jul-2020 21:53

**Form Status:** Data Complete, Frozen

**Site No:** 1125

**Site Name:** (1125) Meridian Clinical Research

**Subject No:** 11251154

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 11:09

Mar-04-2021 14:15:05 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Applicable	Initial Entry
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**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit **Form:** ILLNESS DETAILS - eCRF Audit Trail History  
on Feb/04/2021

**Form Version:** 06-Jul-2020 21:52

**Form Status:** Data Complete

**Site No:** 1125

**Site Name:** (1125) Meridian Clinical Research

**Subject No:** 11251154

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 11:09

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**1. Category of Clinical Event:**

Date	Location	User	Value	Reason
Mar-04-2021 14:15:42 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> POTENTIAL COVID-19 ILLNE SS	Initial Entry

**2. Was a diagnosis obtained for Potential COVID-19 Illness?**

Date	Location	User	Value	Reason
Mar-04-2021 14:21:15 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Closed	Close Auto Query
Mar-04-2021 14:21:15 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> YES <i>Respiratory Illness Diagnosis</i> :  Covid-19  Date of Diagnosis:  Jan/26/2021	Transcription Error
Mar-04-2021 14:15:42 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Opened	Yes is selected, however, either the diagnosis details or date of diagnosis is missing. Please correct.
Mar-04-2021 14:15:42 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> YES <i>Respiratory Illness Diagnosis</i> :  Covid-19	Initial Entry

**3. Toxicity Grade:**

090177e196ae3d1e\Final\Final On: 01-Apr-2021 04:27 (GMT)

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit **Form:** ILLNESS DETAILS - eCRF Audit Trail History on Feb/04/2021

**Form Version:** 06-Jul-2020 21:52

**Form Status:** Data Complete

**Site No:** 1125

**Site Name:** (1125) Meridian Clinical Research

**Subject No:** 11251154

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 11:09

Date	Location	User	Value	Reason
Mar-04-2021 14:15:42 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> 3	Initial Entry

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit **Form:** ILLNESS DETAILS - SEVERE - eCRF Audit Trail History on Feb/04/2021

**Form Version:** 17-Jul-2020 21:55

**Form Status:** Data Complete, Frozen

**Site No:** 1125

**Site Name:** (1125) Meridian Clinical Research

**Subject No:** 11251154

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 11:09

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**1. Category of Clinical Event:**

Date	Location	User	Value	Reason
Mar-04-2021 14:16:15 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Applicable	Initial Entry

**2. Subcategory of Clinical Event:**

Date	Location	User	Value	Reason
Mar-04-2021 14:16:15 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Applicable	Initial Entry

**3. Was a diagnosis obtained?**

Date	Location	User	Value	Reason
Mar-04-2021 14:16:15 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Applicable	Initial Entry

**4. Toxicity Grade:**

Date	Location	User	Value	Reason
Mar-04-2021 14:16:15 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Applicable	Initial Entry

090177e196ae3d1e\Final\Final On: 01-Apr-2021 04:27 (GMT)

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit **Form:** LOCAL LABORATORY DATA - REPEATING CHEMISTRY  
on Feb/04/2021 - eCRF Audit Trail History

**Form Version:** 21-Aug-2020 02:49

**Form Status:** Data Complete, Frozen

**Site No:** 1125

**Site Name:** (1125) Meridian Clinical Research

**Subject No:** 11251154

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 11:09

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**1. Lab Panel:**

Date	Location	User	Value	Reason
Mar-04-2021 14:16:40 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Applicable	Initial Entry

**2. Laboratory Name and Address**

Date	Location	User	Value	Reason
Mar-04-2021 14:16:40 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Applicable	Initial Entry

**3. Collection Date:**

Date	Location	User	Value	Reason
Mar-04-2021 14:16:40 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Applicable	Initial Entry

**4. Specimen Type:**

Date	Location	User	Value	Reason
Mar-04-2021 14:16:40 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Applicable	Initial Entry

**5.a**

Date	Location	User	Value	Reason
Mar-04-2021 14:16:40 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Sponsor-Defined I</b> Not Appli <b>dentifier:</b> cable <b>Test::</b> Not Appli cable	Initial Entry

090177e196ae3d1e\Final\Final On: 01-Apr-2021 04:27 (GMT)

Header Text: c4591001

Visit: POT\_COVID\_ILL 1 - Unscheduled Visit Form: LOCAL LABORATORY DATA - REPEATING CHEMISTRY  
on Feb/04/2021 - eCRF Audit Trail History

Form Version: 21-Aug-2020 02:49

Form Status: Data Complete, Frozen

Site No: 1125

Site Name: (1125) Meridian Clinical Research

Subject No: 11251154

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:09

			Result::	Not Applicable
			Not Done::	Not Applicable
			Lab Normal Range:	Not Applicable

5.a Sponsor ID:

Date	Location	User	Value	Reason
Mar-04-2021 14:16:40 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Applicable	Initial Entry

5.a Test:

Date	Location	User	Value	Reason
Mar-04-2021 14:16:40 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Applicable	Initial Entry

5.a Result:

Date	Location	User	Value	Reason
Mar-04-2021 14:16:40 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Applicable	Initial Entry

5.a Not Done:

Date	Location	User	Value	Reason
Mar-04-2021 14:16:40 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Applicable	Initial Entry

5.a LNMT

Date	Location	User	Value	Reason
Mar-04-2021 14:16:40 (UTC-06:00) Central	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Applicable	Initial Entry

090177e196ae3d1e\Final\Final On: 01-Apr-2021 04:27 (GMT)

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit **Form:** LOCAL LABORATORY DATA - REPEATING CHEMISTRY  
on Feb/04/2021 - eCRF Audit Trail History

**Form Version:** 21-Aug-2020 02:49

**Form Status:** Data Complete, Frozen

**Site No:** 1125

**Site Name:** (1125) Meridian Clinical Research

**Subject No:** 11251154

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 11:09

Time (US & Canada)

(b) (4), (b) (6)

**5.b**

Date	Location	User	Value	Reason
Mar-04-2021 14:16:40 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Sponsor-Defined Identifier:</b> Not Applicable <b>Test::</b> Not Applicable <b>Result::</b> Not Applicable <b>Not Done::</b> Not Applicable <b>Lab Normal Range:</b> Not Applicable	Initial Entry

090177e196ae3d1e\Final\Final On: 01-Apr-2021 04:27 (GMT)

Header Text: c4591001

Visit: POT\_COVID\_ILL 1 - Unscheduled Visit Form: LOCAL LABORATORY DATA - REPEATING CHEMISTRY  
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Form Version: 21-Aug-2020 02:49

Form Status: Data Complete, Frozen

Site No: 1125

Site Name: (1125) Meridian Clinical Research

Subject No: 11251154

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:09

**5.b Sponsor ID:**

Date	Location	User	Value	Reason
Mar-04-2021 14:16:40 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Applicable	Initial Entry

**5.b Test:**

Date	Location	User	Value	Reason
Mar-04-2021 14:16:40 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Applicable	Initial Entry

**5.b Result:**

Date	Location	User	Value	Reason
Mar-04-2021 14:16:40 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Applicable	Initial Entry

**5.b Not Done:**

Date	Location	User	Value	Reason
Mar-04-2021 14:16:40 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Applicable	Initial Entry

**5.b LNMT**

Date	Location	User	Value	Reason
Mar-04-2021 14:16:40 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Applicable	Initial Entry

**5.c**

Date	Location	User	Value	Reason
Mar-04-2021 14:16:40 (UTC-06:00) Central	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Sponsor-Defined I Not Appli	Initial Entry

