

**Header Text:** c4591001

**Visit:** COHORT\_SELECTION

**Form:** COHORT\_SELECTION

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

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

**Site No:** 1093

**Site Name:** (1093) Meridian Clinical Research

**Subject No:** 10931141

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 10:31

[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	08 SEP 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:** 1093

**Site Name:** (1093) Meridian Clinical Research

**Subject No:** 10931141

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 10:31

[eCRF Audit Trail History](#)

**Informed Consent**

1.	Consent Was:	OBTAINED Date Written Consent Obtained Sep/22/2020
----	--------------	--

**Header Text:** c4591001

**Visit:** COHORT\_SELECTION

**Form:** DEMOGRAPHY

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

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

**Site No:** 1093

**Site Name:** (1093) Meridian Clinical Research

**Subject No:** 10931141

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 10:31

[eCRF Audit Trail History](#)

**Demography**

1.	Subject ID	[10931141]
2.	Birth Date:	(b) (6) 1957
3.	Sex:	FEMALE
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:** 1093

**Subject No:** 10931141

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

**Form:** DATE OF VISIT

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

**Site Name:** (1093) Meridian Clinical Research

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 10:31

[eCRF Audit Trail History](#)

**Date of Visit**

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

**Header Text:** c4591001

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

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

**Site No:** 1093

**Subject No:** 10931141

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

**Form:** INCLUSION/EXCLUSION CRITERIA

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

**Site Name:** (1093) Meridian Clinical Research

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 10:31

[Form Comments](#)

**Inclusion Criteria Not Met**

1.	Description of Inclusion Criterion Not Met	Not Applicable
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**Exclusion Criteria Met**

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

**Header Text:** c4591001

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

**Form Version:** 15-Sep-2020 21:52

**Site No:** 1093

**Subject No:** 10931141

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

**Form:** DISPOSITION - SCREENING

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

**Site Name:** (1093) Meridian Clinical Research

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 10:31

[eCRF Audit Trail History](#)

**Disposition - Screening**

1.	Date of Completion/Discontinuation /Death	Sep/22/2020
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:** 1093

**Subject No:** 10931141

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

**Form:** GENERAL MEDICAL HISTORY

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

**Site Name:** (1093) Meridian Clinical Research

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 10:31

[eCRF Audit Trail History](#)

**Medical History Details**

1.a	Line/MH Number:	[1]
	Disease/Syndrome/Surgery /Non-Drug Allergies/Drug Allergies:	[HYSTERECTOMY]
	Start Date:	UNK/UNK/2001
	Ongoing:	NO End Date: UNK/UNK/2001
1.b	Line/MH Number:	[2]
	Disease/Syndrome/Surgery /Non-Drug Allergies/Drug Allergies:	[PENICILLIN ALLERGY]
	Start Date:	UNK/UNK/1980
	Ongoing:	YES
1.c	Line/MH Number:	[3]
	Disease/Syndrome/Surgery /Non-Drug Allergies/Drug Allergies:	[CERVICAL FUSION]
	Start Date:	UNK/UNK/1996
	Ongoing:	NO End Date: UNK/UNK/1996

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**Header Text:** c4591001

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

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

**Site No:** 1093

**Subject No:** 10931141

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

**Form:** GENERAL MEDICAL HISTORY

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

**Site Name:** (1093) Meridian Clinical Research

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 10:31

1.d	Line/MH Number:	[4]
	Disease/Syndrome/Surgery /Non-Drug Allergies/Drug Allergies:	[UTERINE CYSTS]
	Start Date:	UNK/UNK/1975
	Ongoing:	NO End Date: UNK/UNK/1977
1.e	Line/MH Number:	[5]
	Disease/Syndrome/Surgery /Non-Drug Allergies/Drug Allergies:	[BILATERAL TUBAL LIGATION]
	Start Date:	UNK/UNK/1977
	Ongoing:	NO End Date: UNK/UNK/1977
1.f	Line/MH Number:	[6]
	Disease/Syndrome/Surgery /Non-Drug Allergies/Drug Allergies:	[MENORRHAGIA]
	Start Date:	UNK/UNK/1968
	Ongoing:	NO End Date: UNK/UNK/2001
1.g	Line/MH Number:	[7]
	Disease/Syndrome/Surgery /Non-Drug Allergies/Drug Allergies:	[HERNIATED DISCS]
	Start Date:	UNK/UNK/1994
	Ongoing:	NO End Date: UNK/UNK/1996

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**Header Text:** c4591001

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

**Form Version:** 15-Sep-2020 21:57

**Site No:** 1093

**Subject No:** 10931141

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

**Form:** HIV STATUS

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

**Site Name:** (1093) Meridian Clinical Research

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 10:31

[eCRF Audit Trail History](#)

**HIV Status**

1.	Select appropriate response - What is the subject HIV status?	The subject is NOT known to be HIV POSITIVE
----	--	---

**Header Text:** c4591001

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

**Form Version:** 15-Sep-2020 21:56

**Site No:** 1093

**Subject No:** 10931141

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

**Form:** VITAL SIGNS - BASELINE

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

**Site Name:** (1093) Meridian Clinical Research

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 10:31

[eCRF Audit Trail History](#)

**Vital Signs**

1.	Date:	Sep/22/2020
2.	Weight:	[266.2]
3.	Unit:	LB
4.	Height:	[68.0]
5.	Unit:	in
6.	Body Mass Index:	[40.5]

**Vital Signs Details**

7.a	Record Identifier:	1
	Temperature:	[98.1]
	Unit:	F
	Temperature Location:	ORAL CAVITY

090177e196ae2f53\Final\Final On: 01-Apr-2021 03:39 (GMT)

**Header Text:** c4591001

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

**Form Version:** 15-Sep-2020 21:51

**Site No:** 1093

**Subject No:** 10931141

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

**Form:** LAB URINALYSIS - PREGNANCY TEST

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

**Site Name:** (1093) Meridian Clinical Research

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 10:31

[eCRF Audit Trail History](#)

**Lab Urinalysis**

1.	Lab Panel:	URINALYSIS
2.	Lab Sub-Panel:	PREGNANCY
3.	Collection Date:	Sep/22/2020
4.	Laboratory Name and Address (Derived)	[STUDY SITE]
5.	Specimen Type:	URINE

**Lab Result**

6.a	Sponsor ID:	[113]
	Test:	Choriogonadotropin Beta_PX113
	Result:	
	Not Done:	NOT DONE

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**Header Text:** c4591001

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

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

**Site No:** 1093

**Subject No:** 10931141

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

**Form:** RANDOMIZATION

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

**Site Name:** (1093) Meridian Clinical Research

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 10:31

[eCRF Audit Trail History](#)

**Disposition**

1.	Randomization Date :	Sep/22/2020
2.	Randomization Number:	[263817]
3.	Randomization Group:	[ ]

**Header Text:** c4591001

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

**Form:** ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY

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

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

**Site No:** 1093

**Site Name:** (1093) Meridian Clinical Research

**Subject No:** 10931141

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 10:31

[eCRF Audit Trail History](#)

**Electronic Sample Tracking**

1.	Data Origin	SITE
2.	Sample Type	SERUM
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	[BP5DF9]
5.b	Sample ID	[BPR6SJ]
5.c	Sample ID	[BPR6SH]

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**Header Text:** c4591001

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

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

**Site No:** 1093

**Subject No:** 10931141

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

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

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

**Site Name:** (1093) Meridian Clinical Research

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 10:31

[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	[BPR6SD]
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090177e196ae2f53\Final\Final On: 01-Apr-2021 03:39 (GMT)

**Header Text:** c4591001

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

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

**Site No:** 1093

**Subject No:** 10931141

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

**Form:** VACCINATION

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

**Site Name:** (1093) Meridian Clinical Research

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 10:31

[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 14:31
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

090177e196ae2f53\Final\Final On: 01-Apr-2021 03:39 (GMT)

**Header Text:** c4591001

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

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

**Site No:** 1093

**Subject No:** 10931141

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

**Form:** REACTOGENICITY DIARY

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

**Site Name:** (1093) Meridian Clinical Research

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 10:31

[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:** 1093

**Subject No:** 10931141

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

**Form:** DATE OF VISIT

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

**Site Name:** (1093) Meridian Clinical Research

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 10:31

[eCRF Audit Trail History](#)

**Date of Visit**

1.	Date of Visit	Oct/14/2020
2.	Erroneous Visit	

**Header Text:** c4591001

**Visit:** V2\_VAX2\_L

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

**Site No:** 1093

**Subject No:** 10931141

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

**Form:** VITAL SIGNS - TEMP

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

**Site Name:** (1093) Meridian Clinical Research

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 10:31

[eCRF Audit Trail History](#)

**Vital Signs**

1.	Date:	Oct/14/2020
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**Vital Signs Details**

2.a	Record Identifier:	1
	Temperature:	[97.6]
	Unit:	F
	Temperature Location:	ORAL CAVITY

**Header Text:** c4591001

**Visit:** V2\_VAX2\_L

**Form Version:** 15-Sep-2020 21:51

**Site No:** 1093

**Subject No:** 10931141

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

**Form:** LAB URINALYSIS - PREGNANCY TEST

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

**Site Name:** (1093) Meridian Clinical Research

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 10:31

[eCRF Audit Trail History](#)

**Lab Urinalysis**

1.	Lab Panel:	URINALYSIS
2.	Lab Sub-Panel:	PREGNANCY
3.	Collection Date:	Oct/14/2020
4.	Laboratory Name and Address (Derived)	[STUDY SITE]
5.	Specimen Type:	URINE

**Lab Result**

6.a	Sponsor ID:	[113]
	Test:	Choriogonadotropin Beta_PX113
	Result:	
	Not Done:	NOT DONE

090177e196ae2f53\Final\Final On: 01-Apr-2021 03:39 (GMT)

**Header Text:** c4591001

**Visit:** V2\_VAX2\_L

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

**Site No:** 1093

**Subject No:** 10931141

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

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

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

**Site Name:** (1093) Meridian Clinical Research

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 10:31

[eCRF Audit Trail History](#)

**Electronic Sample Tracking**

1.	Data Origin	SITE
2.	Sample Type	NASAL_SWAB
3.	Sample Collected?	YES Date of Collection: Oct/14/2020
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	[BRD94B]
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090177e196ae2f53\Final\Final On: 01-Apr-2021 03:39 (GMT)

**Header Text:** c4591001

**Visit:** V2\_VAX2\_L

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

**Site No:** 1093

**Subject No:** 10931141

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

**Form:** VACCINATION

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

**Site Name:** (1093) Meridian Clinical Research

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 10:31

[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:	Oct/14/2020 14:00
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

090177e196ae2f53\Final\Final On: 01-Apr-2021 03:39 (GMT)

**Header Text:** c4591001

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

**Form:** DATE OF VISIT

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

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

**Site No:** 1093

**Site Name:** (1093) Meridian Clinical Research

**Subject No:** 10931141

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 10:31

[eCRF Audit Trail History](#)

**Date of Visit**

1.	Date of Visit	Nov/11/2020
2.	Erroneous Visit	

**Header Text:** c4591001

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

**Form:** ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY

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

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

**Site No:** 1093

**Site Name:** (1093) Meridian Clinical Research

**Subject No:** 10931141

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 10:31

[eCRF Audit Trail History](#)

**Electronic Sample Tracking**

1.	Data Origin	SITE
2.	Sample Type	SERUM
3.	Sample Collected?	YES Date of Collection: Nov/11/2020
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	[BJ88H4]
5.b	Sample ID	[BSHLVP]
5.c	Sample ID	[BSHLT0]

090177e196ae2f53\Final\Final On: 01-Apr-2021 03:39 (GMT)

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled  
Visit on Dec/28/2020

**Form:** DATE OF VISIT - ILLNESS ONSET

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

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

**Site No:** 1093

**Site Name:** (1093) Meridian Clinical Research

**Subject No:** 10931141

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 10:31

[eCRF Audit Trail History](#)

**Date of Visit**

1.	Date of Visit	Dec/28/2020
2.	Erroneous Visit	

**COVID-19 Illness Visit**

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



**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled  
Visit on Dec/28/2020

**Form:** SIGNS AND SYMPTOMS OF POTENTIAL COVID-19

**Form Version:** 10-Dec-2020 02:29

**Form Status:** Data Complete

**Site No:** 1093

**Site Name:** (1093) Meridian Clinical Research

**Subject No:** 10931141

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 10:31

[eCRF Audit Trail History](#)

**Signs and Symptoms**

1.	Date of Assessment:	Dec/28/2020
2.	Date of First Symptom Started:	Dec/25/2020
3.	Symptoms Ongoing?	NO
	Date of Last Symptom Resolved:	Jan/31/2021

**Symptoms**

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

090177e196ae2f53\Final\Final On: 01-Apr-2021 03:39 (GMT)

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled  
Visit on Dec/28/2020

**Form:** SIGNS AND SYMPTOMS OF POTENTIAL COVID-19

**Form Version:** 10-Dec-2020 02:29

**Form Status:** Data Complete

**Site No:** 1093

**Site Name:** (1093) Meridian Clinical Research

**Subject No:** 10931141

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 10:31

4.i	Symptoms:	VOMITING
	Was symptom present?	NO

**Symptoms - Other**

5.a	Symptoms - Other Text:	[HEADACHE]
-----	------------------------	------------

5.b	Symptoms - Other Text:	[FATIGUE]
-----	------------------------	-----------

**Header Text:** c4591001

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

**Form:** MICROBIOLOGY SPECIMEN

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

**Site No:** 1093

**Site Name:** (1093) Meridian Clinical Research

**Subject No:** 10931141

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 10:31

#	Date of Collection	Specimen Type	Specimen Collection Location	Assay Code and Description	Device Type	Form Instance
1.	Dec/26/2020	SWABBED MATERIAL	NASOPHARYNX	SEVERE ACUTE RESPIRATORY SYNDROME CORONAVIRUS 2	SARS-COV-2 DIAGNOSTIC TEST	<a href="#">Repeating Pages</a>

090177e196ae2f53\Final\Final On: 01-Apr-2021 03:39 (GMT)

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled  
Visit on Dec/28/2020

**Form:** MICROBIOLOGY SPECIMEN

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

**Form Status:** Data Complete

**Site No:** 1093

**Site Name:** (1093) Meridian Clinical Research

**Subject No:** 10931141

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 10:31

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[Form Comments](#)

[eCRF Audit Trail History](#)

[Form Audit Trail](#)

**Microbiology Specimen**

1.	Actual Date of Collection:	Dec/26/2020	<a href="#">Comments</a>
2.	Specimen Type:	SWABBED MATERIAL	<a href="#">Comments</a>
3.	Specimen Collection Location:	NASOPHARYNX	<a href="#">Comments</a>
4.	Assay Code and Description:	SEVERE ACUTE RESP SYNDROME CORONAVIRUS 2	<a href="#">Comments</a>
5.	Device Type:	SARS-COV-2 DIAGNOSTIC TEST	<a href="#">Comments</a>
6.	Trade Name:	OTHER	<a href="#">Comments</a>
7.	Test Result:	NEGATIVE	<a href="#">Comments</a>
8.	Comments/Findings/Details:	[ ]	<a href="#">Comments</a>
9.	Trade Name Other, Specify:	[NALT UNKNOWN]	<a href="#">Comments</a>

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled  
Visit on Dec/28/2020

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

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

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

**Site No:** 1093

**Site Name:** (1093) Meridian Clinical Research

**Subject No:** 10931141

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 10:31

[eCRF Audit Trail History](#)

**Electronic Sample Tracking**

1.	Data Origin	SITE
2.	Sample Type	NASAL_SWAB_SELF
3.	Sample Collected?	YES Date of Collection: Dec/28/2020
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	[CV33957]
-----	-----------	-----------

090177e196ae2f53\Final\Final On: 01-Apr-2021 03:39 (GMT)

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled  
Visit on Dec/28/2020

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

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

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

**Site No:** 1093

**Site Name:** (1093) Meridian Clinical Research

**Subject No:** 10931141

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 10:31

[eCRF Audit Trail History](#)

**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:	[SUBJECT DID A SELF SWAB]

**Aliquot**

Please enter barcode for each aliquot.