090177e196ae3d1e\Final\Final On: 01-Apr-2021 04:27 (GMT)

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit **Form:** LOCAL LABORATORY DATA - REPEATING CHEMISTRY  
on Feb/04/2021 - eCRF Audit Trail History

**Form Version:** 21-Aug-2020 02:49

**Form Status:** Data Complete, Frozen

**Site No:** 1125

**Site Name:** (1125) Meridian Clinical Research

**Subject No:** 11251154

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 11:09

Time (US & Canada)	(b) (4), (b) (6)	<b>dentifier:</b> cable
		<b>Test::</b> Not Appli cable
		<b>Result::</b> Not Appli cable
		<b>Not Done::</b> Not Appli cable
		<b>Lab Normal Rang e:</b> Not Appli cable

Header Text: c4591001

Visit: POT\_COVID\_ILL 1 - Unscheduled Visit Form: LOCAL LABORATORY DATA - REPEATING CHEMISTRY - eCRF Audit Trail History  
on Feb/04/2021

Form Version: 21-Aug-2020 02:49

Form Status: Data Complete, Frozen

Site No: 1125

Site Name: (1125) Meridian Clinical Research

Subject No: 11251154

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:09

5.c Sponsor ID:

Date	Location	User	Value	Reason
Mar-04-2021 14:16:40 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Applicable	Initial Entry

5.c Test:

Date	Location	User	Value	Reason
Mar-04-2021 14:16:40 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Applicable	Initial Entry

5.c Result:

Date	Location	User	Value	Reason
Mar-04-2021 14:16:40 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Applicable	Initial Entry

5.c Not Done:

Date	Location	User	Value	Reason
Mar-04-2021 14:16:40 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Applicable	Initial Entry

5.c LNMT

Date	Location	User	Value	Reason
Mar-04-2021 14:16:40 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Applicable	Initial Entry

5.d

Date	Location	User	Value	Reason
Mar-04-2021 14:16:40 (UTC-06:00) Central	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Sponsor-Defined I Not Appli	Initial Entry

090177e196ae3d1e\Final\Final On: 01-Apr-2021 04:27 (GMT)

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit **Form:** LOCAL LABORATORY DATA - REPEATING CHEMISTRY  
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**Form Version:** 21-Aug-2020 02:49

**Form Status:** Data Complete, Frozen

**Site No:** 1125

**Site Name:** (1125) Meridian Clinical Research

**Subject No:** 11251154

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 11:09

Time (US & Canada)	(b) (4), (b) (6)	<b>dentifier:</b> cable
		<b>Test::</b> Not Appli cable
		<b>Result::</b> Not Appli cable
		<b>Not Done::</b> Not Appli cable
		<b>Lab Normal Rang e:</b> Not Appli cable

Header Text: c4591001

Visit: POT\_COVID\_ILL 1 - Unscheduled Visit Form: LOCAL LABORATORY DATA - REPEATING CHEMISTRY  
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Form Version: 21-Aug-2020 02:49

Form Status: Data Complete, Frozen

Site No: 1125

Site Name: (1125) Meridian Clinical Research

Subject No: 11251154

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:09

5.d Sponsor ID:

Date	Location	User	Value	Reason
Mar-04-2021 14:16:40 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Applicable	Initial Entry

5.d Test:

Date	Location	User	Value	Reason
Mar-04-2021 14:16:40 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Applicable	Initial Entry

5.d Result:

Date	Location	User	Value	Reason
Mar-04-2021 14:16:40 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Applicable	Initial Entry

5.d Not Done:

Date	Location	User	Value	Reason
Mar-04-2021 14:16:40 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Applicable	Initial Entry

5.d LNMT

Date	Location	User	Value	Reason
Mar-04-2021 14:16:40 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Applicable	Initial Entry

5.e

Date	Location	User	Value	Reason
Mar-04-2021 14:16:40 (UTC-06:00) Central	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Sponsor-Defined I Not Appli	Initial Entry

090177e196ae3d1e\Final\Final On: 01-Apr-2021 04:27 (GMT)

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit **Form:** LOCAL LABORATORY DATA - REPEATING CHEMISTRY  
on Feb/04/2021 - eCRF Audit Trail History

**Form Version:** 21-Aug-2020 02:49

**Form Status:** Data Complete, Frozen

**Site No:** 1125

**Site Name:** (1125) Meridian Clinical Research

**Subject No:** 11251154

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 11:09

Time (US & Canada)	(b) (4), (b) (6)	<b>dentifier:</b>	cable
		<b>Test::</b>	Not Appli cable
		<b>Result::</b>	Not Appli cable
		<b>Not Done::</b>	Not Appli cable
		<b>Lab Normal Rang e:</b>	Not Appli cable

Header Text: c4591001

Visit: POT\_COVID\_ILL 1 - Unscheduled Visit Form: LOCAL LABORATORY DATA - REPEATING CHEMISTRY - eCRF Audit Trail History

Form Version: 21-Aug-2020 02:49

Form Status: Data Complete, Frozen

Site No: 1125

Site Name: (1125) Meridian Clinical Research

Subject No: 11251154

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:09

5.e Sponsor ID:

Date	Location	User	Value	Reason
Mar-04-2021 14:16:40 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Applicable	Initial Entry

5.e Test:

Date	Location	User	Value	Reason
Mar-04-2021 14:16:40 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Applicable	Initial Entry

5.e Result:

Date	Location	User	Value	Reason
Mar-04-2021 14:16:40 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Applicable	Initial Entry

5.e Not Done:

Date	Location	User	Value	Reason
Mar-04-2021 14:16:40 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Applicable	Initial Entry

5.e LNMT

Date	Location	User	Value	Reason
Mar-04-2021 14:16:40 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Applicable	Initial Entry

5.f

Date	Location	User	Value	Reason
Mar-04-2021 14:16:40 (UTC-06:00) Central	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Sponsor-Defined I Not Appli	Initial Entry

090177e196ae3d1e\Final\Final On: 01-Apr-2021 04:27 (GMT)

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit **Form:** LOCAL LABORATORY DATA - REPEATING CHEMISTRY  
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**Form Version:** 21-Aug-2020 02:49

**Form Status:** Data Complete, Frozen

**Site No:** 1125

**Site Name:** (1125) Meridian Clinical Research

**Subject No:** 11251154

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 11:09

Time (US & Canada)	(b) (4), (b) (6)	<b>dentifier:</b> cable
		<b>Test::</b> Not Appli cable
		<b>Result::</b> Not Appli cable
		<b>Not Done::</b> Not Appli cable
		<b>Lab Normal Rang e:</b> Not Appli cable

Header Text: c4591001

Visit: POT\_COVID\_ILL 1 - Unscheduled Visit Form: LOCAL LABORATORY DATA - REPEATING CHEMISTRY  
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Form Version: 21-Aug-2020 02:49

Form Status: Data Complete, Frozen

Site No: 1125

Site Name: (1125) Meridian Clinical Research

Subject No: 11251154

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:09

5.f Sponsor ID:

Date	Location	User	Value	Reason
Mar-04-2021 14:16:40 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Applicable	Initial Entry

5.f Test:

Date	Location	User	Value	Reason
Mar-04-2021 14:16:40 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Applicable	Initial Entry

5.f Result:

Date	Location	User	Value	Reason
Mar-04-2021 14:16:40 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Applicable	Initial Entry

5.f Not Done:

Date	Location	User	Value	Reason
Mar-04-2021 14:16:40 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Applicable	Initial Entry

5.f LNMT

Date	Location	User	Value	Reason
Mar-04-2021 14:16:40 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Applicable	Initial Entry