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

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled  
Visit on Dec/28/2020

**Form:** HEALTH CARE UTILIZATION

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

**Form Status:** Data Complete

**Site No:** 1093

**Site Name:** (1093) Meridian Clinical Research

**Subject No:** 10931141

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 10:31

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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:	NO
1.c	Physician or Healthcare Professional:	PRIMARY CARE PHYSICIAN
	Occurrence of Visits or Contacts:	NO
1.d	Physician or Healthcare Professional:	URGENT CARE
	Occurrence of Visits or Contacts:	YES Number of Visits or Contacts: [1]
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:	NO

**Health Care Utilization Other**

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**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled  
Visit on Dec/28/2020

**Form:** HEALTH CARE UTILIZATION

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

**Form Status:** Data Complete

**Site No:** 1093

**Site Name:** (1093) Meridian Clinical Research

**Subject No:** 10931141

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 10:31

2.	Other Type of Practitioner Specify:	[ ]
----	-------------------------------------	-----

**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:** 1093

**Site Name:** (1093) Meridian Clinical Research

**Subject No:** 10931141

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 10:31

#	Hospitalization Category	Hospitalization Term	Admission Date	Ongoing	Form Instance
1.	HOSPITALIZATION STATUS	HOSPITAL	Dec/26/2020	YES	<a href="#">Repeating Pages</a>

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled  
Visit on Dec/28/2020

**Form:** HOSPITALIZATION DETAILS

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

**Form Status:** Data Complete

**Site No:** 1093

**Site Name:** (1093) Meridian Clinical Research

**Subject No:** 10931141

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 10:31

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**Hospitalization Details**

1.	Hospitalization Category:	HOSPITALIZATION STATUS
2.	Hospitalization Term:	HOSPITAL
3.	Admission Date:	Dec/26/2020
4.	Ongoing?	YES

**Header Text:** c4591001

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

**Form:** RESPIRATORY TREATMENT

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

**Site No:** 1093

**Site Name:** (1093) Meridian Clinical Research

**Subject No:** 10931141

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 10:31

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

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**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled  
Visit on Dec/28/2020

**Form:** RESPIRATORY TREATMENT

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

**Form Status:** Data Complete, Frozen

**Site No:** 1093

**Site Name:** (1093) Meridian Clinical Research

**Subject No:** 10931141

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 10:31

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**Respiratory Treatment**

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

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**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled  
Visit on Dec/28/2020

**Form:** ILLNESS DETAILS

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

**Form Status:** Data Complete

**Site No:** 1093

**Site Name:** (1093) Meridian Clinical Research

**Subject No:** 10931141

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 10:31

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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: [UPPER RESPIRATORY INFECTION]  Date of Diagnosis: Dec/26/2020
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:** 1093

**Site Name:** (1093) Meridian Clinical Research

**Subject No:** 10931141

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 10:31

#	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 on Dec/28/2020

**Form:** ILLNESS DETAILS - SEVERE

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

**Form Status:** Data Complete, Frozen

**Site No:** 1093

**Site Name:** (1093) Meridian Clinical Research

**Subject No:** 10931141

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 10:31

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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:** 15-Sep-2020 21:51

**Site No:** 1093

**Site Name:** (1093) Meridian Clinical Research

**Subject No:** 10931141

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 10:31

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

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**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled  
Visit on Dec/28/2020

**Form:** LOCAL LABORATORY DATA - REPEATING  
CHEMISTRY

**Form Version:** 15-Sep-2020 21:51

**Form Status:** Data Complete, Frozen

**Site No:** 1093

**Site Name:** (1093) Meridian Clinical Research

**Subject No:** 10931141

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 10:31

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**Lab Chemistry Details**

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

**Lab Result**

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

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**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled  
Visit on Dec/28/2020

**Form:** LOCAL LABORATORY DATA - REPEATING  
CHEMISTRY

**Form Version:** 15-Sep-2020 21:51

**Form Status:** Data Complete, Frozen

**Site No:** 1093

**Site Name:** (1093) Meridian Clinical Research

**Subject No:** 10931141

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 10:31

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

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

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**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled  
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**Form:** LOCAL LABORATORY DATA - REPEATING  
CHEMISTRY

**Form Version:** 15-Sep-2020 21:51

**Form Status:** Data Complete, Frozen

**Site No:** 1093

**Site Name:** (1093) Meridian Clinical Research

**Subject No:** 10931141

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 10:31

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

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**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled  
Visit on Dec/28/2020

**Form:** LOCAL LABORATORY DATA - REPEATING  
CHEMISTRY

**Form Version:** 15-Sep-2020 21:51

**Form Status:** Data Complete, Frozen

**Site No:** 1093

**Site Name:** (1093) Meridian Clinical Research

**Subject No:** 10931141

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 10:31

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

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

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Header Text: c4591001

Visit: POT\_COVID\_ILL 1

Form: LOCAL LABORATORY DATA - REPEATING Hematology

Form Version: 15-Sep-2020 21:55

Site No: 1093

Site Name: (1093) Meridian Clinical Research

Subject No: 10931141

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:31

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

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Header Text: c4591001

Visit: POT\_COVID\_ILL 1 - Unscheduled  
Visit on Dec/28/2020

Form: LOCAL LABORATORY DATA - REPEATING Hematology

Form Version: 15-Sep-2020 21:55

Form Status: Data Complete, Frozen

Site No: 1093

Site Name: (1093) Meridian Clinical Research

Subject No: 10931141

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:31

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**Laboratory Data Hematology**

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

**Lab Result**

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

090177e196ae2f53\Final\Final On: 01-Apr-2021 03:39 (GMT)

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled  
Visit on Dec/28/2020

**Form:** LOCAL LABORATORY DATA - REPEATING Hematology

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

**Form Status:** Data Complete, Frozen

**Site No:** 1093

**Site Name:** (1093) Meridian Clinical Research

**Subject No:** 10931141

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 10:31

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

090177e196ae2f53\Final\Final On: 01-Apr-2021 03:39 (GMT)

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled  
Visit on Dec/28/2020

**Form:** LOCAL LABORATORY DATA - REPEATING Hematology

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

**Form Status:** Data Complete, Frozen

**Site No:** 1093

**Site Name:** (1093) Meridian Clinical Research

**Subject No:** 10931141

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 10:31

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

090177e196ae2f53\Final\Final On: 01-Apr-2021 03:39 (GMT)



**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled  
Visit on Dec/28/2020

**Form:** LOCAL LABORATORY DATA - REPEATING Hematology

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

**Form Status:** Data Complete, Frozen

**Site No:** 1093

**Site Name:** (1093) Meridian Clinical Research

**Subject No:** 10931141

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 10:31

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

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

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**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled  
Visit on Dec/28/2020

**Form:** LOCAL LABORATORY DATA - REPEATING Hematology

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

**Form Status:** Data Complete, Frozen

**Site No:** 1093

**Site Name:** (1093) Meridian Clinical Research

**Subject No:** 10931141

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 10:31

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

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

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**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled  
Visit on Dec/28/2020

**Form:** LOCAL LABORATORY DATA - REPEATING Hematology

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

**Form Status:** Data Complete, Frozen

**Site No:** 1093

**Site Name:** (1093) Meridian Clinical Research

**Subject No:** 10931141

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 10:31

5.j	Sponsor ID:	Not Done _____ [ ]	<a href="#">Comments</a>
	Test:	Lymphocytes_PX611	
	Result:	Not Done _____ [ ]	<a href="#">Comments</a>
	Not Done:	Not Done _____ [ ]	<a href="#">Comments</a>
	LNMT	Not Done _____ 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:** 15-Sep-2020 21:52

**Site No:** 1093

**Site Name:** (1093) Meridian Clinical Research

**Subject No:** 10931141

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 10:31

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

**Header Text:** c4591001

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

**Form:** VITAL SIGNS - COVID

Visit on Dec/28/2020

**Form Version:** 15-Sep-2020 21:52

**Form Status:** Data Complete, Frozen

**Site No:** 1093

**Site Name:** (1093) Meridian Clinical Research

**Subject No:** 10931141

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 10:31

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**Vital Signs**

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

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

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**Header Text:** c4591001

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

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

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

**Site No:** 1093

**Site Name:** (1093) Meridian Clinical Research

**Subject No:** 10931141

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 10:31

#	Date:	Vital Signs Details		Form Instance
1.	Jan/19/2021	<b>Record Identifier:</b>	<b>Oxygen Saturation</b>	<a href="#">Repeating Pages</a>
		Not Done	85.0	

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled  
Visit on Dec/28/2020

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

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

**Form Status:** Data Complete

**Site No:** 1093

**Site Name:** (1093) Meridian Clinical Research

**Subject No:** 10931141

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 10:31

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**Vital Signs**

1.	Date:	Jan/19/2021	<a href="#">Comments</a>
----	-------	-------------	--------------------------

**Vital Signs Details**

2.a	Record Identifier:	1	
	SPO2 Pulse Oximetry %	[85.0]	<a href="#">Comments</a>

**Header Text:** c4591001

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

**Form:** OXYGENATION PARAMETERS

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

**Site No:** 1093

**Site Name:** (1093) Meridian Clinical Research

**Subject No:** 10931141

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 10:31

#	Date Time of Assessment	Arterial Blood Gases PaO <sub>2</sub>	FiO <sub>2</sub> (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 on Dec/28/2020

**Form:** OXYGENATION PARAMETERS

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

**Form Status:** Data Complete, Frozen

**Site No:** 1093

**Site Name:** (1093) Meridian Clinical Research

**Subject No:** 10931141

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 10:31

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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>

090177e196ae2f53\Final\Final On: 01-Apr-2021 03:39 (GMT)

**Header Text:** c4591001

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

**Form:** CONCOMITANT MEDICATIONS - VASOPRESSORS

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

**Site No:** 1093

**Site Name:** (1093) Meridian Clinical Research

**Subject No:** 10931141

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 10:31

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

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled  
Visit on Dec/28/2020

**Form:** CONCOMITANT MEDICATIONS - VASOPRESSORS

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

**Form Status:** Data Complete, Frozen

**Site No:** 1093

**Site Name:** (1093) Meridian Clinical Research

**Subject No:** 10931141

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 10:31

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**Concomitant Medications**

1.	What is the medication identifier?	Not Done _____ [ ]	<a href="#">Comments</a>
2.	Category:	Not Done _____	<a href="#">Comments</a>
3.	Concomitant Medications Pre-specified:	Not Done _____	<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 Done _____ [ ]	<a href="#">Comments</a>
5.	Start Date:	Not Done _____ //	<a href="#">Comments</a>
6.	Ongoing?	Not Done _____	<a href="#">Comments</a>

090177e196ae2f53\Final\Final On: 01-Apr-2021 03:39 (GMT)

**Header Text:** c4591001

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

**Form:** IMAGING

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

**Site No:** 1093

**Site Name:** (1093) Meridian Clinical Research

**Subject No:** 10931141

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 10:31

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

**Header Text:** c4591001

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

**Form:** IMAGING

Visit on Dec/28/2020

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

**Form Status:** Data Complete, Frozen

**Site No:** 1093

**Site Name:** (1093) Meridian Clinical Research

**Subject No:** 10931141

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 10:31

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**Imaging**

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

090177e196ae2f53\Final\Final On: 01-Apr-2021 03:39 (GMT)

**Header Text:** c4591001

**Visit:** POT\_COVID\_CONVA 1 -  
Unscheduled Visit on Feb/11/2021

**Form:** DATE OF VISIT - ILLNESS CONVALESCENT

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

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

**Site No:** 1093

**Site Name:** (1093) Meridian Clinical Research

**Subject No:** 10931141

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 10:31

[eCRF Audit Trail History](#)

**Date of Visit**

1.	Date of Visit	Feb/11/2021
2.	Erroneous Visit	

**COVID-19 Illness Visit**

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

**Header Text:** c4591001

**Visit:** POT\_COVID\_CONVA 1 -  
Unscheduled Visit on Feb/11/2021

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

**Site No:** 1093

**Subject No:** 10931141

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

**Form:** ELECTRONIC SAMPLE TRACKING -  
IMMUNOGENICITY

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

**Site Name:** (1093) Meridian Clinical Research

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 10:31

[eCRF Audit Trail History](#)

**Electronic Sample Tracking**

1.	Data Origin	SITE
2.	Sample Type	SERUM
3.	Sample Collected?	YES Date of Collection: Feb/11/2021
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	[BSHLV7]
5.b	Sample ID	[BSHLV8]
5.c	Sample ID	[BJ88JJ]

090177e196ae2f53\Final\Final On: 01-Apr-2021 03:39 (GMT)

**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:** 1093

**Site Name:** (1093) Meridian Clinical Research

**Subject No:** 10931141

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 10:31

**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:** 1093

**Site Name:** (1093) Meridian Clinical Research

**Subject No:** 10931141

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 10:31

**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	[ ]
----	-----------	-----

090177e196ae2f53\Final\Final On: 01-Apr-2021 03:39 (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:** 1093

**Site Name:** (1093) Meridian Clinical Research

**Subject No:** 10931141

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 10:31

**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:** 1093

**Site Name:** (1093) Meridian Clinical Research

**Subject No:** 10931141

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 10:31

**Unplanned Assessments**

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

**Header Text:** c4591001

**Visit:** Logs

**Form:** ADVERSE EVENT REPORT

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

**Site No:** 1093

**Site Name:** (1093) Meridian Clinical Research

**Subject No:** 10931141

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 10:31

#	Category	AE Identifier	Adverse Event	Start Date	Is the Adverse Event Still Ongoing	Form Instance
1.	ADVERSE EVENT	1	URINARY TRACT INFECTION	Dec/26/2020 UNK:UNK	NO End Date Time:  Dec/28/2020 UNK:UNK	<a href="#">Repeating Pages</a>
2.	ADVERSE EVENT	2	UPPER RESPIRATORY INFECTION	Dec/26/2020 UNK:UNK	NO End Date Time:  Dec/28/2020 UNK:UNK	<a href="#">Repeating Pages</a>

090177e196ae2f53\Final\Final On: 01-Apr-2021 03:39 (GMT)

**Header Text:** c4591001

**Visit:** Logs - Unscheduled

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

**Site No:** 1093

**Subject No:** 10931141

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

**Form:** ADVERSE EVENT REPORT

**Form Status:** Data Complete, Frozen

**Site Name:** (1093) Meridian Clinical Research

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 10:31

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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)	[URINARY TRACT INFECTION]
4.	Start Date Time:	Dec/26/2020 UNK:UNK
5.	Is the adverse event still ongoing?	NO End Date Time: Dec/28/2020 UNK:UNK
6.	Toxicity Grade:	1
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

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**Header Text:** c4591001

**Visit:** Logs - Unscheduled

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

**Site No:** 1093

**Subject No:** 10931141

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

**Form:** ADVERSE EVENT REPORT

**Form Status:** Data Complete, Frozen

**Site Name:** (1093) Meridian Clinical Research

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 10:31

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
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: [GYNOCOLOGY]
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	[2021107150]

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**Header Text:** c4591001

**Visit:** Logs - Unscheduled

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

**Site No:** 1093

**Subject No:** 10931141

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

**Form:** ADVERSE EVENT REPORT

**Form Status:** Data Complete, Frozen

**Site Name:** (1093) Meridian Clinical Research

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 10:31

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**Adverse Event Report**

1.	Category:	ADVERSE EVENT
2.	AE ID:	[2]
3.	Adverse Event: (If possible specify diagnosis, not individual symptoms)	[UPPER RESPIRATORY INFECTION]
4.	Start Date Time:	Dec/26/2020 UNK:UNK
5.	Is the adverse event still ongoing?	NO End Date Time: Dec/28/2020 UNK:UNK
6.	Toxicity Grade:	1
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

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**Header Text:** c4591001

**Visit:** Logs - Unscheduled

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

**Site No:** 1093

**Subject No:** 10931141

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

**Form:** ADVERSE EVENT REPORT

**Form Status:** Data Complete, Frozen

**Site Name:** (1093) Meridian Clinical Research

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 10:31

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
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: [VIRAL]
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	[2021107150]

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**Header Text:** c4591001

**Visit:** Logs

**Form:** MEDICATION ERROR

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

**Site No:** 1093

**Site Name:** (1093) Meridian Clinical Research

**Subject No:** 10931141

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 10:31

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

**Header Text:** c4591001

**Visit:** Logs - Unscheduled

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

**Site No:** 1093

**Subject No:** 10931141

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

**Form:** MEDICATION ERROR

**Form Status:** Not Started

**Site Name:** (1093) Meridian Clinical Research

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 10:31

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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	[ ]

090177e196ae2f53\Final\Final On: 01-Apr-2021 03:39 (GMT)

**Header Text:** c4591001

**Visit:** Logs

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

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

**Site No:** 1093

**Site Name:** (1093) Meridian Clinical Research

**Subject No:** 10931141

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 10:31

#	Sponsor-Defined Identifier	Category for Medication	Concomitant Medications Pre-specified	Name of Medication	Start Date	Form Instance
1.	1	VACCINATION S	NO	INFLUENZA VACCINE	Oct/4/2020	<a href="#">Repeating Pages</a>

090177e196ae2f53\Final\Final On: 01-Apr-2021 03:39 (GMT)

**Header Text:** c4591001

**Visit:** Logs - Unscheduled

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

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

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

**Site No:** 1093

**Site Name:** (1093) Meridian Clinical Research

**Subject No:** 10931141

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 10:31

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**Concomitant Medications**

1.	What is the medication identifier?	[1]
2.	Category:	VACCINATIONS
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).	[INFLUENZA VACCINE]
5.	Date:	Oct/4/2020

**Header Text:** c4591001

**Visit:** Logs

**Form:** CONCOMITANT MEDICATIONS - PROHIBITED

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

**Site No:** 1093

**Site Name:** (1093) Meridian Clinical Research

**Subject No:** 10931141

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 10:31

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

**Header Text:** c4591001

**Visit:** Logs - Unscheduled

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

**Site No:** 1093

**Subject No:** 10931141

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

**Form:** CONCOMITANT MEDICATIONS - PROHIBITED

**Form Status:** Not Started

**Site Name:** (1093) Meridian Clinical Research

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 10:31

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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.	Dose:	[ ]
6.	Dose Unit:	
7.	Dose Frequency:	
8.	Route:	
9.	Start Date:	//
10.	Ongoing?	

090177e196ae2f53\Final\Final On: 01-Apr-2021 03:39 (GMT)

**Header Text:** c4591001

**Visit:** Logs

**Form:** RADIATION TREATMENT

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

**Site No:** 1093

**Site Name:** (1093) Meridian Clinical Research

**Subject No:** 10931141

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 10:31

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

**Header Text:** c4591001

**Visit:** Logs - Unscheduled

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

**Site No:** 1093

**Subject No:** 10931141

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

**Form:** RADIATION TREATMENT

**Form Status:** Not Started

**Site Name:** (1093) Meridian Clinical Research

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 10:31

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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:** 1093

**Site Name:** (1093) Meridian Clinical Research

**Subject No:** 10931141

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 10:31

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

**Header Text:** c4591001

**Visit:** Logs - Unscheduled

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

**Site No:** 1093

**Subject No:** 10931141

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

**Form:** TRANSFUSIONS

**Form Status:** Not Started

**Site Name:** (1093) Meridian Clinical Research

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 10:31

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

**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:** 1093

**Site Name:** (1093) Meridian Clinical Research

**Subject No:** 10931141

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 10:31

[eCRF Audit Trail History](#)

**Disposition - Treatment**

1.	Date of Completion/Discontinuation /Death :	Nov/11/2020
2.	Phase of Disposition:	VACCINATION
3.	Status:	COMPLETED
4.	Specify Status:	[ ]

**Header Text:** c4591001

**Visit:** Unplanned Vaccination - Unscheduled    **Form:** DATE OF VISIT

**Form Version:** 22-Apr-2020 21:02    **Form Status:** Not Started

**Site No:** 1093    **Site Name:** (1093) Meridian Clinical Research

**Subject No:** 10931141    **Subject Initials:** ---

**Generated By:** (b) (4)    **Generated Time (GMT):** 29-Mar-2021 10:31

**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:** 1093 **Site Name:** (1093) Meridian Clinical Research

**Subject No:** 10931141 **Subject Initials:** ---

**Generated By:** (b) (4) **Generated Time (GMT):** 29-Mar-2021 10:31

**Vital Signs**

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

**Vital Signs Details**

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

**Header Text:** c4591001

**Visit:** Unplanned Vaccination - Unscheduled

**Form:** LAB URINALYSIS - PREGNANCY TEST

**Form Version:** 20-Feb-2021 02:14

**Form Status:** Not Started

**Site No:** 1093

**Site Name:** (1093) Meridian Clinical Research

**Subject No:** 10931141

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 10:31

**Lab Urinalysis**

1.	Lab Panel:	
2.	Lab Sub-Panel:	
3.	Collection Date:	//
4.	Laboratory Name and Address (Derived)	[ ]
5.	Specimen Type:	

**Lab Result**

6.	Sponsor ID:	[ ]
	Test:	
	Result:	
	Not Done:	

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**Header Text:** c4591001

**Visit:** Unplanned Vaccination - Unscheduled **Form:** VACCINATION

**Form Version:** 10-Dec-2020 02:26 **Form Status:** Not Started

**Site No:** 1093

**Site Name:** (1093) Meridian Clinical Research

**Subject No:** 10931141

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 10:31

**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?	

090177e196ae2f53\Final\Final On: 01-Apr-2021 03:39 (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:** 1093

**Site Name:** (1093) Meridian Clinical Research

**Subject No:** 10931141

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 10:31

**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:** 1093    **Site Name:** (1093) Meridian Clinical Research

**Subject No:** 10931141    **Subject Initials:** ---

**Generated By:** (b) (4)    **Generated Time (GMT):** 29-Mar-2021 10:31

**Contact Outcome**

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

**Header Text:** c4591001

**Visit:** Follow-Up - Unscheduled

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

**Site No:** 1093

**Subject No:** 10931141

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

**Form:** DISPOSITION - FOLLOW-UP

**Form Status:** Not Started

**Site Name:** (1093) Meridian Clinical Research

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 10:31

**Disposition - Follow-Up**

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

**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:** 1093

**Site Name:** (1093) Meridian Clinical Research

**Subject No:** 10931141

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 10:31

[eCRF Audit Trail History](#)

**Date of Visit**

1.	Date of Visit	Feb/19/2021
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:** 1093

**Site Name:** (1093) Meridian Clinical Research

**Subject No:** 10931141

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 10:31

[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 local/national recommendations and confirmed to have received only placebo at Vaccination 1/2
----	---	---

**Header Text:** c4591001

**Visit:** Disposition - Unscheduled

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

**Site No:** 1093

**Subject No:** 10931141

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

**Form:** TREATMENT UNBLINDED

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

**Site Name:** (1093) Meridian Clinical Research

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 10:31

[eCRF Audit Trail History](#)

**Treatment Unblinded**

1.	Date Treatment Unblinded :	Feb/19/2021
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:** 1093

**Site Name:** (1093) Meridian Clinical Research

**Subject No:** 10931141

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 10:31

**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:** 1093

**Site Name:** (1093) Meridian Clinical Research

**Subject No:** 10931141

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 10:31

**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:** 1093

**Subject No:** 10931141

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

**Form:** DATE OF VISIT

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

**Site Name:** (1093) Meridian Clinical Research

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 10:31

[eCRF Audit Trail History](#)

**Date of Visit**

1.	Date of Visit	Feb/23/2021
2.	Erroneous Visit	



**Header Text:** c4591001

**Visit:** V101\_VAX3

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

**Site No:** 1093

**Subject No:** 10931141

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

**Form:** INFORMED CONSENT - FURTHER VACCINATION

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

**Site Name:** (1093) Meridian Clinical Research

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 10:31

[eCRF Audit Trail History](#)

**Informed Consent - Further Vaccination**

1.	Consent Was:	OBTAINED Date Written Consent Obtained Feb/23/2021
----	--------------	--

**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:** 1093

**Site Name:** (1093) Meridian Clinical Research

**Subject No:** 10931141

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 10:31

**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:** 1093

**Site Name:** (1093) Meridian Clinical Research

**Subject No:** 10931141

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 10:31

[eCRF Audit Trail History](#)

**Disposition - Screening for Further Vaccination**

1.	Date of Completion/Discontinuation /Death :	Feb/23/2021
2.	Phase of Disposition:	REPEAT SCREENING 1
3.	Status:	COMPLETED
4.	Specify Status:	[ ]

**Header Text:** c4591001

**Visit:** V101\_VAX3

**Form Version:** 20-Feb-2021 02:14

**Site No:** 1093

**Subject No:** 10931141

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

**Form:** LAB URINALYSIS - PREGNANCY TEST

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

**Site Name:** (1093) Meridian Clinical Research

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 10:31

[Form Comments](#)

[eCRF Audit Trail History](#)

**Lab Urinalysis**

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

**Lab Result**

6.a	Sponsor ID:	Not Applicable _____ [ ]	<a href="#">Comments</a>
	Test:	Not Applicable _____ Choriogonadotropin Beta_PX113	
	Result:	Not Applicable _____	<a href="#">Comments</a>
	Not Done:	Not Applicable _____	<a href="#">Comments</a>

090177e196ae2f53\Final\Final On: 01-Apr-2021 03:39 (GMT)

**Header Text:** c4591001

**Visit:** V101\_VAX3

**Form:** ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY

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

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

**Site No:** 1093

**Site Name:** (1093) Meridian Clinical Research

**Subject No:** 10931141

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 10:31

[eCRF Audit Trail History](#)

**Electronic Sample Tracking**

1.	Data Origin	SITE
2.	Sample Type	SERUM
3.	Sample Collected?	YES Date of Collection: Feb/23/2021
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	[BSHLWV]
5.b	Sample ID	[BSHLWT]
5.c	Sample ID	[BJ88GS]

090177e196ae2f53\Final\Final On: 01-Apr-2021 03:39 (GMT)

**Header Text:** c4591001

**Visit:** V101\_VAX3

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

**Site No:** 1093

**Subject No:** 10931141

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

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

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

**Site Name:** (1093) Meridian Clinical Research

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 10:31

[eCRF Audit Trail History](#)

**Electronic Sample Tracking**

1.	Data Origin	SITE
2.	Sample Type	NASAL_SWAB
3.	Sample Collected?	YES Date of Collection: Feb/23/2021
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	[BJ88GV]
-----	-----------	----------

090177e196ae2f53\Final\Final On: 01-Apr-2021 03:39 (GMT)

**Header Text:** c4591001

**Visit:** V101\_VAX3

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

**Site No:** 1093

**Subject No:** 10931141

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

**Form:** VACCINATION

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

**Site Name:** (1093) Meridian Clinical Research

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 10:31

[eCRF Audit Trail History](#)

**Vaccination**

1.	Was there a temporary delay of vaccination?	NO
2.	Treatment Name	[BNT162b2]
3.	Formulation:	INJECTION
4.	Dose Date Time:	Feb/23/2021 14:27
5.	Anatomical Location:	DELTOID MUSCLE
6.	Body Side:	LEFT
7.	Route:	INTRAMUSCULAR
8.	Actual Dose:	[30.0]
9.	Unit:	ug
10.	Timeframe Subject Was Observed	30 MINUTES
11.	Was the subject observed for at least the protocol specified observation period after investigational product administration?	YES

090177e196ae2f53\Final\Final On: 01-Apr-2021 03:39 (GMT)

**Header Text:** c4591001

**Visit:** V102\_VAX4

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

**Site No:** 1093

**Subject No:** 10931141

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

**Form:** DATE OF VISIT

**Form Status:** Not Started

**Site Name:** (1093) Meridian Clinical Research

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 10:31

**Date of Visit**

1.	Date of Visit	//
2.	Erroneous Visit	



**Header Text:** c4591001

**Visit:** V102\_VAX4

**Form Version:** 20-Feb-2021 02:14

**Site No:** 1093

**Subject No:** 10931141

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

**Form:** LAB URINALYSIS - PREGNANCY TEST

**Form Status:** Not Started

**Site Name:** (1093) Meridian Clinical Research

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 10:31

**Lab Urinalysis**

1.	Lab Panel:	
2.	Lab Sub-Panel:	
3.	Collection Date:	//
4.	Laboratory Name and Address (Derived)	[ ]
5.	Specimen Type:	

**Lab Result**

6.a	Sponsor ID:	[ ]
	Test:	
	Result:	
	Not Done:	

090177e196ae2f53\Final\Final On: 01-Apr-2021 03:39 (GMT)

**Header Text:** c4591001

**Visit:** V102\_VAX4

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

**Site No:** 1093

**Subject No:** 10931141

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

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

**Form Status:** Not Started

**Site Name:** (1093) Meridian Clinical Research

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 10:31

**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	[ ]
----	-----------	-----

**Header Text:** c4591001

**Visit:** V102\_VAX4

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

**Site No:** 1093

**Subject No:** 10931141

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

**Form:** VACCINATION

**Form Status:** Not Started

**Site Name:** (1093) Meridian Clinical Research

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 10:31

**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?	

090177e196ae2f53\Final\Final On: 01-Apr-2021 03:39 (GMT)