5.g

Date	Location	User	Value	Reason
Mar-04-2021 14:16:40 (UTC-06:00) Central	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Sponsor-Defined I Not Appli	Initial Entry

090177e196ae3d1e\Final\Final On: 01-Apr-2021 04:27 (GMT)

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit **Form:** LOCAL LABORATORY DATA - REPEATING CHEMISTRY  
on Feb/04/2021 - eCRF Audit Trail History

**Form Version:** 21-Aug-2020 02:49

**Form Status:** Data Complete, Frozen

**Site No:** 1125

**Site Name:** (1125) Meridian Clinical Research

**Subject No:** 11251154

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 11:09

Time (US & Canada)	(b) (4), (b) (6)	<b>dentifier:</b> cable
		<b>Test::</b> Not Appli cable
		<b>Result::</b> Not Appli cable
		<b>Not Done::</b> Not Appli cable
		<b>Lab Normal Rang e:</b> Not Appli cable

Header Text: c4591001

Visit: POT\_COVID\_ILL 1 - Unscheduled Visit Form: LOCAL LABORATORY DATA - REPEATING CHEMISTRY  
on Feb/04/2021 - eCRF Audit Trail History

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Form Status: Data Complete, Frozen

Site No: 1125

Site Name: (1125) Meridian Clinical Research

Subject No: 11251154

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:09

**5.g Sponsor ID:**

Date	Location	User	Value	Reason
Mar-04-2021 14:16:40 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Applicable	Initial Entry

**5.g Test:**

Date	Location	User	Value	Reason
Mar-04-2021 14:16:40 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Applicable	Initial Entry

**5.g Result:**

Date	Location	User	Value	Reason
Mar-04-2021 14:16:40 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Applicable	Initial Entry

**5.g Not Done:**

Date	Location	User	Value	Reason
Mar-04-2021 14:16:40 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Applicable	Initial Entry

**5.g LNMT**

Date	Location	User	Value	Reason
Mar-04-2021 14:16:40 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Applicable	Initial Entry

090177e196ae3d1e\Final\Final On: 01-Apr-2021 04:27 (GMT)

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit **Form:** LOCAL LABORATORY DATA - REPEATING Hematology - on Feb/04/2021 eCRF Audit Trail History

**Form Version:** 21-Aug-2020 02:51

**Form Status:** Data Complete, Frozen

**Site No:** 1125

**Site Name:** (1125) Meridian Clinical Research

**Subject No:** 11251154

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 11:09

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**1. Lab Panel:**

Date	Location	User	Value	Reason
Mar-04-2021 14:17:35 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Applicable	Initial Entry

**2. Laboratory Name and Address**

Date	Location	User	Value	Reason
Mar-04-2021 14:17:35 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Applicable	Initial Entry

**3. Collection Date:**

Date	Location	User	Value	Reason
Mar-04-2021 14:17:35 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Applicable	Initial Entry

**4. Specimen Type:**

Date	Location	User	Value	Reason
Mar-04-2021 14:17:35 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Applicable	Initial Entry

**5.a**

Date	Location	User	Value	Reason
Mar-04-2021 14:17:35 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Sponsor-Defined I</b> Not Appli <b>dentifier:</b> cable <b>Test::</b> Not Appli cable	Initial Entry

090177e196ae3d1e\Final\Final On: 01-Apr-2021 04:27 (GMT)

Header Text: c4591001

Visit: POT\_COVID\_ILL 1 - Unscheduled Visit Form: LOCAL LABORATORY DATA - REPEATING Hematology - eCRF Audit Trail History on Feb/04/2021

Form Version: 21-Aug-2020 02:51

Form Status: Data Complete, Frozen

Site No: 1125

Site Name: (1125) Meridian Clinical Research

Subject No: 11251154

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:09

			Result::	Not Applicable
			Not Done::	Not Applicable
			Lab Normal Range:	Not Applicable

5.a Sponsor ID:

Date	Location	User	Value	Reason
Mar-04-2021 14:17:35 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry

5.a Test:

Date	Location	User	Value	Reason
Mar-04-2021 14:17:35 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry

5.a Result:

Date	Location	User	Value	Reason
Mar-04-2021 14:17:35 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry

5.a Not Done:

Date	Location	User	Value	Reason
Mar-04-2021 14:17:35 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry

5.a LNMT

Date	Location	User	Value	Reason
Mar-04-2021 14:17:35 (UTC-06:00) Central	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry

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**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit **Form:** LOCAL LABORATORY DATA - REPEATING Hematology - on Feb/04/2021  
**eCRF Audit Trail History**

**Form Version:** 21-Aug-2020 02:51

**Form Status:** Data Complete, Frozen

**Site No:** 1125

**Site Name:** (1125) Meridian Clinical Research

**Subject No:** 11251154

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 11:09

Time (US & Canada)

(b) (4), (b) (6)

**5.b**

Date	Location	User	Value	Reason
Mar-04-2021 14:17:35 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Sponsor-Defined Identifier:</b> Not Applicable <b>Test::</b> Not Applicable <b>Result::</b> Not Applicable <b>Not Done::</b> Not Applicable <b>Lab Normal Range:</b> Not Applicable	Initial Entry

090177e196ae3d1e\Final\Final On: 01-Apr-2021 04:27 (GMT)

Header Text: c4591001

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Date	Location	User	Value	Reason
Mar-04-2021 14:17:35 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Applicable	Initial Entry

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Date	Location	User	Value	Reason
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5.b Result:

Date	Location	User	Value	Reason
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Date	Location	User	Value	Reason
Mar-04-2021 14:17:35 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Applicable	Initial Entry

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Date	Location	User	Value	Reason
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5.c

Date	Location	User	Value	Reason
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**Generated Time (GMT):** 29-Mar-2021 11:09

Time (US & Canada)	(b) (4), (b) (6)	<b>dentifier:</b> cable	
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		<b>Lab Normal Range:</b> Not Appli cable	

Header Text: c4591001

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Date	Location	User	Value	Reason
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Date	Location	User	Value	Reason
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Time (US & Canada)	(b) (4), (b) (6)	<b>dentifier:</b>	cable
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		<b>Not Done::</b>	Not Appli cable
		<b>Lab Normal Rang e:</b>	Not Appli cable

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**Generated Time (GMT):** 29-Mar-2021 11:09

Time (US & Canada)	(b) (4), (b) (6)	<b>dentifier:</b> cable
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Header Text: c4591001

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Date	Location	User	Value	Reason
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Time (US & Canada)	(b) (4), (b) (6)	<b>dentifier:</b>	cable
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		<b>Not Done::</b>	Not Appli cable
		<b>Lab Normal Rang e:</b>	Not Appli cable

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Date	Location	User	Value	Reason
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Date	Location	User	Value	Reason
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Date	Location	User	Value	Reason
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5.j Not Done:

Date	Location	User	Value	Reason
Mar-04-2021 14:17:35 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Applicable	Initial Entry

5.j LNMT

Date	Location	User	Value	Reason
Mar-04-2021 14:17:35 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Applicable	Initial Entry

090177e196ae3d1e\Final\Final On: 01-Apr-2021 04:27 (GMT)

Header Text: c4591001

Visit: POT\_COVID\_ILL 1 - Unscheduled Visit Form: VITAL SIGNS - COVID - eCRF Audit Trail History on Feb/04/2021

Form Version: 21-Aug-2020 02:50

Form Status: Data Complete, Frozen

Site No: 1125

Site Name: (1125) Meridian Clinical Research

Subject No: 11251154

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:09

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**1. Date:**

Date	Location	User	Value	Reason
Mar-04-2021 14:18:00 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Applicable	Initial Entry