**Header Text:** c4591001

**Visit:** V103\_MONTH1

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

**Site No:** 1093

**Subject No:** 10931141

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

**Form:** DATE OF VISIT

**Form Status:** Not Started

**Site Name:** (1093) Meridian Clinical Research

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 10:31

**Date of Visit**

1.	Date of Visit	//
2.	Erroneous Visit	

**Header Text:** c4591001

**Visit:** V103\_MONTH1

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

**Site No:** 1093

**Subject No:** 10931141

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

**Form:** CONTACT OUTCOME

**Form Status:** Not Started

**Site Name:** (1093) Meridian Clinical Research

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 10:31

**Contact Outcome**

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

**Header Text:** c4591001

**Visit:** V104\_MONTH6

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

**Site No:** 1093

**Subject No:** 10931141

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

**Form:** DATE OF VISIT

**Form Status:** Not Started

**Site Name:** (1093) Meridian Clinical Research

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 10:31

**Date of Visit**

1.	Date of Visit	//
2.	Erroneous Visit	

**Header Text:** c4591001

**Visit:** V104\_MONTH6

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

**Site No:** 1093

**Subject No:** 10931141

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

**Form:** CONTACT OUTCOME

**Form Status:** Not Started

**Site Name:** (1093) Meridian Clinical Research

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 10:31

**Contact Outcome**

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

**Header Text:** c4591001

**Visit:** V105\_MONTH18

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

**Site No:** 1093

**Subject No:** 10931141

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

**Form:** DATE OF VISIT

**Form Status:** Not Started

**Site Name:** (1093) Meridian Clinical Research

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 10:31

**Date of Visit**

1.	Date of Visit	//
2.	Erroneous Visit	



**Header Text:** c4591001

**Visit:** V105\_MONTH18

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

**Site No:** 1093

**Subject No:** 10931141

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

**Form:** CONTACT OUTCOME

**Form Status:** Not Started

**Site Name:** (1093) Meridian Clinical Research

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 10:31

**Contact Outcome**

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

**Header Text:** c4591001

**Visit:** FURTHER\_VACCINATION\_EOT -  
Unscheduled

**Form:** DISPOSITION - TREATMENT

**Form Version:** 20-Feb-2021 02:26

**Form Status:** Not Started

**Site No:** 1093

**Site Name:** (1093) Meridian Clinical Research

**Subject No:** 10931141

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 10:31

**Disposition - Treatment**

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

**Header Text:** c4591001

**Visit:** Subject Status - Unscheduled

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

**Site No:** 1093

**Subject No:** 10931141

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

**Form:** SUBJECT STATUS

**Form Status:** Data Complete, Verified

**Site Name:** (1093) Meridian Clinical Research

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 10:31

[eCRF Audit Trail History](#)

**Subject Status**

1.	Subject Status	FOLLOW-UP
2.	Subject Status Date	Nov/11/2020

**Header Text:** c4591001

**Visit:** Investigator Signature - Unscheduled

**Form:** CASEBOOK SIGNATURE FORM

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

**Form Status:** Data Complete, Verified

**Site No:** 1093

**Site Name:** (1093) Meridian Clinical Research

**Subject No:** 10931141

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 10:31

[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, Verified

**Site No:** 1093

**Site Name:** (1093) Meridian Clinical Research

**Subject No:** 10931141

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 10:31

[Audit Trail](#)

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

- CRF\_Sign
- CRF\_Sign\_1

Name	Signature Meaning	Date	Type	Action
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**Header Text:** c4591001  
**Visit:** V1\_DAY1\_VAX1\_L  
**Form Version:** 15-Sep-2020 21:53  
**Site No:** 1093  
**Subject No:** 10931141  
**Generated By:** (b) (4)

**Form:** INCLUSION/EXCLUSION CRITERIA - Comments  
**Form Status:** Data Complete, Locked, Frozen, Verified  
**Site Name:** (1093) Meridian Clinical Research  
**Subject Initials:** ---  
**Generated Time (GMT):** 29-Mar-2021 10:31

[Back to Form](#)

Item	Date	User	Comment
Form	Sep-22-2020 15:35:17 (UTC-06:00) Central Time (US & Canada)	(b) (4), (b) (6)	Not Applicable

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled  
Visit on Dec/28/2020

**Form:** MICROBIOLOGY SPECIMEN - Comments

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

**Form Status:** Data Complete

**Site No:** 1093

**Site Name:** (1093) Meridian Clinical Research

**Subject No:** 10931141

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 10:31

[Back to Form](#)

Item	Date	User	Comment
Form	Dec-28-2020 17:11:17 (UTC-06:00) Central Time (US & Canada)	(b) (4), (b) (6)	
Form	Dec-28-2020 17:10:58 (UTC-06:00) Central Time (US & Canada)	(b) (4), (b) (6)	Not Done

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled  
Visit on Dec/28/2020

**Form:** MICROBIOLOGY SPECIMEN - Comments

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

**Form Status:** Data Complete

**Site No:** 1093

**Site Name:** (1093) Meridian Clinical Research

**Subject No:** 10931141

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 10:31

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Item	Date	User	Comment
1	Dec-28-2020 17:11:17 (UTC-06:00) Central Time (US & Canada)	(b) (4), (b) (6)	
1	Dec-28-2020 17:10:58 (UTC-06:00) Central Time (US & Canada)	(b) (4), (b) (6)	Not Done



**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled  
Visit on Dec/28/2020

**Form:** MICROBIOLOGY SPECIMEN - Comments

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

**Form Status:** Data Complete

**Site No:** 1093

**Site Name:** (1093) Meridian Clinical Research

**Subject No:** 10931141

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 10:31

[Back to Form](#)

Item	Date	User	Comment
2	Dec-28-2020 17:11:17 (UTC-06:00) Central Time (US & Canada)	(b) (4), (b) (6)	
2	Dec-28-2020 17:10:58 (UTC-06:00) Central Time (US & Canada)	(b) (4), (b) (6)	Not Done

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled  
Visit on Dec/28/2020

**Form:** MICROBIOLOGY SPECIMEN - Comments

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

**Form Status:** Data Complete

**Site No:** 1093

**Site Name:** (1093) Meridian Clinical Research

**Subject No:** 10931141

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 10:31

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Item	Date	User	Comment
3	Dec-28-2020 17:11:17 (UTC-06:00) Central Time (US & Canada)	(b) (4), (b) (6)	
3	Dec-28-2020 17:10:58 (UTC-06:00) Central Time (US & Canada)	(b) (4), (b) (6)	Not Done

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled  
Visit on Dec/28/2020

**Form:** MICROBIOLOGY SPECIMEN - Comments

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

**Form Status:** Data Complete

**Site No:** 1093

**Site Name:** (1093) Meridian Clinical Research

**Subject No:** 10931141

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 10:31

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Item	Date	User	Comment
4	Dec-28-2020 17:11:17 (UTC-06:00) Central Time (US & Canada)	(b) (4), (b) (6)	
4	Dec-28-2020 17:10:58 (UTC-06:00) Central Time (US & Canada)	(b) (4), (b) (6)	Not Done

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled  
Visit on Dec/28/2020

**Form:** MICROBIOLOGY SPECIMEN - Comments

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

**Form Status:** Data Complete

**Site No:** 1093

**Site Name:** (1093) Meridian Clinical Research

**Subject No:** 10931141

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 10:31

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Item	Date	User	Comment
5	Dec-28-2020 17:11:17 (UTC-06:00) Central Time (US & Canada)	(b) (4), (b) (6)	
5	Dec-28-2020 17:10:58 (UTC-06:00) Central Time (US & Canada)	(b) (4), (b) (6)	Not Done

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**Form:** MICROBIOLOGY SPECIMEN - Comments

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

**Form Status:** Data Complete

**Site No:** 1093

**Site Name:** (1093) Meridian Clinical Research

**Subject No:** 10931141

**Subject Initials:** ---

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

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6	Dec-28-2020 17:11:17 (UTC-06:00) Central Time (US & Canada)	(b) (4), (b) (6)	
6	Dec-28-2020 17:10:58 (UTC-06:00) Central Time (US & Canada)	(b) (4), (b) (6)	Not Done

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9	Dec-28-2020 17:10:58 (UTC-06:00) Central Time (US & Canada)	(b) (4), (b) (6)	Not Done



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Form	Feb-16-2021 08:40:32 (UTC-06:00) Central Time (US & Canada)	(b) (4), (b) (6)	Not Applicable
Form	Feb-16-2021 08:40:08 (UTC-06:00) Central Time (US & Canada)	(b) (4), (b) (6)	
Form	Dec-28-2020 17:14:02 (UTC-06:00) Central Time (US & Canada)	(b) (4), (b) (6)	Not Done



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Item	Date	User	Comment
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**Form Version:** 15-Sep-2020 21:55

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**Form Status:** Data Complete, Frozen

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**Subject No:** 10931141

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 10:31

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Item	Date	User	Comment
Form	Dec-28-2020 17:15:26 (UTC-06:00) Central Time (US & Canada)	(b) (4), (b) (6)	Not Done



**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled  
Visit on Dec/28/2020

**Form:** CONCOMITANT MEDICATIONS - VASOPRESSORS -  
Comments

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

**Form Status:** Data Complete, Frozen

**Site No:** 1093

**Site Name:** (1093) Meridian Clinical Research

**Subject No:** 10931141

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 10:31

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Item	Date	User	Comment
1	Dec-28-2020 17:15:26 (UTC-06:00) Central Time (US & Canada)	(b) (4), (b) (6)	Not Done

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled  
Visit on Dec/28/2020

**Form:** CONCOMITANT MEDICATIONS - VASOPRESSORS -  
Comments

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

**Form Status:** Data Complete, Frozen

**Site No:** 1093

**Site Name:** (1093) Meridian Clinical Research

**Subject No:** 10931141

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 10:31

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Item	Date	User	Comment
2	Dec-28-2020 17:15:26 (UTC-06:00) Central Time (US & Canada)	(b) (4), (b) (6)	Not Done

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled  
Visit on Dec/28/2020

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

**Site No:** 1093

**Subject No:** 10931141

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

**Form:** CONCOMITANT MEDICATIONS - VASOPRESSORS -  
Comments

**Form Status:** Data Complete, Frozen

**Site Name:** (1093) Meridian Clinical Research

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 10:31

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Item	Date	User	Comment
3	Dec-28-2020 17:15:26 (UTC-06:00) Central Time (US & Canada)	(b) (4), (b) (6)	Not Done

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled  
Visit on Dec/28/2020

**Form:** CONCOMITANT MEDICATIONS - VASOPRESSORS -  
Comments

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

**Form Status:** Data Complete, Frozen

**Site No:** 1093

**Site Name:** (1093) Meridian Clinical Research

**Subject No:** 10931141

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 10:31

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Item	Date	User	Comment
4	Dec-28-2020 17:15:26 (UTC-06:00) Central Time (US & Canada)	(b) (4), (b) (6)	Not Done

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled  
Visit on Dec/28/2020

**Form:** CONCOMITANT MEDICATIONS - VASOPRESSORS -  
Comments

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

**Form Status:** Data Complete, Frozen

**Site No:** 1093

**Site Name:** (1093) Meridian Clinical Research

**Subject No:** 10931141

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 10:31

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Item	Date	User	Comment
5	Dec-28-2020 17:15:26 (UTC-06:00) Central Time (US & Canada)	(b) (4), (b) (6)	Not Done

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled  
Visit on Dec/28/2020

**Form:** CONCOMITANT MEDICATIONS - VASOPRESSORS -  
Comments

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

**Form Status:** Data Complete, Frozen

**Site No:** 1093

**Site Name:** (1093) Meridian Clinical Research

**Subject No:** 10931141

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 10:31

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Item	Date	User	Comment
6	Dec-28-2020 17:15:26 (UTC-06:00) Central Time (US & Canada)	(b) (4), (b) (6)	Not Done

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled  
Visit on Dec/28/2020

**Form:** IMAGING - Comments

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

**Form Status:** Data Complete, Frozen

**Site No:** 1093

**Site Name:** (1093) Meridian Clinical Research

**Subject No:** 10931141

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 10:31

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Item	Date	User	Comment
Form	Dec-28-2020 17:15:38 (UTC-06:00) Central Time (US & Canada)	(b) (4), (b) (6)	Not Done

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled  
Visit on Dec/28/2020

**Form:** IMAGING - Comments

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

**Form Status:** Data Complete, Frozen

**Site No:** 1093

**Site Name:** (1093) Meridian Clinical Research

**Subject No:** 10931141

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 10:31

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Item	Date	User	Comment
1	Dec-28-2020 17:15:38 (UTC-06:00) Central Time (US & Canada)	(b) (4), (b) (6)	Not Done



**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled  
Visit on Dec/28/2020

**Form:** IMAGING - Comments

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

**Form Status:** Data Complete, Frozen

**Site No:** 1093

**Site Name:** (1093) Meridian Clinical Research

**Subject No:** 10931141

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

**Generated Time (GMT):** 29-Mar-2021 10:31

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Item	Date	User	Comment
2	Dec-28-2020 17:15:38 (UTC-06:00) Central Time (US & Canada)	(b) (4), (b) (6)	Not Done

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled  
Visit on Dec/28/2020

**Form:** IMAGING - Comments

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

**Form Status:** Data Complete, Frozen

**Site No:** 1093

**Site Name:** (1093) Meridian Clinical Research

**Subject No:** 10931141

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**Generated Time (GMT):** 29-Mar-2021 10:31

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Item	Date	User	Comment
3	Dec-28-2020 17:15:38 (UTC-06:00) Central Time (US & Canada)	(b) (4), (b) (6)	Not Done

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled  
Visit on Dec/28/2020

**Form:** IMAGING - Comments

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

**Form Status:** Data Complete, Frozen

**Site No:** 1093

**Site Name:** (1093) Meridian Clinical Research

**Subject No:** 10931141

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 10:31

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Item	Date	User	Comment
4	Dec-28-2020 17:15:38 (UTC-06:00) Central Time (US & Canada)	(b) (4), (b) (6)	Not Done

**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:** 1093

**Site Name:** (1093) Meridian Clinical Research

**Subject No:** 10931141

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 10:31

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Item	Date	User	Comment
Form	Feb-24-2021 08:24:56 (UTC-06:00) Central Time (US & Canada)	(b) (4), (b) (6)	Not Applicable

**Header Text:** c4591001

**Visit:** V101\_VAX3

**Form Version:** 20-Feb-2021 02:14

**Site No:** 1093

**Subject No:** 10931141

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

**Form:** LAB URINALYSIS - PREGNANCY TEST - Comments

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

**Site Name:** (1093) Meridian Clinical Research

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 10:31

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Item	Date	User	Comment
Form	Feb-24-2021 08:25:38 (UTC-06:00) Central Time (US & Canada)	(b) (4), (b) (6)	Not Applicable

**Header Text:** c4591001

**Visit:** V101\_VAX3

**Form Version:** 20-Feb-2021 02:14

**Site No:** 1093

**Subject No:** 10931141

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

**Form:** LAB URINALYSIS - PREGNANCY TEST - Comments

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

**Site Name:** (1093) Meridian Clinical Research

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 10:31

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Item	Date	User	Comment
1	Feb-24-2021 08:25:38 (UTC-06:00) Central Time (US & Canada)	(b) (4), (b) (6)	Not Applicable

**Header Text:** c4591001

**Visit:** V101\_VAX3

**Form Version:** 20-Feb-2021 02:14

**Site No:** 1093

**Subject No:** 10931141

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

**Form:** LAB URINALYSIS - PREGNANCY TEST - Comments

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

**Site Name:** (1093) Meridian Clinical Research

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 10:31

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Item	Date	User	Comment
2	Feb-24-2021 08:25:38 (UTC-06:00) Central Time (US & Canada)	(b) (4), (b) (6)	Not Applicable

**Header Text:** c4591001

**Visit:** V101\_VAX3

**Form Version:** 20-Feb-2021 02:14

**Site No:** 1093

**Subject No:** 10931141

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

**Form:** LAB URINALYSIS - PREGNANCY TEST - Comments

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

**Site Name:** (1093) Meridian Clinical Research

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 10:31

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Item	Date	User	Comment
3	Feb-24-2021 08:25:38 (UTC-06:00) Central Time (US & Canada)	(b) (4), (b) (6)	Not Applicable



**Header Text:** c4591001

**Visit:** V101\_VAX3

**Form Version:** 20-Feb-2021 02:14

**Site No:** 1093

**Subject No:** 10931141

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**Form:** LAB URINALYSIS - PREGNANCY TEST - Comments

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

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**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 10:31

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Item	Date	User	Comment
4	Feb-24-2021 08:25:38 (UTC-06:00) Central Time (US & Canada)	(b) (4), (b) (6)	Not Applicable

**Header Text:** c4591001

**Visit:** V101\_VAX3

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**Site No:** 1093

**Subject No:** 10931141

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

**Form:** LAB URINALYSIS - PREGNANCY TEST - Comments

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

**Site Name:** (1093) Meridian Clinical Research

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 10:31

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Item	Date	User	Comment
5	Feb-24-2021 08:25:38 (UTC-06:00) Central Time (US & Canada)	(b) (4), (b) (6)	Not Applicable

**Header Text:** c4591001

**Visit:** V101\_VAX3

**Form Version:** 20-Feb-2021 02:14

**Site No:** 1093

**Subject No:** 10931141

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

**Form:** LAB URINALYSIS - PREGNANCY TEST - Comments

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

**Site Name:** (1093) Meridian Clinical Research

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 10:31

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Item	Date	User	Comment
6.a	Feb-24-2021 08:25:38 (UTC-06:00) Central Time (US & Canada)	(b) (4), (b) (6)	Not Applicable

**Header Text:** c4591001

**Visit:** V101\_VAX3

**Form Version:** 20-Feb-2021 02:14

**Site No:** 1093

**Subject No:** 10931141

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

**Form:** LAB URINALYSIS - PREGNANCY TEST - Comments

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

**Site Name:** (1093) Meridian Clinical Research

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 10:31

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Item	Date	User	Comment
6.a	Feb-24-2021 08:25:38 (UTC-06:00) Central Time (US & Canada)	(b) (4), (b) (6)	Not Applicable

**Header Text:** c4591001

**Visit:** V101\_VAX3

**Form Version:** 20-Feb-2021 02:14

**Site No:** 1093

**Subject No:** 10931141

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

**Form:** LAB URINALYSIS - PREGNANCY TEST - Comments

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

**Site Name:** (1093) Meridian Clinical Research

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 10:31

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Item	Date	User	Comment
6.a	Feb-24-2021 08:25:38 (UTC-06:00) Central Time (US & Canada)	(b) (4), (b) (6)	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, Verified

**Site No:** 1093

**Site Name:** (1093) Meridian Clinical Research

**Subject No:** 10931141

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 10:31

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

- CRF\_Sign
- CRF\_Sign\_1

Name	Signature Meaning	Date	Type	Action
(b) (6)	N/A	Dec-28-2020 17:09:43 (UTC-06:00) Central Time (US & Canada)		Edit - All signatures invalidated

**Affidavit:**

N/A

David Ensز	Approved	Nov-16-2020 12:14:10 (UTC-06:00) Central Time (US & Canada)	BOOK	Signed
------------	----------	---	------	--------

**Affidavit:**

By my dated signature below, I, DavidEnsز, 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	Nov-12-2020 08:26:35 (UTC-06:00) Central Time (US & Canada)		Edit - All signatures invalidated
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**Affidavit:**

N/A

David Ensز	Approved	Oct-29-2020 08:41:24 (UTC-06:00) Central Time (US & Canada)	BOOK	Signed
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090177e196ae2f53\Final\Final On: 01-Apr-2021 03:39 (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, Verified

**Site No:** 1093

**Site Name:** (1093) Meridian Clinical Research

**Subject No:** 10931141

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 10:31

**Affidavit:**

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

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090177e196ae2f53\Final\Final On: 01-Apr-2021 03:39 (GMT)

**Header Text:** c4591001

**Visit:** COHORT\_SELECTION

**Form:** COHORT SELECTION - eCRF Audit Trail History

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

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

**Site No:** 1093

**Site Name:** (1093) Meridian Clinical Research

**Subject No:** 10931141

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 10:31

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*1. Select appropriate response - Protocol version*

Date	Location	User	Value	Reason
Sep-22-2020 15:34:01 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> 08 SEP 2020	Initial Entry

*2. Select appropriate response - What cohort does the subject belong to?*

Date	Location	User	Value	Reason
Sep-22-2020 15:34:01 (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:** MAIN INFORMED CONSENT - eCRF Audit Trail History

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

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

**Site No:** 1093

**Site Name:** (1093) Meridian Clinical Research

**Subject No:** 10931141

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 10:31

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*I. Consent Was:*

Date	Location	User	Value	Reason
Sep-22-2020 15:34:21 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> OBTAINED Date Written Consent Obtain ed  Sep/22/2020	Initial Entry

Header Text: c4591001

Visit: COHORT\_SELECTION

Form: DEMOGRAPHY - eCRF Audit Trail History

Form Version: 15-Sep-2020 21:54

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1093

Site Name: (1093) Meridian Clinical Research

Subject No: 10931141

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:31

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**1. Subject ID**

Date	Location	User	Value	Reason
Sep-22-2020 15:33:54 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> 10931141	Item copied from previous form

**2. Birth Date:**

Date	Location	User	Value	Reason
Sep-22-2020 15:33:50 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> (b) (6) 1957	Enrollment Entry

**3. Sex:**

Date	Location	User	Value	Reason
Sep-22-2020 15:34:38 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> FEMALE	Initial Entry

**4. Ethnicity:**

Date	Location	User	Value	Reason
Sep-22-2020 15:34:38 (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-22-2020 15:34:38 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> WHITE	Initial Entry

090177e196ae2f53\Final\Final On: 01-Apr-2021 03:39 (GMT)

**Header Text:** c4591001

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

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

**Site No:** 1093

**Subject No:** 10931141

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

**Form:** DATE OF VISIT - eCRF Audit Trail History

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

**Site Name:** (1093) Meridian Clinical Research

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 10:31

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*I. Date of Visit*

Date	Location	User	Value	Reason
Sep-22-2020 15:34:49 (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:** V1\_DAY1\_VAX1\_L

**Form Version:** 15-Sep-2020 21:52

**Site No:** 1093

**Subject No:** 10931141

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

**Form:** DISPOSITION - SCREENING - eCRF Audit Trail History

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

**Site Name:** (1093) Meridian Clinical Research

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 10:31

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**1. Date of Completion/Discontinuation/Death**

Date	Location	User	Value	Reason
Sep-22-2020 15:35:26 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Sep/22/2020	Initial Entry

**2. Phase of Disposition:**

Date	Location	User	Value	Reason
Sep-22-2020 15:35:26 (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-22-2020 15:35:26 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> COMPLETED	Initial Entry

090177e196ae2f53\Final\Final On: 01-Apr-2021 03:39 (GMT)

Header Text: c4591001

Visit: V1\_DAY1\_VAX1\_L

Form Version: 22-Apr-2020 21:03

Site No: 1093

Subject No: 10931141

Generated By: (b) (4)

Form: GENERAL MEDICAL HISTORY - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1093) Meridian Clinical Research

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 10:31

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I.a

Date	Location	User	Value	Reason
Sep-22-2020 15:35:42 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> <b>Line/MH Number:</b> 1 <b>Medical History Term:</b> HYSTERECTOMY <b>Start Date:</b> UNK/UNK/2001 <b>Ongoing:</b> NO End Date:  UNK/UNK/2001	Initial Entry

I.a Line/MH Number:

Date	Location	User	Value	Reason
Sep-22-2020 15:35:42 (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-28-2020 07:54:03 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Hayley Wyper (b) (4)	Query 1: Closed	Response satisfies query
Sep-25-2020 15:05:26 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Answered	ENTRY BEING ADDED
Sep-23-2020 12:18:19 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Hayley Wyper (b) (4)	Query 1: Opened	CLINQUERY: Please review the medical condition linked to this procedure and

090177e196ae2f53\Final\Final On: 01-Apr-2021 03:39 (GMT)

**Header Text:** c4591001  
**Visit:** V1\_DAY1\_VAX1\_L  
**Form Version:** 22-Apr-2020 21:03  
**Site No:** 1093  
**Subject No:** 10931141  
**Generated By:** (b) (4)  
**Form:** GENERAL MEDICAL HISTORY - eCRF Audit Trail History  
**Form Status:** Data Complete, Locked, Frozen, Verified  
**Site Name:** (1093) Meridian Clinical Research  
**Subject Initials:** ---  
**Generated Time (GMT):** 29-Mar-2021 10:31

				report as a separate entry in the MH listing, as appropriate.
Sep-22-2020 15:35:42 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> HYSTERECTOMY	Initial Entry

**I.a Start Date:**

Date	Location	User	Value	Reason
Sep-22-2020 15:35:42 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> UNK/UNK/2001	Initial Entry

**I.a Ongoing:**

Date	Location	User	Value	Reason
Sep-22-2020 15:35:42 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO End Date:  UNK/UNK/2001	Initial Entry

**I.b**

Date	Location	User	Value	Reason
Sep-22-2020 15:35:55 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> Line/MH Number: 2 Medical History Term: PENICILLIN ALLERGY Start Date: UNK/UNK/1980 Ongoing: YES	Initial Entry

090177e196ae2f53\Final\Final On: 01-Apr-2021 03:39 (GMT)

Header Text: c4591001

Visit: V1\_DAY1\_VAX1\_L

Form Version: 22-Apr-2020 21:03

Site No: 1093

Subject No: 10931141

Generated By: (b) (4)

Form: GENERAL MEDICAL HISTORY - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1093) Meridian Clinical Research

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 10:31

***1.b Line/MH Number:***

Date	Location	User	Value	Reason
Sep-22-2020 15:35:55 (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-22-2020 15:35:55 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> PENICILLIN ALLERGY	Initial Entry

***1.b Start Date:***

Date	Location	User	Value	Reason
Sep-22-2020 15:35:55 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> UNK/UNK/1980	Initial Entry

***1.b Ongoing:***

Date	Location	User	Value	Reason
Sep-22-2020 15:35:55 (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-22-2020 15:36:10 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> <b>Line/MH Num 3</b> <b>ber:</b> <b>Medical Histo</b> CERVICAL F <b>ry Term:</b> USION <b>Start Date:</b> UNK/UNK/19 96	Initial Entry

090177e196ae2f53\Final\Final On: 01-Apr-2021 03:39 (GMT)

**Header Text:** c4591001

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

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

**Site No:** 1093

**Subject No:** 10931141

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

**Form:** GENERAL MEDICAL HISTORY - eCRF Audit Trail History

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

**Site Name:** (1093) Meridian Clinical Research

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 10:31

			<b>Ongoing:</b> NO	
			End Date:	
			UNK/UNK/ 1996	



**Header Text:** c4591001**Visit:** V1\_DAY1\_VAX1\_L**Form Version:** 22-Apr-2020 21:03**Site No:** 1093**Subject No:** 10931141**Generated By:** (b) (4)**Form:** GENERAL MEDICAL HISTORY - eCRF Audit Trail History**Form Status:** Data Complete, Locked, Frozen, Verified**Site Name:** (1093) Meridian Clinical Research**Subject Initials:** ---**Generated Time (GMT):** 29-Mar-2021 10:31**I.c Line/MH Number:**

Date	Location	User	Value	Reason
Sep-22-2020 15:36:10 (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-28-2020 07:54:03 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Hayley Wyper (b) (4)	Query 1: Closed	Response satisfies query
Sep-25-2020 15:05:41 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Answered	ENTRY BEING ADDED
Sep-23-2020 12:18:04 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Hayley Wyper (b) (4)	Query 1: Opened	CLINQUERY: Please review the medical condition linked to this procedure and report as a separate entry in the MH listing, as appropriate.
Sep-22-2020 15:36:10 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> CERVICAL FUSION	Initial Entry

**I.c Start Date:**

Date	Location	User	Value	Reason
Sep-22-2020 15:36:10 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> UNK/UNK/1996	Initial Entry

**I.c Ongoing:**

Date	Location	User	Value	Reason
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**Header Text:** c4591001  
**Visit:** V1\_DAY1\_VAX1\_L  
**Form Version:** 22-Apr-2020 21:03  
**Site No:** 1093  
**Subject No:** 10931141  
**Generated By:** (b) (4)  
**Form:** GENERAL MEDICAL HISTORY - eCRF Audit Trail History  
**Form Status:** Data Complete, Locked, Frozen, Verified  
**Site Name:** (1093) Meridian Clinical Research  
**Subject Initials:** ---  
**Generated Time (GMT):** 29-Mar-2021 10:31

Sep-22-2020 15:36:10 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO End Date:  UNK/UNK/1996	Initial Entry
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*I.d*

Date	Location	User	Value	Reason
Sep-25-2020 15:05:57 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> <b>Line/MH Num</b> 4 <b>ber:</b> <b>Medical Histor</b> UTERINE CY <b>y Term:</b> STS <b>Start Date:</b> UNK/UNK/19 75 <b>Ongoing:</b> NO End Date:  UNK/UNK /1977	Initial Entry

090177e196ae2f53\Final\Final On: 01-Apr-2021 03:39 (GMT)

**Header Text:** c4591001  
**Visit:** V1\_DAY1\_VAX1\_L  
**Form Version:** 22-Apr-2020 21:03  
**Site No:** 1093  
**Subject No:** 10931141  
**Generated By:** (b) (4)

**Form:** GENERAL MEDICAL HISTORY - eCRF Audit Trail History  
**Form Status:** Data Complete, Locked, Frozen, Verified  
**Site Name:** (1093) Meridian Clinical Research  
**Subject Initials:** ---  
**Generated Time (GMT):** 29-Mar-2021 10:31

***1.d Line/MH Number:***

Date	Location	User	Value	Reason
Sep-25-2020 15:05:57 (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
Sep-25-2020 15:05:57 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> UTERINE CYSTS	Initial Entry

***1.d Start Date:***

Date	Location	User	Value	Reason
Sep-25-2020 15:05:57 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> UNK/UNK/1975	Initial Entry

***1.d Ongoing:***

Date	Location	User	Value	Reason
Sep-25-2020 15:05:57 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO End Date:  UNK/UNK/1977	Initial Entry

***1.e***

Date	Location	User	Value	Reason
Sep-25-2020 15:06:14 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> <b>Line/MH Number:</b> 5 <b>Medical History Term:</b> BILATERAL TUBAL LIGATION <b>Start Date:</b> UNK/UNK/1977	Initial Entry

090177e196ae2f53\Final\Final On: 01-Apr-2021 03:39 (GMT)

**Header Text:** c4591001  
**Visit:** V1\_DAY1\_VAX1\_L  
**Form Version:** 22-Apr-2020 21:03  
**Site No:** 1093  
**Subject No:** 10931141  
**Generated By:** (b) (4)

**Form:** GENERAL MEDICAL HISTORY - eCRF Audit Trail History  
**Form Status:** Data Complete, Locked, Frozen, Verified  
**Site Name:** (1093) Meridian Clinical Research  
**Subject Initials:** ---  
**Generated Time (GMT):** 29-Mar-2021 10:31

			<b>Ongoing:</b> NO End Date:  UNK/UNK/19 77	
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**I.e Line/MH Number:**

Date	Location	User	Value	Reason
Sep-25-2020 15:06:14 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> 5	Initial Entry