**2.a**

Date	Location	User	Value	Reason
Mar-04-2021 14:18:00 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Record Identifier::</b> Not Applicable <b>Systolic::</b> Not Applicable <b>Diastolic::</b> Not Applicable <b>Respiratory Rate in respirations/minute:</b> Not Applicable <b>Heart Rate in beats/minute:</b> Not Applicable	Initial Entry

**2.a Record Identifier:**

Date	Location	User	Value	Reason
Mar-04-2021 14:18:00 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Applicable	Initial Entry

**2.a Systolic:**

Date	Location	User	Value	Reason
Mar-04-2021 14:18:00 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Applicable	Initial Entry

**2.a Diastolic:**

090177e196ae3d1e\Final\Final On: 01-Apr-2021 04:27 (GMT)

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit **Form:** VITAL SIGNS - COVID - eCRF Audit Trail History on Feb/04/2021

**Form Version:** 21-Aug-2020 02:50

**Form Status:** Data Complete, Frozen

**Site No:** 1125

**Site Name:** (1125) Meridian Clinical Research

**Subject No:** 11251154

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 11:09

Date	Location	User	Value	Reason
Mar-04-2021 14:18:00 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Applicable	Initial Entry

**2.a Respiratory Rate in respirations/minute:**

Date	Location	User	Value	Reason
Mar-04-2021 14:18:00 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Applicable	Initial Entry

**2.a Heart Rate in beats/minute:**

Date	Location	User	Value	Reason
Mar-04-2021 14:18:00 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Applicable	Initial Entry

090177e196ae3d1e\Final\Final On: 01-Apr-2021 04:27 (GMT)

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit **Form:** VITAL SIGNS - PULSE OX ROOM AIR - eCRF Audit Trail on Feb/04/2021 History

**Form Version:** 21-Aug-2020 02:51

**Form Status:** Data Complete, Frozen

**Site No:** 1125

**Site Name:** (1125) Meridian Clinical Research

**Subject No:** 11251154

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 11:09

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**1. Date:**

Date	Location	User	Value	Reason
Mar-04-2021 14:18:31 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Applicable	Initial Entry

**2.a**

Date	Location	User	Value	Reason
Mar-04-2021 14:18:31 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Record Identifier:</b> Not Applicable <b>Oxygen Saturation:</b> Not Applicable	Initial Entry

**2.a Record Identifier:**

Date	Location	User	Value	Reason
Mar-04-2021 14:18:31 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Applicable	Initial Entry

**2.a SPO2 Pulse Oximetry %**

Date	Location	User	Value	Reason
Mar-04-2021 14:18:31 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Applicable	Initial Entry

090177e196ae3d1e\Final\Final On: 01-Apr-2021 04:27 (GMT)

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit **Form:** OXYGENATION PARAMETERS - eCRF Audit Trail History on Feb/04/2021

**Form Version:** 06-Jul-2020 21:52

**Form Status:** Data Complete, Frozen

**Site No:** 1125

**Site Name:** (1125) Meridian Clinical Research

**Subject No:** 11251154

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 11:09

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**1. Date Time of Assessment:**

Date	Location	User	Value	Reason
Mar-04-2021 14:18:59 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Applicable	Initial Entry

**2. Arterial Blood Gases PaO2 (mmHg):**

Date	Location	User	Value	Reason
Mar-04-2021 14:18:59 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Applicable	Initial Entry

**3. FiO2 (Fraction of Inhaled Oxygen):**

Date	Location	User	Value	Reason
Mar-04-2021 14:18:59 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Applicable	Initial Entry

090177e196ae3d1e\Final\Final On: 01-Apr-2021 04:27 (GMT)

Header Text: c4591001

Visit: POT\_COVID\_ILL 1 - Unscheduled Visit Form: CONCOMITANT MEDICATIONS - VASOPRESSORS - eCRF Audit Trail History on Feb/04/2021

Form Version: 06-Jul-2020 21:55

Form Status: Data Complete, Frozen

Site No: 1125

Site Name: (1125) Meridian Clinical Research

Subject No: 11251154

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:09

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**1. What is the medication identifier?**

Date	Location	User	Value	Reason
Mar-04-2021 14:19:33 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Applicable	Initial Entry

**2. Category:**

Date	Location	User	Value	Reason
Mar-04-2021 14:19:33 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Applicable	Initial Entry

**3. Concomitant Medications Pre-specified:**

Date	Location	User	Value	Reason
Mar-04-2021 14:19:33 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Applicable	Initial Entry

**4. Medication:**

*Provide the complete generic drug name (including salt form, where applicable). Where generic name is unknown, enter the full trade or proprietary name. Include clarifying information in the Medication text (e.g., Ingredient(s), route, use, formulation).*

Date	Location	User	Value	Reason
Mar-04-2021 14:19:33 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Applicable	Initial Entry

**5. Start Date:**

Date	Location	User	Value	Reason
Mar-04-2021 14:19:33 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Applicable	Initial Entry

090177e196ae3d1e\Final\Final On: 01-Apr-2021 04:27 (GMT)

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit **Form:** CONCOMITANT MEDICATIONS - VASOPRESSORS -  
on Feb/04/2021 eCRF Audit Trail History

**Form Version:** 06-Jul-2020 21:55

**Form Status:** Data Complete, Frozen

**Site No:** 1125

**Site Name:** (1125) Meridian Clinical Research

**Subject No:** 11251154

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 11:09

**6. Ongoing?**

Date	Location	User	Value	Reason
Mar-04-2021 14:19:33 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Applicable	Initial Entry

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit **Form:** IMAGING - eCRF Audit Trail History  
on Feb/04/2021

**Form Version:** 06-Jul-2020 21:53

**Form Status:** Data Complete, Frozen

**Site No:** 1125

**Site Name:** (1125) Meridian Clinical Research

**Subject No:** 11251154

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 11:09

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**1. Date of Assessment:**

Date	Location	User	Value	Reason
Mar-04-2021 14:19:57 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Applicable	Initial Entry

**2. Location of Assessment:**

Date	Location	User	Value	Reason
Mar-04-2021 14:19:57 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Applicable	Initial Entry

**3. Type of Imaging Exam:**

Date	Location	User	Value	Reason
Mar-04-2021 14:19:57 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Applicable	Initial Entry

**4. Assessment:**

Date	Location	User	Value	Reason
Mar-04-2021 14:19:57 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Applicable	Initial Entry

090177e196ae3d1e\Final\Final On: 01-Apr-2021 04:27 (GMT)

**Header Text:** c4591001

**Visit:** POT\_COVID\_CONVA 1 - Unscheduled **Form:** DATE OF VISIT - ILLNESS CONVALESCENT - eCRF Audit Trail History  
Visit on Feb/27/2021

**Form Version:** 22-Apr-2020 21:04

**Form Status:** Data Complete, Frozen, Verified

**Site No:** 1125

**Site Name:** (1125) Meridian Clinical Research

**Subject No:** 11251154

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 11:09

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**1. Date of Visit**

Date	Location	User	Value	Reason
Feb-27-2021 10:52:45 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> Feb/27/2021	Initial Entry

**3. COVID-19 Illness Visit:**

Date	Location	User	Value	Reason
Feb-27-2021 10:52:45 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> COVID_A1	Initial Entry

090177e196ae3d1e\Final\Final On: 01-Apr-2021 04:27 (GMT)

Header Text: c4591001

Visit: POT\_COVID\_CONVA 1 - Unscheduled Form: ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY  
Visit on Feb/27/2021 - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Frozen, Verified

Site No: 1125

Site Name: (1125) Meridian Clinical Research

Subject No: 11251154

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:09

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**1. Data Origin**

Date	Location	User	Value	Reason
Feb-27-2021 10:53:04 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> SITE	Initial Entry