**I.e Disease/Syndrome/Surgery/Non-Drug Allergies/Drug Allergies:**

Date	Location	User	Value	Reason
Sep-25-2020 15:06:14 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> BILATERAL TUBAL LIGATI ON	Initial Entry

**I.e Start Date:**

Date	Location	User	Value	Reason
Sep-25-2020 15:06:14 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> UNK/UNK/1977	Initial Entry

**I.e Ongoing:**

Date	Location	User	Value	Reason
Sep-25-2020 15:06:14 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO End Date:  UNK/UNK/1977	Initial Entry

**I.f**

Date	Location	User	Value	Reason
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090177e196ae2f53\Final\Final On: 01-Apr-2021 03:39 (GMT)

**Header Text:** c4591001

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

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

**Site No:** 1093

**Subject No:** 10931141

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

**Form:** GENERAL MEDICAL HISTORY - eCRF Audit Trail History

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

**Site Name:** (1093) Meridian Clinical Research

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 10:31

<p>Sep-25-2020 15:06:33 (UTC-06:00) Central Time (US &amp; Canada)</p>	<p>ACV0PFEINFP6000</p>	<p>auto calc (autocalc)</p>	<p><b>Data Entry:</b>  <b>Line/MH Number:</b> 6  <b>Medical History Term:</b> MENORRHAGIA  <b>Start Date:</b> UNK/UNK/1968  <b>Ongoing:</b> NO  End Date:  UNK/UNK/2001</p>	<p>Initial Entry</p>
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090177e196ae2f53\Final\Final On: 01-Apr-2021 03:39 (GMT)

Header Text: c4591001

Visit: V1\_DAY1\_VAX1\_L

Form Version: 22-Apr-2020 21:03

Site No: 1093

Subject No: 10931141

Generated By: (b) (4)

Form: GENERAL MEDICAL HISTORY - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1093) Meridian Clinical Research

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 10:31

**I.f Line/MH Number:**

Date	Location	User	Value	Reason
Sep-25-2020 15:06:33 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> 6	Initial Entry

**I.f Disease/Syndrome/Surgery/Non-Drug Allergies/Drug Allergies:**

Date	Location	User	Value	Reason
Sep-25-2020 15:06:33 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> MENORRHAGIA	Initial Entry

**I.f Start Date:**

Date	Location	User	Value	Reason
Sep-25-2020 15:06:33 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> UNK/UNK/1968	Initial Entry

**I.f Ongoing:**

Date	Location	User	Value	Reason
Sep-25-2020 15:06:33 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO End Date:  UNK/UNK/2001	Initial Entry

**I.g**

Date	Location	User	Value	Reason
Sep-25-2020 15:06:54 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> <b>Line/MH Number:</b> 7 <b>Medical History Term:</b> HERNIATED DISCS <b>Start Date:</b> UNK/UNK/1994	Initial Entry

090177e196ae2f53\Final\Final On: 01-Apr-2021 03:39 (GMT)

Header Text: c4591001

Visit: V1\_DAY1\_VAX1\_L

Form Version: 22-Apr-2020 21:03

Site No: 1093

Subject No: 10931141

Generated By: (b) (4)

Form: GENERAL MEDICAL HISTORY - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1093) Meridian Clinical Research

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 10:31

			<b>Ongoing:</b> NO End Date:  UNK/UNK/ 1996	
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**I.g Line/MH Number:**

Date	Location	User	Value	Reason
Sep-25-2020 15:06:54 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> 7	Initial Entry

**I.g Disease/Syndrome/Surgery/Non-Drug Allergies/Drug Allergies:**

Date	Location	User	Value	Reason
Sep-25-2020 15:06:54 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> HERNIATED DISCS	Initial Entry

**I.g Start Date:**

Date	Location	User	Value	Reason
Sep-25-2020 15:06:54 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> UNK/UNK/1994	Initial Entry

**I.g Ongoing:**

Date	Location	User	Value	Reason
Sep-25-2020 15:06:54 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO End Date:  UNK/UNK/1996	Initial Entry

090177e196ae2f53\Final\Final On: 01-Apr-2021 03:39 (GMT)

**Header Text:** c4591001

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

**Form Version:** 15-Sep-2020 21:57

**Site No:** 1093

**Subject No:** 10931141

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

**Form:** HIV STATUS - eCRF Audit Trail History

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

**Site Name:** (1093) Meridian Clinical Research

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 10:31

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*1. Select appropriate response - What is the subject HIV status?*

Date	Location	User	Value	Reason
Sep-22-2020 15:36:16 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> The subject is NOT known to be HIV POSITIVE	Initial Entry



Header Text: c4591001

Visit: V1\_DAY1\_VAX1\_L

Form Version: 15-Sep-2020 21:56

Site No: 1093

Subject No: 10931141

Generated By: (b) (4)

Form: VITAL SIGNS - BASELINE - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1093) Meridian Clinical Research

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 10:31

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**1. Date:**

Date	Location	User	Value	Reason
Sep-22-2020 15:36:30 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Sep/22/2020	Initial Entry

**2. Weight:**

Date	Location	User	Value	Reason
Sep-22-2020 15:36:30 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> 266.2	Initial Entry

**3. Unit:**

Date	Location	User	Value	Reason
Sep-22-2020 15:36:30 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> LB	Initial Entry

**4. Height:**

Date	Location	User	Value	Reason
Sep-22-2020 15:36:30 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> 68.0	Initial Entry

**5. Unit:**

Date	Location	User	Value	Reason
Sep-22-2020 15:36:30 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> in	Initial Entry

**6. Body Mass Index:**

Date	Location	User	Value	Reason
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090177e196ae2f53\Final\Final On: 01-Apr-2021 03:39 (GMT)

**Header Text:** c4591001  
**Visit:** V1\_DAY1\_VAX1\_L **Form:** VITAL SIGNS - BASELINE - eCRF Audit Trail History  
**Form Version:** 15-Sep-2020 21:56 **Form Status:** Data Complete, Locked, Frozen, Verified  
**Site No:** 1093 **Site Name:** (1093) Meridian Clinical Research  
**Subject No:** 10931141 **Subject Initials:** ---  
**Generated By:** (b) (4) **Generated Time (GMT):** 29-Mar-2021 10:31

Sep-22-2020 15:36:30 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> 40.5	Initial Entry
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**7.a**

Date	Location	User	Value	Reason
Sep-22-2020 15:36:30 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Record Identifier:</b> 1 <b>Temperature:</b> 98.1 <b>Temperature Unit:</b> F <b>Temperature Location:</b> ORAL CAVITY	Initial Entry

**7.a Record Identifier:**

Date	Location	User	Value	Reason
Sep-22-2020 15:36:30 (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-22-2020 15:36:30 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> 98.1	Initial Entry

**7.a Unit:**

Date	Location	User	Value	Reason
Sep-22-2020 15:36:30 (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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090177e196ae2f53\Final\Final On: 01-Apr-2021 03:39 (GMT)

**Header Text:** c4591001

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

**Form Version:** 15-Sep-2020 21:56

**Site No:** 1093

**Subject No:** 10931141

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

**Form:** VITAL SIGNS - BASELINE - eCRF Audit Trail History

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

**Site Name:** (1093) Meridian Clinical Research

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 10:31

Sep-22-2020 15:36:30 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> ORAL CAVITY	Initial Entry
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090177e196ae2f53\Final\Final On: 01-Apr-2021 03:39 (GMT)

**Header Text:** c4591001

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

**Form:** LAB URINALYSIS - PREGNANCY TEST - eCRF Audit Trail History

**Form Version:** 15-Sep-2020 21:51

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

**Site No:** 1093

**Site Name:** (1093) Meridian Clinical Research

**Subject No:** 10931141

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 10:31

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**1. Lab Panel:**

Date	Location	User	Value	Reason
Sep-22-2020 15:36:36 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> URINALYSIS	Initial Entry

**2. Lab Sub-Panel:**

Date	Location	User	Value	Reason
Sep-22-2020 15:36:36 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> PREGNANCY	Initial Entry

**3. Collection Date:**

Date	Location	User	Value	Reason
Sep-22-2020 15:36:36 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Sep/22/2020	Initial Entry

**4. Laboratory Name and Address (Derived)**

Date	Location	User	Value	Reason
Sep-22-2020 15:36:36 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> STUDY SITE	Initial Entry

**5. Specimen Type:**

Date	Location	User	Value	Reason
Sep-22-2020 15:36:36 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> URINE	Initial Entry

**6.a**

090177e196ae2f53\Final\Final On: 01-Apr-2021 03:39 (GMT)

Header Text: c4591001

Visit: V1\_DAY1\_VAX1\_L

Form: LAB URINALYSIS - PREGNANCY TEST - eCRF Audit Trail History

Form Version: 15-Sep-2020 21:51

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1093

Site Name: (1093) Meridian Clinical Research

Subject No: 10931141

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:31

Date	Location	User	Value	Reason
Sep-22-2020 15:36:36 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> <b>Sponsor-Defined Identifier:</b> 113 <b>Test::</b> Choriogonadotropin Beta_PX13 <b>Result::</b> <b>Not Done::</b> NOT DONE	Initial Entry

6.a Sponsor ID:

Date	Location	User	Value	Reason
Sep-22-2020 15:36:36 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> 113	Initial Entry

6.a Test:

Date	Location	User	Value	Reason
Sep-22-2020 15:36:36 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Choriogonadotropin Beta_PX13	Initial Entry

6.a Not Done:

Date	Location	User	Value	Reason
Sep-22-2020 15:36:36 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NOT DONE	Initial Entry

090177e196ae2f53\Final\Final On: 01-Apr-2021 03:39 (GMT)

**Header Text:** c4591001

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

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

**Site No:** 1093

**Subject No:** 10931141

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

**Form:** RANDOMIZATION - eCRF Audit Trail History

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

**Site Name:** (1093) Meridian Clinical Research

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 10:31

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**1. Randomization Date :**

Date	Location	User	Value	Reason
Sep-22-2020 15:36:55 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Sep/22/2020	Initial Entry

**2. Randomization Number:**

Date	Location	User	Value	Reason
Sep-22-2020 15:36:55 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> 263817	Initial Entry

**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:** 1093**Site Name:** (1093) Meridian Clinical Research**Subject No:** 10931141**Subject Initials:** ---**Generated By:** (b) (4)**Generated Time (GMT):** 29-Mar-2021 10:31[Back to Form](#)**1. Data Origin**

Date	Location	User	Value	Reason
Sep-22-2020 15:37:02 (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
Sep-22-2020 15:37:02 (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
Sep-22-2020 15:53:15 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Sep-22-2020 15:37:02 (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.
Sep-22-2020 15:37:02 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> YES Date of Collection:  Sep/22/2020	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: 1093

Site Name: (1093) Meridian Clinical Research

Subject No: 10931141

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:31

Sep-22-2020 15:53:15 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Sample ID:</b> BP5DF9	Initial Entry
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5.a Sample ID

Date	Location	User	Value	Reason
Sep-22-2020 15:53:15 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> BP5DF9	Initial Entry

5.b

Date	Location	User	Value	Reason
Sep-22-2020 15:53:32 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Sample ID:</b> BPR6SJ	Initial Entry

5.b Sample ID

Date	Location	User	Value	Reason
Sep-22-2020 15:53:32 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> BPR6SJ	Initial Entry

5.c

Date	Location	User	Value	Reason
Sep-22-2020 15:53:39 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Sample ID:</b> BPR6SH	Initial Entry

5.c Sample ID

Date	Location	User	Value	Reason
Sep-22-2020 15:53:39 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> BPR6SH	Initial Entry

090177e196ae2f53\Final\Final On: 01-Apr-2021 03:39 (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:** 1093**Site Name:** (1093) Meridian Clinical Research**Subject No:** 10931141**Subject Initials:** ---**Generated By:** (b) (4)**Generated Time (GMT):** 29-Mar-2021 10:31[Back to Form](#)**1. Data Origin**

Date	Location	User	Value	Reason
Sep-22-2020 15:37:07 (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
Sep-22-2020 15:37:07 (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
Sep-22-2020 15:57:10 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Sep-22-2020 15:37:07 (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 15:37:07 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> YES Date of Collection:  Sep/22/2020	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 - NASAL SWAB -  
eCRF Audit Trail History

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

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

**Site No:** 1093

**Site Name:** (1093) Meridian Clinical Research

**Subject No:** 10931141

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 10:31

Sep-22-2020 15:57:10 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Sample ID:</b> BPR6SD	Initial Entry
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**5.a Sample ID**

Date	Location	User	Value	Reason
Sep-22-2020 15:57:10 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> BPR6SD	Initial Entry

Header Text: c4591001

Visit: V1\_DAY1\_VAX1\_L

Form Version: 22-Apr-2020 21:04

Site No: 1093

Subject No: 10931141

Generated By: (b) (4)

Form: VACCINATION - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1093) Meridian Clinical Research

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 10:31

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**1. Was there a temporary delay of vaccination?**

Date	Location	User	Value	Reason
Sep-22-2020 15:37:24 (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 15:37:24 (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 15:37:24 (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 15:37:24 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Sep/22/2020 14:31	Initial Entry

**5. Anatomical Location:**

Date	Location	User	Value	Reason
Sep-22-2020 15:37:24 (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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090177e196ae2f53\Final\Final On: 01-Apr-2021 03:39 (GMT)

**Header Text:** c4591001

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

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

**Site No:** 1093

**Subject No:** 10931141

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

**Form:** VACCINATION - eCRF Audit Trail History

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

**Site Name:** (1093) Meridian Clinical Research

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 10:31

Sep-22-2020 15:37:24 (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 15:37:24 (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 15:37:24 (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 15:37:24 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> YES	Initial Entry

090177e196ae2f53\Final\Final On: 01-Apr-2021 03:39 (GMT)

**Header Text:** c4591001

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

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

**Site No:** 1093

**Subject No:** 10931141

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

**Form:** REACTOGENICITY DIARY - eCRF Audit Trail History

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

**Site Name:** (1093) Meridian Clinical Research

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 10:31

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*1. Select appropriate response - Reactogenicity diary collection*

Date	Location	User	Value	Reason
Sep-22-2020 15:37:30 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO - REACTOGENICITY E- DIARY NOT COLLECTED F OR THIS SUBJECT	Initial Entry

**Header Text:** c4591001

**Visit:** V2\_VAX2\_L

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

**Site No:** 1093

**Subject No:** 10931141

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

**Form:** DATE OF VISIT - eCRF Audit Trail History

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

**Site Name:** (1093) Meridian Clinical Research

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 10:31

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*I. Date of Visit*

Date	Location	User	Value	Reason
Oct-14-2020 14:58:56 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Oct/14/2020	Initial Entry

Header Text: c4591001

Visit: V2\_VAX2\_L

Form Version: 10-Oct-2020 16:01

Site No: 1093

Subject No: 10931141

Generated By: (b) (4)

Form: VITAL SIGNS - TEMP - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1093) Meridian Clinical Research

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 10:31

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**1. Date:**

Date	Location	User	Value	Reason
Oct-14-2020 14:59:23 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Oct/14/2020	Initial Entry

**2.a**

Date	Location	User	Value	Reason
Oct-14-2020 14:59:23 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Record Identifier:</b> <b>Temperature:</b> 97.6 <b>Temperature Unit:</b> <b>Temperature Location:</b> ORAL CAVITY	Initial Entry

**2.a Record Identifier:**

Date	Location	User	Value	Reason
Oct-14-2020 14:59:23 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> 1	Initial Entry

**2.a Temperature:**

Date	Location	User	Value	Reason
Oct-14-2020 14:59:23 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> 97.6	Initial Entry

**2.a Unit:**

Date	Location	User	Value	Reason
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090177e196ae2f53\Final\Final On: 01-Apr-2021 03:39 (GMT)

**Header Text:** c4591001

**Visit:** V2\_VAX2\_L

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

**Site No:** 1093

**Subject No:** 10931141

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

**Form:** VITAL SIGNS - TEMP - eCRF Audit Trail History

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

**Site Name:** (1093) Meridian Clinical Research

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 10:31

Oct-14-2020 14:59:23 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> F	Initial Entry
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**2.a Temperature Location:**

Date	Location	User	Value	Reason
Oct-14-2020 14:59:23 (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:** LAB URINALYSIS - PREGNANCY TEST - eCRF Audit Trail History

**Form Version:** 15-Sep-2020 21:51

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

**Site No:** 1093

**Site Name:** (1093) Meridian Clinical Research

**Subject No:** 10931141

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 10:31

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**1. Lab Panel:**

Date	Location	User	Value	Reason
Oct-14-2020 14:59:35 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> URINALYSIS	Initial Entry

**2. Lab Sub-Panel:**

Date	Location	User	Value	Reason
Oct-14-2020 14:59:35 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> PREGNANCY	Initial Entry

**3. Collection Date:**

Date	Location	User	Value	Reason
Oct-14-2020 14:59:35 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Oct/14/2020	Initial Entry

**4. Laboratory Name and Address (Derived)**

Date	Location	User	Value	Reason
Oct-14-2020 14:59:35 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> STUDY SITE	Initial Entry

**5. Specimen Type:**

Date	Location	User	Value	Reason
Oct-14-2020 14:59:35 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> URINE	Initial Entry

**6.a**

090177e196ae2f53\Final\Final On: 01-Apr-2021 03:39 (GMT)

Header Text: c4591001

Visit: V2\_VAX2\_L

Form: LAB URINALYSIS - PREGNANCY TEST - eCRF Audit Trail History

Form Version: 15-Sep-2020 21:51

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1093

Site Name: (1093) Meridian Clinical Research

Subject No: 10931141

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:31

Date	Location	User	Value	Reason
Oct-14-2020 14:59:35 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> <b>Sponsor-Defined Identifier:</b> 113 <b>Test::</b> Choriogonadotropin Beta_PX13 <b>Result::</b> <b>Not Done::</b> NOT DONE	Initial Entry

6.a Sponsor ID:

Date	Location	User	Value	Reason
Oct-14-2020 14:59:35 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> 113	Initial Entry

6.a Test:

Date	Location	User	Value	Reason
Oct-14-2020 14:59:35 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Choriogonadotropin Beta_PX13	Initial Entry

6.a Not Done:

Date	Location	User	Value	Reason
Oct-14-2020 14:59:35 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NOT DONE	Initial Entry

090177e196ae2f53\Final\Final On: 01-Apr-2021 03:39 (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:** 1093

**Site Name:** (1093) Meridian Clinical Research

**Subject No:** 10931141

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 10:31

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**1. Data Origin**

Date	Location	User	Value	Reason
Oct-14-2020 14:59:42 (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-14-2020 14:59:42 (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
Oct-15-2020 15:28:52 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Closed	Close Auto Query
Oct-15-2020 03:40:52 (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.
Oct-14-2020 14:59:42 (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-14-2020 14:59:42 (UTC-06:00) Central	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> YES	Initial Entry

090177e196ae2f53\Final\Final On: 01-Apr-2021 03:39 (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:** 1093

**Site Name:** (1093) Meridian Clinical Research

**Subject No:** 10931141

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 10:31

Time (US & Canada)	(b) (4), (b) (6)	Date of Collection:	Oct/14/2020
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**5.a**

Date	Location	User	Value	Reason
Oct-15-2020 15:28:52 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Sample ID:</b> BRD94B	Initial Entry

**5.a Sample ID**

Date	Location	User	Value	Reason
Oct-15-2020 15:28:52 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> BRD94B	Initial Entry

090177e196ae2f53\Final\Final On: 01-Apr-2021 03:39 (GMT)

Header Text: c4591001

Visit: V2\_VAX2\_L

Form Version: 22-Apr-2020 21:04

Site No: 1093

Subject No: 10931141

Generated By: (b) (4)

Form: VACCINATION - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1093) Meridian Clinical Research

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 10:31

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**1. Was there a temporary delay of vaccination?**

Date	Location	User	Value	Reason
Oct-14-2020 15:00:07 (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
Oct-14-2020 15:00:07 (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
Oct-14-2020 15:00:07 (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
Oct-14-2020 15:00:07 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Oct/14/2020 14:00	Initial Entry

**5. Anatomical Location:**

Date	Location	User	Value	Reason
Oct-14-2020 15:00:07 (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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090177e196ae2f53\Final\Final On: 01-Apr-2021 03:39 (GMT)

**Header Text:** c4591001

**Visit:** V2\_VAX2\_L

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

**Site No:** 1093

**Subject No:** 10931141

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

**Form:** VACCINATION - eCRF Audit Trail History

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

**Site Name:** (1093) Meridian Clinical Research

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 10:31

Oct-14-2020 15:00:07 (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
Oct-14-2020 15:00:07 (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
Oct-14-2020 15:00:07 (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
Oct-14-2020 15:00:07 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> YES	Initial Entry

090177e196ae2f53\Final\Final On: 01-Apr-2021 03:39 (GMT)

**Header Text:** c4591001

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

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

**Site No:** 1093

**Subject No:** 10931141

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

**Form:** DATE OF VISIT - eCRF Audit Trail History

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

**Site Name:** (1093) Meridian Clinical Research

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 10:31

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*I. Date of Visit*

Date	Location	User	Value	Reason
Nov-12-2020 08:26:35 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Nov/11/2020	Initial Entry

**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:** 1093**Site Name:** (1093) Meridian Clinical Research**Subject No:** 10931141**Subject Initials:** ---**Generated By:** (b) (4)**Generated Time (GMT):** 29-Mar-2021 10:31[Back to Form](#)**1. Data Origin**

Date	Location	User	Value	Reason
Nov-12-2020 08:26:42 (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
Nov-12-2020 08:26:42 (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
Nov-12-2020 08:27:04 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Nov-12-2020 08:26:42 (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.
Nov-12-2020 08:26:42 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> YES Date of Collection:  Nov/11/2020	Initial Entry

**5.a**

Date	Location	User	Value	Reason
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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: 1093

Site Name: (1093) Meridian Clinical Research

Subject No: 10931141

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:31

Nov-12-2020 08:27:04 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Sample ID:</b> BJ88H4	Initial Entry
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5.a Sample ID

Date	Location	User	Value	Reason
Nov-12-2020 08:27:04 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> BJ88H4	Initial Entry

5.b

Date	Location	User	Value	Reason
Nov-12-2020 08:27:23 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Sample ID:</b> BSHLVP	Initial Entry

5.b Sample ID

Date	Location	User	Value	Reason
Nov-12-2020 08:27:23 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> BSHLVP	Initial Entry

5.c

Date	Location	User	Value	Reason
Nov-12-2020 08:27:59 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Sample ID:</b> BSHLT0	Initial Entry

5.c Sample ID

Date	Location	User	Value	Reason
Nov-12-2020 08:27:59 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> BSHLT0	Initial Entry

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**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled  
Visit on Dec/28/2020

**Form:** DATE OF VISIT - ILLNESS ONSET - eCRF Audit Trail  
History

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

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

**Site No:** 1093

**Site Name:** (1093) Meridian Clinical Research

**Subject No:** 10931141

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 10:31

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**I. Date of Visit**

Date	Location	User	Value	Reason
Feb-17-2021 00:18:50 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 3: Closed	Response satisfies query
Feb-16-2021 08:36:56 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 3: Answered	subject had their convalescent visit 11feb2021
Feb-11-2021 06:16:53 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 3: Reissued:Opened	PDQ RQ1: Thank you for the response, please confirm the date scheduled in query response and requesting to respond to query once data available. Else clarify.
Feb-10-2021 16:05:20 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 3: Answered	subject is coming in tomorrow for their convalescent
Feb-04-2021 07:15:27 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 3: Opened	PDQ: Convalescent visit is missing and 35+ days (38) have passed since COVID Illness Visit. If visit occurred record the data as a matching CONVA visit; if the visit did not occur attempt to schedule the visit

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**Header Text:** c4591001**Visit:** POT\_COVID\_ILL 1 - Unscheduled  
Visit on Dec/28/2020**Form:** DATE OF VISIT - ILLNESS ONSET - eCRF Audit Trail  
History**Form Version:** 22-Apr-2020 21:03**Form Status:** Data Complete, Frozen, Verified**Site No:** 1093**Site Name:** (1093) Meridian Clinical Research**Subject No:** 10931141**Subject Initials:** ---**Generated By:** (b) (4)**Generated Time (GMT):** 29-Mar-2021 10:31

				and obtain the CONVA sample else clarify.
Dec-28-2020 17:11:54 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Dec-28-2020 17:10:23 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 2: Deleted	Close Auto Query
Dec-28-2020 17:09:41 (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.
Dec-28-2020 17:09:41 (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.
Dec-28-2020 17:09:41 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Dec/28/2020	Initial Entry

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

Date	Location	User	Value	Reason
Dec-28-2020 17:09:41 (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 on Dec/28/2020**Form:** SIGNS AND SYMPTOMS OF POTENTIAL COVID-19 -  
eCRF Audit Trail History**Form Version:** 10-Dec-2020 02:29**Form Status:** Data Complete**Site No:** 1093**Site Name:** (1093) Meridian Clinical Research**Subject No:** 10931141**Subject Initials:** ---**Generated By:** (b) (4)**Generated Time (GMT):** 29-Mar-2021 10:31[Back to Form](#)**1. Date of Assessment:**

Date	Location	User	Value	Reason
Dec-28-2020 17:10:23 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Dec/28/2020	Initial Entry

**2. Date of First Symptom Started:**

Date	Location	User	Value	Reason
Dec-28-2020 17:10:23 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Dec/25/2020	Initial Entry

**3. Symptoms Ongoing?**

Date	Location	User	Value	Reason
Feb-16-2021 08:39:19 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO Date of Last Symptom Reso lved:  Jan/31/2021	Transcription Error
Dec-28-2020 17:10:23 (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
Dec-28-2020 17:10:23 (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:**

Header Text: c4591001

Visit: POT\_COVID\_ILL 1 - Unscheduled  
Visit on Dec/28/2020

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Site Name: (1093) Meridian Clinical Research

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Generated By: (b) (4)

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Date	Location	User	Value	Reason
Dec-28-2020 17:10:23 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> FEVER	Initial Entry

**4.a Was symptom present?**

Date	Location	User	Value	Reason
Dec-28-2020 17:10:23 (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
Dec-28-2020 17:10:23 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Symptom</b> NEW OR INCRE <b>s:</b> ASSED COUGH <b>Symptom</b> NO <b>Present:</b>	Initial Entry

**4.b Symptoms:**

Date	Location	User	Value	Reason
Dec-28-2020 17:10:23 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NEW OR INCREASED COU GH	Initial Entry

**4.b Was symptom present?**

Date	Location	User	Value	Reason
Dec-28-2020 17:10:23 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO	Initial Entry

**4.c**

Date	Location	User	Value	Reason
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**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled  
Visit on Dec/28/2020

**Form:** SIGNS AND SYMPTOMS OF POTENTIAL COVID-19 -  
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**Form Version:** 10-Dec-2020 02:29

**Form Status:** Data Complete

**Site No:** 1093

**Site Name:** (1093) Meridian Clinical Research

**Subject No:** 10931141

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 10:31

Dec-28-2020 17:10:23 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Symptoms:</b> NEW OR INCREASED SHORTNESS OF BREATH <b>Symptom Present:</b> YES	Initial Entry
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**4.c Symptoms:**

Date	Location	User	Value	Reason
Dec-28-2020 17:10:23 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NEW OR INCREASED SHORTNESS OF BREATH	Initial Entry

**4.c Was symptom present?**

Date	Location	User	Value	Reason
Dec-28-2020 17:10:23 (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
Dec-28-2020 17:10:23 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Symptoms:</b> CHILLS <b>Symptom Present:</b> YES	Initial Entry

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Header Text: c4591001

Visit: POT\_COVID\_ILL 1 - Unscheduled  
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Form: SIGNS AND SYMPTOMS OF POTENTIAL COVID-19 -  
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Form Status: Data Complete

Site No: 1093

Site Name: (1093) Meridian Clinical Research

Subject No: 10931141

Subject Initials: ---

Generated By: (b) (4)

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4.d Symptoms:

Date	Location	User	Value	Reason
Dec-28-2020 17:10:23 (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
Dec-28-2020 17:10:23 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> YES	Initial Entry

4.e

Date	Location	User	Value	Reason
Dec-28-2020 17:10:23 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Symptoms: NEW OR INCREASED MUSCLE PAIN Symptom Present: YES	Initial Entry

4.e Symptoms:

Date	Location	User	Value	Reason
Dec-28-2020 17:10:23 (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
Dec-28-2020 17:10:23 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> YES	Initial Entry

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Header Text: c4591001

Visit: POT\_COVID\_ILL 1 - Unscheduled  
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Form: SIGNS AND SYMPTOMS OF POTENTIAL COVID-19 -  
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Form Status: Data Complete

Site No: 1093

Site Name: (1093) Meridian Clinical Research

Subject No: 10931141

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:31

4.f

Date	Location	User	Value	Reason
Dec-28-2020 17:10:23 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Symptom</b> NEW LOSS OF T s:           ASTE OR SMELL <b>Symptom</b> NO <b>Present:</b>	Initial Entry

4.f Symptoms:

Date	Location	User	Value	Reason
Dec-28-2020 17:10:23 (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
Dec-28-2020 17:10:23 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO	Initial Entry

4.g

Date	Location	User	Value	Reason
Dec-28-2020 17:10:23 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Sympto</b> NEW OR INCREA ms:       SED SORE THRO AT <b>Sympto</b> NO <b>m Presen</b> <b>t:</b>	Initial Entry

090177e196ae2f53\Final\Final On: 01-Apr-2021 03:39 (GMT)



Header Text: c4591001

Visit: POT\_COVID\_ILL 1 - Unscheduled  
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Form Status: Data Complete

Site No: 1093

Site Name: (1093) Meridian Clinical Research

Subject No: 10931141

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:31

4.g Symptoms:

Date	Location	User	Value	Reason
Dec-28-2020 17:10:23 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NEW OR INCREASED SOR E THROAT	Initial Entry

4.g Was symptom present?