**2. Sample Type**

Date	Location	User	Value	Reason
Feb-27-2021 10:53:04 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> SERUM	Initial Entry

**3. Sample Collected?**

Date	Location	User	Value	Reason
Mar-01-2021 11:24:24 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Closed	Close Auto Query
Mar-01-2021 05:08:12 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Opened	'Sample Collected?' is Yes, however no barcodes are entered. Please review and correct as appropriate.
Feb-27-2021 10:53:04 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Candidate	'Sample Collected?' is Yes, however no barcodes are entered. Please review and correct as appropriate.
Feb-27-2021 10:53:04 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> YES Date of Collection:	Initial Entry

090177e196ae3d1e\Final\Final On: 01-Apr-2021 04:27 (GMT)

Header Text: c4591001

Visit: POT\_COVID\_CONVA 1 - Unscheduled Form: ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY  
Visit on Feb/27/2021 - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Frozen, Verified

Site No: 1125

Site Name: (1125) Meridian Clinical Research

Subject No: 11251154

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:09

			Feb/27/2021	
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5.a

Date	Location	User	Value	Reason
Mar-01-2021 11:24:24 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> Sample ID: BRHFYK	Initial Entry

5.a Sample ID

Date	Location	User	Value	Reason
Mar-01-2021 11:24:24 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> BRHFYK	Initial Entry

5.b

Date	Location	User	Value	Reason
Mar-01-2021 11:24:34 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> Sample ID: BMPGV7	Initial Entry

5.b Sample ID

Date	Location	User	Value	Reason
Mar-01-2021 11:24:34 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> BMPGV7	Initial Entry

5.c

Date	Location	User	Value	Reason
Mar-01-2021 11:24:44 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> Sample ID: BS5H6C	Initial Entry

090177e196ae3d1e\Final\Final On: 01-Apr-2021 04:27 (GMT)

**Header Text:** c4591001

**Visit:** POT\_COVID\_CONVA 1 - Unscheduled **Form:** ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY  
Visit on Feb/27/2021 - eCRF Audit Trail History

**Form Version:** 22-Apr-2020 21:03

**Form Status:** Data Complete, Frozen, Verified

**Site No:** 1125

**Site Name:** (1125) Meridian Clinical Research

**Subject No:** 11251154

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 11:09

*5.c Sample ID*

Date	Location	User	Value	Reason
Mar-01-2021 11:24:44 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> BS5H6C	Initial Entry

**Header Text:** c4591001

**Visit:** End of Treatment - Unscheduled

**Form:** DISPOSITION - TREATMENT - eCRF Audit Trail History

**Form Version:** 15-Sep-2020 21:55

**Form Status:** Data Complete, Locked, Frozen, Verified

**Site No:** 1125

**Site Name:** (1125) Meridian Clinical Research

**Subject No:** 11251154

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 11:09

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**1. Date of Completion/Discontinuation/Death :**

Date	Location	User	Value	Reason
Oct-23-2020 08:43:46 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Oct/23/2020	Initial Entry

**2. Phase of Disposition:**

Date	Location	User	Value	Reason
Oct-23-2020 08:43:46 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> VACCINATION	Initial Entry

**3. Status:**

Date	Location	User	Value	Reason
Oct-23-2020 08:43:46 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> COMPLETED	Initial Entry

090177e196ae3d1e\Final\Final On: 01-Apr-2021 04:27 (GMT)

**Header Text:** c4591001

**Visit:** Logs - Unscheduled

**Form Version:** 22-Apr-2020 21:02

**Site No:** 1125

**Subject No:** 11251154

**Generated By:** (b) (4)

**Form:** ADVERSE EVENT REPORT - Audit Trail

**Form Status:**

**Site Name:** (1125) Meridian Clinical Research

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 11:09

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Date	Location	User	Value	Reason
Feb-19-2021 13:44:32 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Form Created	

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1125

Subject No: 11251154

Generated By: (b) (4)

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Status: Data Complete, Answered Queries, Verified

Site Name: (1125) Meridian Clinical Research

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 11:09

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**1. Category:**

Date	Location	User	Value	Reason
Feb-19-2021 13:44:32 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> ADVERSE EVENT	Initial Entry

**2. AE ID:**

Date	Location	User	Value	Reason
Feb-19-2021 13:44:32 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> 1	Initial Entry

**3. Adverse Event:**

*(If possible specify diagnosis, not individual symptoms)*

Date	Location	User	Value	Reason
Feb-19-2021 13:44:32 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Covid-19	Initial Entry

**4. Start Date Time:**

Date	Location	User	Value	Reason
Mar-10-2021 23:46:17 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Closed	Response satisfies query
Mar-10-2021 16:18:10 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Answered	Transcription Error
Mar-10-2021 16:18:10 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Jan/20/2021 UNK:UNK	Transcription Error
Mar-10-2021 14:19:07 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Reissued:Opened	SAE RECON1: Thanks for your response. However onset date in EDC

090177e196ae3d1e\Final\Final On: 01-Apr-2021 04:27 (GMT)

**Header Text:** c4591001**Visit:** Logs - Unscheduled**Form Version:** 22-Apr-2020 21:02**Site No:** 1125**Subject No:** 11251154**Generated By:** (b) (4)**Form:** ADVERSE EVENT REPORT - eCRF Audit Trail History**Form Status:** Data Complete, Answered Queries, Verified**Site Name:** (1125) Meridian Clinical Research**Subject Initials:** ---**Generated Time (GMT):** 29-Mar-2021 11:09

				still shows 25JAN21. If safety database is correct, with onset date of 20JAN21, please update EDC or clarify.
Mar-10-2021 10:26:43 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Answered	corrected in EDC
Mar-10-2021 03:26:21 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Opened	SAE RECON: AER#2021123725 ,onset date was recorded as 20Jan2021 in Safety database however, recorded as 25Jan2021 on AE CRF. Please confirm correct Onset Date. If safety update is required, please submit a follow-up SAE form.
Feb-19-2021 13:44:32 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Jan/25/2021 UNK:UNK	Initial Entry

**5. Is the adverse event still ongoing?**

Date	Location	User	Value	Reason
Feb-27-2021 10:46:09 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO End Date Time:  Feb/14/2021 UNK:UNK	New Information
Feb-19-2021 13:44:32 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> YES	Initial Entry

**6. Toxicity Grade:**

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1125

Subject No: 11251154

Generated By: (b) (4)

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Status: Data Complete, Answered Queries, Verified

Site Name: (1125) Meridian Clinical Research

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 11:09

Date	Location	User	Value	Reason
Feb-19-2021 13:44:32 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> 3	Initial Entry

**7. Is the adverse event serious?**

**If Yes, NOTIFY PFIZER IMMEDIATELY.**

**Fatal; Life-threatening; Inpatient hospitalization or prolongation of existing hospitalization; Persistent or significant disability/incapacity; Congenital anomaly/birth defect; Important medical event (i.e. may jeopardize subject and may require medical/surgical intervention to prevent above outcomes).**

Date	Location	User	Value	Reason
Feb-21-2021 08:25:21 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Feb-19-2021 13:44:32 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Candidate	For AE Covid-19: Response to "Is the adverse event serious?" is 'Yes' but "Serious Adverse Event Number" is blank.
Feb-19-2021 13:44:32 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> YES Is this serious event associate d with congenital anomaly or birth defect?  NO  Did this serious event result i n death?  NO  Did this serious event require or prolong hospitalization?  YES	Initial Entry

090177e196ae3d1e\Final\Final On: 01-Apr-2021 04:27 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1125

Subject No: 11251154

Generated By: (b) (4)

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Status: Data Complete, Answered Queries, Verified

Site Name: (1125) Meridian Clinical Research

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 11:09

			<p>Did this serious event result in persistent or significant disability/incapacity?</p> <p>NO</p> <p>Is this serious event life threatening?</p> <p>NO</p> <p>Other medically important serious event</p> <p>NO</p>	
--	--	--	--	--

**8. Is this adverse event the result of a study Medication Error?**  
**If Yes, record the type of medication error on the Medication Error Log.**

Date	Location	User	Value	Reason
Feb-19-2021 13:44:32 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO	Initial Entry

**9. Is this event related to study treatment:**

Date	Location	User	Value	Reason
Feb-24-2021 10:19:29 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Closed	Response satisfies query
Feb-23-2021 14:09:53 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Answered	Correct as entered, PI assessed causality as Covid-19 infection
Feb-22-2021 00:56:41 (UTC-06:00)	ACV0PFEINFP6000.InFormAdapter.Discrepancy	PFE SDQ PROD (b) (4)	Query 1: Opened	Please review "If not related to study

090177e196ae3d1e\Final\Final On: 01-Apr-2021 04:27 (GMT)

**Header Text:** c4591001  
**Visit:** Logs - Unscheduled  
**Form Version:** 22-Apr-2020 21:02  
**Site No:** 1125  
**Subject No:** 11251154  
**Generated By:** (b) (4)

**Form:** ADVERSE EVENT REPORT - eCRF Audit Trail History  
**Form Status:** Data Complete, Answered Queries, Verified  
**Site Name:** (1125) Meridian Clinical Research  
**Subject Initials:** ---  
**Generated Time (GMT):** 29-Mar-2021 11:09

Central Time (US & Canada)				treatment other" field, the following text was indicated in the comment field [infection]. Any symptoms, AEs or other key data should be collected on the appropriate page. Please review and update as necessary. (b) (4) 
Feb-19-2021 13:44:32 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NOT RELATED  If Not Related to study treatment(s), this event is due to:  OTHER  <i>If Other, specify</i>	Initial Entry

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1125

Subject No: 11251154

Generated By: (b) (4)

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Status: Data Complete, Answered Queries, Verified

Site Name: (1125) Meridian Clinical Research

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 11:09

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10. Latest Action Taken with Study Treatment:

Date	Location	User	Value	Reason
Feb-19-2021 13:44:32 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NOT APPLICABLE	Initial Entry

11. Was a Concomitant Medication given?

Date	Location	User	Value	Reason
Feb-19-2021 13:44:32 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> YES	Initial Entry

12. Was a Non-Drug Treatment given?

Date	Location	User	Value	Reason
Feb-19-2021 13:44:32 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO	Initial Entry

13. What was the outcome of this adverse event?:

Date	Location	User	Value	Reason
Mar-12-2021 13:47:27 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 2: Answered	Follow up report is being completed to send
Mar-12-2021	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 2: Opened	SAE

090177e196ae3d1e\Final\Final On: 01-Apr-2021 04:27 (GMT)

**Header Text:** c4591001**Visit:** Logs - Unscheduled**Form Version:** 22-Apr-2020 21:02**Site No:** 1125**Subject No:** 11251154**Generated By:** (b) (4)**Form:** ADVERSE EVENT REPORT - eCRF Audit Trail History**Form Status:** Data Complete, Answered Queries, Verified**Site Name:** (1125) Meridian Clinical Research**Subject Initials:** ---**Generated Time (GMT):** 29-Mar-2021 11:09

07:26:29 (UTC-06:00) Central Time (US & Canada)		(b) (4), (b) (6)		RECON:AER#2021123725,outcome was updated to RECOVERED/RESOLVED on AE CRF while reported as Recovering/resolving in Safety database. Please confirm correct outcome. If safety update is required, please submit a follow-up form.
Feb-27-2021 10:46:44 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Closed	Close Auto Query
Feb-27-2021 10:46:44 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> RECOVERED/RE SOLVED	New Information
Feb-27-2021 10:46:09 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Opened	For AE Covid-19: Response to "What was the outcome of this adverse event?" is 'Recovering/Resolving' but AE End Date/Time is present.
Feb-19-2021 13:44:32 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> RECOVERING/R ESOLVING	Initial Entry

**14. Did the adverse event cause the subject to be discontinued from the study?**

Date	Location	User	Value	Reason
Feb-19-2021 13:44:32 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO	Initial Entry

**15. Serious Adverse Event Number: For Pfizer Use Only**

Date	Location	User	Value	Reason
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**Header Text:** c4591001

**Visit:** Logs - Unscheduled

**Form Version:** 22-Apr-2020 21:02

**Site No:** 1125

**Subject No:** 11251154

**Generated By:** (b) (4)

**Form:** ADVERSE EVENT REPORT - eCRF Audit Trail History

**Form Status:** Data Complete, Answered Queries, Verified

**Site Name:** (1125) Meridian Clinical Research

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 11:09

Feb-21-2021 08:25:21 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) [Redacted] [Redacted]	<b>Data Entry:</b> 2021123725	Initial Entry
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**Header Text:** c4591001

**Visit:** Logs - Unscheduled

**Form:** CONCOMITANT MEDICATIONS - PROHIBITED - Audit Trail

**Form Version:** 22-Apr-2020 21:03

**Form Status:**

**Site No:** 1125

**Site Name:** (1125) Meridian Clinical Research

**Subject No:** 11251154

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 11:09

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Date	Location	User	Value	Reason
Feb-15-2021 17:45:38 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Form Created	

Header Text: c4591001

Visit: Logs - Unscheduled

Form: CONCOMITANT MEDICATIONS - PROHIBITED - eCRF  
Audit Trail History

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Frozen, Verified

Site No: 1125

Site Name: (1125) Meridian Clinical Research

Subject No: 11251154

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:09

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**1. What is the medication identifier?**

Date	Location	User	Value	Reason
Feb-15-2021 17:45:38 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> 1	Initial Entry

**2. Category:**

Date	Location	User	Value	Reason
Feb-15-2021 17:45:38 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> IMMUNOGLOBULINS	Initial Entry

**3. Concomitant Medications Pre-specified:**

Date	Location	User	Value	Reason
Feb-15-2021 17:45:38 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> NO	Initial Entry

**4. Medication:**

*Provide the complete generic drug name (including salt form, where applicable). Where generic name is unknown, enter the full trade or proprietary name. Include clarifying information in the Medication text (e.g., Ingredient(s), route, use, formulation).*

Date	Location	User	Value	Reason
Feb-15-2021 17:45:38 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> bamlanivimab	Initial Entry

**5. Dose:**

Date	Location	User	Value	Reason
Mar-04-2021 06:16:03 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Closed	Response satisfies query

090177e196ae3d1e\Final\Final On: 01-Apr-2021 04:27 (GMT)

**Header Text:** c4591001**Visit:** Logs - Unscheduled**Form:** CONCOMITANT MEDICATIONS - PROHIBITED - eCRF  
Audit Trail History**Form Version:** 22-Apr-2020 21:03**Form Status:** Data Complete, Frozen, Verified**Site No:** 1125**Site Name:** (1125) Meridian Clinical Research**Subject No:** 11251154**Subject Initials:** ---**Generated By:** (b) (4)**Generated Time (GMT):** 29-Mar-2021 11:09

Mar-03-2021 14:54:20 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Answered	Initial Entry
Mar-03-2021 14:54:20 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> 750	Initial Entry
Feb-22-2021 05:27:45 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Reissued:Opened	DM1: Thank you for response. Please confirm by when data can be expected. Query would be re-issues post that date.
Feb-19-2021 13:45:08 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Answered	waiting for records to confirm dosage and dates
Feb-16-2021 23:50:08 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Opened	DM: Kindly review the form and update the missing data with yellow background.

**6. Dose Unit:**

Date	Location	User	Value	Reason
Mar-03-2021 14:54:20 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> mg	Initial Entry

**7. Dose Frequency:**

Date	Location	User	Value	Reason
Mar-03-2021 14:54:20 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> ONCE	Initial Entry

**8. Route:**

**Header Text:** c4591001

**Visit:** Logs - Unscheduled

**Form:** CONCOMITANT MEDICATIONS - PROHIBITED - eCRF  
Audit Trail History

**Form Version:** 22-Apr-2020 21:03

**Form Status:** Data Complete, Frozen, Verified

**Site No:** 1125

**Site Name:** (1125) Meridian Clinical Research

**Subject No:** 11251154

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 11:09

Date	Location	User	Value	Reason
Mar-03-2021 14:54:20 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> INTRAVENOUS	Initial Entry

**9. Start Date:**

Date	Location	User	Value	Reason
Mar-03-2021 14:54:20 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Jan/24/2021	Initial Entry

**10. Ongoing?**

Date	Location	User	Value	Reason
Mar-03-2021 14:54:20 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO End Date: Jan/24/2021	Initial Entry

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**Header Text:** c4591001

**Visit:** Potential ReVax Initial Contact -  
Unscheduled

**Form:** DATE OF VISIT - eCRF Audit Trail History

**Form Version:** 22-Apr-2020 21:02

**Form Status:** Data Complete, Frozen, Verified

**Site No:** 1125

**Site Name:** (1125) Meridian Clinical Research

**Subject No:** 11251154

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 11:09

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*1. Date of Visit*

Date	Location	User	Value	Reason
Feb-25-2021 11:50:59 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Feb/25/2021	Initial Entry

**Header Text:** c4591001

**Visit:** Potential ReVax Initial Contact -  
Unscheduled

**Form:** FURTHER VACCINATION CONFIRMATION - eCRF Audit  
Trail History

**Form Version:** 10-Dec-2020 02:25

**Form Status:** Data Complete, Frozen

**Site No:** 1125

**Site Name:** (1125) Meridian Clinical Research

**Subject No:** 11251154

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 11:09

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**1. Select appropriate response - Is participant willing to return for Vaccination 3?**

Date	Location	User	Value	Reason
Feb-25-2021 11:51:31 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Feb-25-2021 11:51:11 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Candidate	The response indicates participant was unblinded, however the TREATMENT UNBLINDED date is missing in the DISP visit. Please complete this date.
Feb-25-2021 11:51:11 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Participant is willing to return for Vaccination 3 Participant is:  eligible per other protocol allowance(s) and confirmed to have received only placebo at Vaccination 1/2	Initial Entry

090177e196ae3d1e\Final\Final On: 01-Apr-2021 04:27 (GMT)

**Header Text:** c4591001

**Visit:** Disposition - Unscheduled

**Form Version:** 22-Apr-2020 21:03

**Site No:** 1125

**Subject No:** 11251154

**Generated By:** (b) (4)

**Form:** TREATMENT UNBLINDED - eCRF Audit Trail History

**Form Status:** Data Complete, Frozen, Verified

**Site Name:** (1125) Meridian Clinical Research

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 11:09

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**1. Date Treatment Unblinded :**

Date	Location	User	Value	Reason
Feb-25-2021 11:51:31 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Feb/25/2021	Initial Entry

**2. Primary Reason for Unblinding:**

Date	Location	User	Value	Reason
Feb-25-2021 11:51:31 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> ASSESS ELIGIBILITY FOR A DDITIONAL VACCINATION	Initial Entry

090177e196ae3d1e\Final\Final On: 01-Apr-2021 04:27 (GMT)

**Header Text:** c4591001

**Visit:** V101\_VAX3

**Form:** DATE OF VISIT - eCRF Audit Trail History

**Form Version:** 22-Apr-2020 21:02

**Form Status:** Data Complete, Frozen, Verified

**Site No:** 1125

**Site Name:** (1125) Meridian Clinical Research

**Subject No:** 11251154

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 11:09

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*I. Date of Visit*

Date	Location	User	Value	Reason
Mar-03-2021 06:32:40 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Closed	As per site response
Mar-02-2021 17:10:51 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Answered	No, subject only came in for convalescent visit and not Visit 101 at this date
Mar-01-2021 13:59:45 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Reissued:Opened	DM RQ: Please confirm whether the participant received treatment during this visit.
Mar-01-2021 11:23:58 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Answered	Subject actually came in for Convalescent visit on this date. Changed data per query.
Mar-01-2021 04:33:18 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Opened	Erroneous Visit is marked, but date of visit is entered. Please either untick the erroneous visit button if visit occurred, or mark any forms containing data within this visit as Not Done/Not Applicable at the form level.
Feb-27-2021 10:52:29 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Candidate	Erroneous Visit is marked, but date of visit is entered.

090177e196ae3d1e\Final\Final On: 01-Apr-2021 04:27 (GMT)

**Header Text:** c4591001

**Visit:** V101\_VAX3

**Form Version:** 22-Apr-2020 21:02

**Site No:** 1125

**Subject No:** 11251154

**Generated By:** (b) (4)

**Form:** DATE OF VISIT - eCRF Audit Trail History

**Form Status:** Data Complete, Frozen, Verified

**Site Name:** (1125) Meridian Clinical Research

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 11:09

				Please either untick the erroneous visit button if visit occurred, or mark any forms containing data within this visit as Not Done/Not Applicable at the form level.
Feb-27-2021 10:37:41 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Feb/27/2021	Initial Entry

**2. Erroneous Visit**

Date	Location	User	Value	Reason
Feb-27-2021 10:52:29 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> ERRONEOUS VISIT	Initial Entry

090177e196ae3d1e\Final\Final On: 01-Apr-2021 04:27 (GMT)

**Header Text:** c4591001

**Visit:** V101\_VAX3

**Form:** INFORMED CONSENT - FURTHER VACCINATION - eCRF  
Audit Trail History

**Form Version:** 10-Dec-2020 02:31

**Form Status:** Data Complete, Frozen, Verified

**Site No:** 1125

**Site Name:** (1125) Meridian Clinical Research

**Subject No:** 11251154

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 11:09

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***I. Consent Was:***

<b>Date</b>	<b>Location</b>	<b>User</b>	<b>Value</b>	<b>Reason</b>
Mar-01-2021 11:21:59 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Applicable	Initial Entry
Feb-27-2021 10:53:24 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b>	Transcription Error
Feb-27-2021 10:38:10 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> OBTAINED Date Written Consent Obtain ed  Feb/27/2021	Initial Entry

090177e196ae3d1e\Final\Final On: 01-Apr-2021 04:27 (GMT)

Header Text: c4591001

Visit: V101\_VAX3

Form: DISPOSITION - SCREENING FOR FURTHER VACCINATION - eCRF Audit Trail History

Form Version: 10-Dec-2020 02:31

Form Status: Data Complete, Frozen, Verified

Site No: 1125

Site Name: (1125) Meridian Clinical Research

Subject No: 11251154

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:09

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**1. Date of Completion/Discontinuation/Death :**

Date	Location	User	Value	Reason
Mar-01-2021 11:22:36 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Applicable	Initial Entry
Feb-27-2021 10:57:29 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b>	Transcription Error
Feb-27-2021 10:44:49 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Feb/27/2021	Initial Entry

**2. Phase of Disposition:**

Date	Location	User	Value	Reason
Mar-01-2021 11:22:36 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> Not Applicable	Initial Entry
Feb-27-2021 10:57:29 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b>	Transcription Error
Feb-27-2021 10:44:49 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> REPEAT SCREENING 1	Initial Entry

**3. Status:**

Date	Location	User	Value	Reason
Mar-01-2021 11:22:36 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Applicable	Initial Entry
Feb-27-2021 10:54:40 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b>	Transcription Error

090177e196ae3d1e\Final\Final On: 01-Apr-2021 04:27 (GMT)

**Header Text:** c4591001

**Visit:** V101\_VAX3

**Form:** DISPOSITION - SCREENING FOR FURTHER  
VACCINATION - eCRF Audit Trail History

**Form Version:** 10-Dec-2020 02:31

**Form Status:** Data Complete, Frozen, Verified

**Site No:** 1125

**Site Name:** (1125) Meridian Clinical Research

**Subject No:** 11251154

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 11:09

Feb-27-2021 10:44:49 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> COMPLETED	Initial Entry
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**4. Specify Status:**

Date	Location	User	Value	Reason
Mar-01-2021 11:22:36 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Applicable	Initial Entry

Header Text: c4591001

Visit: V101\_VAX3

Form: ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY  
- eCRF Audit Trail History

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Frozen, Verified

Site No: 1125

Site Name: (1125) Meridian Clinical Research

Subject No: 11251154

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:09

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**1. Data Origin**

Date	Location	User	Value	Reason
Mar-01-2021 11:22:52 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> Not Applicable	Initial Entry
Feb-27-2021 10:53:38 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b>	Transcription Error
Feb-27-2021 10:45:02 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> SITE	Initial Entry

**2. Sample Type**

Date	Location	User	Value	Reason
Mar-01-2021 11:22:52 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> Not Applicable	Initial Entry
Feb-27-2021 10:53:38 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b>	Transcription Error
Feb-27-2021 10:45:02 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> SERUM	Initial Entry

**3. Sample Collected?**

Date	Location	User	Value	Reason
Mar-01-2021 11:22:52 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Applicable	Initial Entry
Feb-27-2021 10:53:38 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query

090177e196ae3d1e\Final\Final On: 01-Apr-2021 04:27 (GMT)

Header Text: c4591001

Visit: V101\_VAX3

Form: ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY  
- eCRF Audit Trail History

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Frozen, Verified

Site No: 1125

Site Name: (1125) Meridian Clinical Research

Subject No: 11251154

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:09

Feb-27-2021 10:53:38 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b>	Transcription Error
Feb-27-2021 10:45:02 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Candidate	'Sample Collected?' is Yes, however no barcodes are entered. Please review and correct as appropriate.
Feb-27-2021 10:45:02 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> YES Date of Collection:  Feb/27/2021	Initial Entry

**4. If no sample was collected or sample was not collected according to protocol, please provide reason:**

Date	Location	User	Value	Reason
Mar-01-2021 11:22:52 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Applicable	Initial Entry

090177e196ae3d1e\Final\Final On: 01-Apr-2021 04:27 (GMT)

Header Text: c4591001

Visit: V101\_VAX3

Form: ELECTRONIC SAMPLE TRACKING - NASAL SWAB - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Frozen, Verified

Site No: 1125

Site Name: (1125) Meridian Clinical Research

Subject No: 11251154

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:09

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**1. Data Origin**

Date	Location	User	Value	Reason
Mar-01-2021 11:23:13 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> Not Applicable	Initial Entry
Feb-27-2021 10:53:51 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b>	Transcription Error
Feb-27-2021 10:45:26 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> SITE	Initial Entry

**2. Sample Type**

Date	Location	User	Value	Reason
Mar-01-2021 11:23:13 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> Not Applicable	Initial Entry
Feb-27-2021 10:53:51 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b>	Transcription Error
Feb-27-2021 10:45:26 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> NASAL_SWAB	Initial Entry

**3. Sample Collected?**

Date	Location	User	Value	Reason
Mar-01-2021 11:23:13 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Applicable	Initial Entry
Feb-27-2021 10:53:51 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query

090177e196ae3d1e\Final\Final On: 01-Apr-2021 04:27 (GMT)

Header Text: c4591001

Visit: V101\_VAX3

Form: ELECTRONIC SAMPLE TRACKING - NASAL SWAB - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Frozen, Verified

Site No: 1125

Site Name: (1125) Meridian Clinical Research

Subject No: 11251154

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:09

Feb-27-2021 10:53:51 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b>	Transcription Error
Feb-27-2021 10:45:26 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Candidate	'Sample Collected?' is Yes, however no barcodes are entered. Please review and correct as appropriate.
Feb-27-2021 10:45:26 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> YES Date of Collection:  Feb/27/2021	Initial Entry

**4. If no sample was collected or sample was not collected according to protocol, please provide reason:**

Date	Location	User	Value	Reason
Mar-01-2021 11:23:13 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Applicable	Initial Entry

090177e196ae3d1e\Final\Final On: 01-Apr-2021 04:27 (GMT)

**Header Text:** c4591001

**Visit:** Subject Status - Unscheduled

**Form:** SUBJECT STATUS - eCRF Audit Trail History

**Form Version:** 22-Apr-2020 21:03

**Form Status:** Data Complete, Verified

**Site No:** 1125

**Site Name:** (1125) Meridian Clinical Research

**Subject No:** 11251154

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 11:09

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**1. Subject Status**

Date	Location	User	Value	Reason
Oct-23-2020 08:43:46 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> FOLLOW-UP	Initial Entry
Sep-03-2020 10:44:37 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> ENROLLED/RANDOMIZED	Initial Entry
Sep-03-2020 10:36:30 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> SCREENED	Initial Entry

**2. Subject Status Date**

Date	Location	User	Value	Reason
Feb-01-2021 02:00:53 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Closed	Per site confirmation- entered in error
Jan-29-2021 17:04:59 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Answered	entered in error
Jan-27-2021 07:47:36 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Opened	Illness eDiary: Subject reported "Yes" for the question "Have you experienced any of the following?" for the COVID-19 symptoms or diagnosis on 21JAN2021. But there is no COVID Illness visit reported in the database. Please clarify.

090177e196ae3d1e\Final\Final On: 01-Apr-2021 04:27 (GMT)

**Header Text:** c4591001

**Visit:** Subject Status - Unscheduled

**Form Version:** 22-Apr-2020 21:03

**Site No:** 1125

**Subject No:** 11251154

**Generated By:** (b) (4)

**Form:** SUBJECT STATUS - eCRF Audit Trail History

**Form Status:** Data Complete, Verified

**Site Name:** (1125) Meridian Clinical Research

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 11:09

Oct-23-2020 08:43:46 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> Oct/23/2020	Initial Entry
Sep-03-2020 10:44:37 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> Sep/3/2020	Initial Entry
Sep-03-2020 10:36:30 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> Sep/3/2020	Initial Entry

090177e196ae3d1e\Final\Final On: 01-Apr-2021 04:27 (GMT)

**Header Text:** c4591001

**Visit:** Investigator Signature - Unscheduled

**Form:** CASEBOOK SIGNATURE FORM - eCRF Audit Trail History

**Form Version:** 22-Apr-2020 21:04

**Form Status:** Data Complete, Signed, Verified

**Site No:** 1125

**Site Name:** (1125) Meridian Clinical Research

**Subject No:** 11251154

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 11:09

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*1. Casebook Signature*

Date	Location	User	Value	Reason
Oct-28-2020 17:39:06 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Click Here to Enable	Initial Entry