Date	Location	User	Value	Reason
Dec-28-2020 17:10:23 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO	Initial Entry

4.h

Date	Location	User	Value	Reason
Dec-28-2020 17:10:23 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Symptoms: DIARRHE A Symptom Prese NO nt:	Initial Entry

4.h Symptoms:

Date	Location	User	Value	Reason
Dec-28-2020 17:10:23 (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
Dec-28-2020 17:10:23 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO	Initial Entry

4.i

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Header Text: c4591001

Visit: POT\_COVID\_ILL 1 - Unscheduled  
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Form Status: Data Complete

Site No: 1093

Site Name: (1093) Meridian Clinical Research

Subject No: 10931141

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:31

Date	Location	User	Value	Reason
Dec-28-2020 17:10:23 (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

**4.i Symptoms:**

Date	Location	User	Value	Reason
Dec-28-2020 17:10:23 (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
Dec-28-2020 17:10:23 (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
Dec-28-2020 17:10:36 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Symptoms - Other:</b> HEADACHE	Initial Entry

**5.a Symptoms - Other Text:**

Date	Location	User	Value	Reason
Dec-28-2020 17:10:36 (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
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090177e196ae2f53\Final\Final On: 01-Apr-2021 03:39 (GMT)

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled  
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**Form Status:** Data Complete

**Site No:** 1093

**Site Name:** (1093) Meridian Clinical Research

**Subject No:** 10931141

**Subject Initials:** ---

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

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Dec-28-2020 17:10:43 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Symptoms - Other</b> FATIGU : E	Initial Entry
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**5.b Symptoms - Other Text:**

Date	Location	User	Value	Reason
Dec-28-2020 17:10:43 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> FATIGUE	Initial Entry

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled  
Visit on Dec/28/2020

**Form:** MICROBIOLOGY SPECIMEN - Audit Trail

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

**Form Status:**

**Site No:** 1093

**Site Name:** (1093) Meridian Clinical Research

**Subject No:** 10931141

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 10:31

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Date	Location	User	Value	Reason
Dec-28-2020 17:11:41 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Form Created	

Header Text: c4591001

Visit: POT\_COVID\_ILL 1 - Unscheduled  
Visit on Dec/28/2020

Form: MICROBIOLOGY SPECIMEN - eCRF Audit Trail History

Form Version: 06-Jul-2020 21:54

Form Status: Data Complete

Site No: 1093

Site Name: (1093) Meridian Clinical Research

Subject No: 10931141

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:31

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**1. Actual Date of Collection:**

Date	Location	User	Value	Reason
Dec-28-2020 17:11:41 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Dec/26/2020	Initial Entry
Dec-28-2020 17:11:17 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b>	Initial Entry
Dec-28-2020 17:10:58 (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
Dec-28-2020 17:11:41 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> SWABBED MATERIAL	Initial Entry
Dec-28-2020 17:11:17 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b>	Initial Entry
Dec-28-2020 17:10:58 (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
Dec-28-2020 17:11:41 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NASOPHARYNX	Initial Entry
Dec-28-2020 17:11:17 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b>	Initial Entry

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Header Text: c4591001

Visit: POT\_COVID\_ILL 1 - Unscheduled  
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Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:31

Dec-28-2020 17:10:58 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Done	Initial Entry
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**4. Assay Code and Description:**

Date	Location	User	Value	Reason
Dec-28-2020 17:11:41 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> SEVERE ACUTE RESP SYN DROME CORONAVIRUS 2	Initial Entry
Dec-28-2020 17:11:17 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b>	Initial Entry
Dec-28-2020 17:10:58 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Done	Initial Entry

**5. Device Type:**

Date	Location	User	Value	Reason
Dec-28-2020 17:11:41 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> SARS-COV-2 DIAGNOSTIC TEST	Initial Entry
Dec-28-2020 17:11:17 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b>	Initial Entry
Dec-28-2020 17:10:58 (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
Dec-28-2020 17:11:41 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> OTHER	Initial Entry

090177e196ae2f53\Final\Final On: 01-Apr-2021 03:39 (GMT)

**Header Text:** c4591001**Visit:** POT\_COVID\_ILL 1 - Unscheduled  
Visit on Dec/28/2020**Form:** MICROBIOLOGY SPECIMEN - eCRF Audit Trail History**Form Version:** 06-Jul-2020 21:54**Form Status:** Data Complete**Site No:** 1093**Site Name:** (1093) Meridian Clinical Research**Subject No:** 10931141**Subject Initials:** ---**Generated By:** (b) (4)**Generated Time (GMT):** 29-Mar-2021 10:31

Dec-28-2020 17:11:17 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b>	Initial Entry
Dec-28-2020 17:10:58 (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
Dec-28-2020 17:11:41 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NEGATIVE	Initial Entry
Dec-28-2020 17:11:17 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b>	Initial Entry
Dec-28-2020 17:10:58 (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
Dec-28-2020 17:11:17 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b>	Initial Entry
Dec-28-2020 17:10:58 (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
Dec-31-2020 07:48:23 (UTC-06:00) Central Time (US &	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Clo sed	Query closed data has been updated

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled  
Visit on Dec/28/2020

**Form:** MICROBIOLOGY SPECIMEN - eCRF Audit Trail History

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

**Form Status:** Data Complete

**Site No:** 1093

**Site Name:** (1093) Meridian Clinical Research

**Subject No:** 10931141

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 10:31

Canada)				
Dec-30-2020 08:43:51 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: An swere d	Transcription Error
Dec-30-2020 08:43:51 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry</b> : NALT UNK NOW N	Transcription Error
Dec-29-2020 03:20:01 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000.InFormAdapter.Discrepancy	PFE SDQ PROD (b) (4)	Query 1: Op ened	As per CRF CR, If trade name is not known. Please update NALT Unknown in the specified field, Thank you. (b) (4)
Dec-28-2020 17:11:41 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry</b> : NALT	Initial Entry
Dec-28-2020 17:11:17 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry</b> :	Initial Entry
Dec-28-2020	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data</b>	Initial Entry

090177e196ae2f53\Final\Final On: 01-Apr-2021 03:39 (GMT)



**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled  
Visit on Dec/28/2020

**Form:** MICROBIOLOGY SPECIMEN - eCRF Audit Trail History

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

**Form Status:** Data Complete

**Site No:** 1093

**Site Name:** (1093) Meridian Clinical Research

**Subject No:** 10931141

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 10:31

17:10:58 (UTC-06:00) Central Time (US & Canada)		(b) (4), (b) (6)	<b>Entry</b> : Not D one	
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**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled  
Visit on Dec/28/2020

**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:** 1093

**Site Name:** (1093) Meridian Clinical Research

**Subject No:** 10931141

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 10:31

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**1. Data Origin**

Date	Location	User	Value	Reason
Dec-28-2020 17:11:54 (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
Dec-28-2020 17:11:54 (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
Jan-05-2021 22:43:17 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Closed	Response satisfies query
Jan-05-2021 14:28:35 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Answered	Answer Auto Query
Jan-04-2021 00:38:08 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Reissued:Opened	DM: Thank you for response. Please review if data is available and provide details on this form. Once CRF is updated, respond to the query.
Dec-31-2020 12:43:34 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Answered	BARCODE WILL BE UPDATED WHEN AVAILABLE.

090177e196ae2f53\Final\Final On: 01-Apr-2021 03:39 (GMT)

**Header Text:** c4591001**Visit:** POT\_COVID\_ILL 1 - Unscheduled  
Visit on Dec/28/2020**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:** 1093**Site Name:** (1093) Meridian Clinical Research**Subject No:** 10931141**Subject Initials:** ---**Generated By:** (b) (4)**Generated Time (GMT):** 29-Mar-2021 10:31

Dec-29-2020 02:21:53 (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.
Dec-28-2020 17:11:54 (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.
Dec-28-2020 17:11:54 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> YES Date of Collection:  Dec/28/2020	Initial Entry

**5.a**

Date	Location	User	Value	Reason
Jan-05-2021 14:28:35 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Sample ID:</b> CV33957	Initial Entry

**5.a Sample ID**

Date	Location	User	Value	Reason
Jan-05-2021 14:28:35 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> CV33957	Initial Entry

**Header Text:** c4591001**Visit:** POT\_COVID\_ILL 1 - Unscheduled  
Visit on Dec/28/2020**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:** 1093**Site Name:** (1093) Meridian Clinical Research**Subject No:** 10931141**Subject Initials:** ---**Generated By:** (b) (4)**Generated Time (GMT):** 29-Mar-2021 10:31[Back to Form](#)**1. Data Origin**

Date	Location	User	Value	Reason
Dec-28-2020 17:12:07 (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
Dec-28-2020 17:12:07 (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
Dec-28-2020 17:12:07 (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
Dec-28-2020 17:12:07 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> SUBJECT DID A SELF SWA B	Initial Entry

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled  
Visit on Dec/28/2020

**Form:** HEALTH CARE UTILIZATION - eCRF Audit Trail History

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

**Form Status:** Data Complete

**Site No:** 1093

**Site Name:** (1093) Meridian Clinical Research

**Subject No:** 10931141

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 10:31

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**I.a**

Date	Location	User	Value	Reason
Dec-28-2020 17:12:54 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Type of Practitioner:</b> SPECIALIST <b>Occurrence of Visits or Contacts:</b> NO	Initial Entry

**I.a Physician or Healthcare Professional:**

Date	Location	User	Value	Reason
Dec-28-2020 17:12:54 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> SPECIALIST	Initial Entry

**I.a Occurrence of Visits or Contacts:**

Date	Location	User	Value	Reason
Dec-28-2020 17:12:54 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO	Initial Entry

**I.b**

Date	Location	User	Value	Reason
Dec-28-2020 17:12:54 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Type of Practitioner:</b> EMERGENCY ROOM <b>Occurrence of Visits or Contacts:</b> NO	Initial Entry

090177e196ae2f53\Final\Final On: 01-Apr-2021 03:39 (GMT)

Header Text: c4591001

Visit: POT\_COVID\_ILL 1 - Unscheduled  
Visit on Dec/28/2020

Form: HEALTH CARE UTILIZATION - eCRF Audit Trail History

Form Version: 10-Dec-2020 02:26

Form Status: Data Complete

Site No: 1093

Site Name: (1093) Meridian Clinical Research

Subject No: 10931141

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:31

***1.b Physician or Healthcare Professional:***

Date	Location	User	Value	Reason
Dec-28-2020 17:12:54 (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
Dec-28-2020 17:12:54 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO	Initial Entry

***1.c***

Date	Location	User	Value	Reason
Dec-28-2020 17:12:54 (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> NO	Initial Entry

***1.c Physician or Healthcare Professional:***

Date	Location	User	Value	Reason
Dec-28-2020 17:12:54 (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
Dec-28-2020 17:12:54 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO	Initial Entry

090177e196ae2f53\Final\Final On: 01-Apr-2021 03:39 (GMT)

Header Text: c4591001

Visit: POT\_COVID\_ILL 1 - Unscheduled  
Visit on Dec/28/2020

Form: HEALTH CARE UTILIZATION - eCRF Audit Trail History

Form Version: 10-Dec-2020 02:26

Form Status: Data Complete

Site No: 1093

Site Name: (1093) Meridian Clinical Research

Subject No: 10931141

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:31

**I.d**

Date	Location	User	Value	Reason
Dec-28-2020 17:12:54 (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> YES <i>Number of Visits or Contacts:</i>  1	Initial Entry

**I.d Physician or Healthcare Professional:**

Date	Location	User	Value	Reason
Dec-28-2020 17:12:54 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> URGENT CARE	Initial Entry

**I.d Occurrence of Visits or Contacts:**

Date	Location	User	Value	Reason
Dec-28-2020 17:12:54 (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

**I.e**

Date	Location	User	Value	Reason
Dec-28-2020 17:12:54 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Type of Practitioner:</b> TELEPHONE CONSULTATION	Initial Entry

090177e196ae2f53\Final\Final On: 01-Apr-2021 03:39 (GMT)

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled  
Visit on Dec/28/2020

**Form:** HEALTH CARE UTILIZATION - eCRF Audit Trail History

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

**Form Status:** Data Complete

**Site No:** 1093

**Site Name:** (1093) Meridian Clinical Research

**Subject No:** 10931141

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 10:31

			<b>Occurrence of NO Visits or Contacts:</b>	
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***I.e Physician or Healthcare Professional:***

Date	Location	User	Value	Reason
Dec-28-2020 17:12:54 (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
Dec-28-2020 17:12:54 (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
Dec-28-2020 17:12:54 (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> NO	Initial Entry

090177e196ae2f53\Final\Final On: 01-Apr-2021 03:39 (GMT)



Header Text: c4591001

Visit: POT\_COVID\_ILL 1 - Unscheduled  
Visit on Dec/28/2020

Form: HEALTH CARE UTILIZATION - eCRF Audit Trail History

Form Version: 10-Dec-2020 02:26

Form Status: Data Complete

Site No: 1093

Site Name: (1093) Meridian Clinical Research

Subject No: 10931141

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:31

*1.f Physician or Healthcare Professional:*

Date	Location	User	Value	Reason
Dec-28-2020 17:12:54 (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
Dec-28-2020 17:12:54 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO	Initial Entry

*3. Has the subject been hospitalized due to potential COVID-19 illness?*

Date	Location	User	Value	Reason
Feb-16-2021 08:38:27 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> YES Has the subject been in inten sive care due to potential C OVID-19 illness?  NO	Transcription Error
Feb-16-2021 08:38:17 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> YES Has the subject been in inten sive care due to potential C OVID-19 illness?  YES	Transcription Error
Dec-28-2020 17:12:54 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> YES Has the subject been in inten sive care due to potential C OVID-19 illness?  NO	Initial Entry

090177e196ae2f53\Final\Final On: 01-Apr-2021 03:39 (GMT)

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled  
Visit on Dec/28/2020

**Form:** HOSPITALIZATION DETAILS - Audit Trail

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

**Form Status:**

**Site No:** 1093

**Site Name:** (1093) Meridian Clinical Research

**Subject No:** 10931141

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 10:31

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Date	Location	User	Value	Reason
Dec-28-2020 17:13:08 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Form Created	

Header Text: c4591001

Visit: POT\_COVID\_ILL 1 - Unscheduled  
Visit on Dec/28/2020

Form: HOSPITALIZATION DETAILS - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:02

Form Status: Data Complete

Site No: 1093

Site Name: (1093) Meridian Clinical Research

Subject No: 10931141

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:31

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**1. Hospitalization Category:**

Date	Location	User	Value	Reason
Dec-28-2020 17:13:08 (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
Dec-28-2020 17:13:08 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (4), (b) (6)	<b>Data Entry:</b> HOSPITAL	Initial Entry

**3. Admission Date:**

Date	Location	User	Value	Reason
Jan-27-2021 10:18:01 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Closed	Response satisfies query
Jan-27-2021 08:15:32 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Answered	HOSPITAL RECORDS ARE STILL BEING MAINTANED.
Jan-05-2021 15:03:18 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Reissued:Opened	CLIQUERY: Please respond to query once Hospitalization details are entered.
Jan-05-2021 14:45:01 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Answered	DATA WILL BE UPDATED WHEN HOSPITAL RECORDS ARE RECIEVED.
Jan-04-2021 15:58:29 (UTC-06:00) Central	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Opened	CLIQUERY: Hospitalization:

090177e196ae2f53\Final\Final On: 01-Apr-2021 03:39 (GMT)

**Header Text:** c4591001  
**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit on Dec/28/2020  
**Form:** HOSPITALIZATION DETAILS - eCRF Audit Trail History  
**Form Version:** 22-Apr-2020 21:02  
**Form Status:** Data Complete  
**Site No:** 1093  
**Site Name:** (1093) Meridian Clinical Research  
**Subject No:** 10931141  
**Subject Initials:** ---  
**Generated By:** (b) (4)  
**Generated Time (GMT):** 29-Mar-2021 10:31

Time (US & Canada)		(b) (4), (b) (6)		This subject had COVID-19 Illness and was hospitalized. Please enter any available information (vital signs, pulse oxymet, respiratory treatment, lab results, imaging...). Please make every effort to obtain these information.
Dec-28-2020 17:13:08 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Dec/26/2020	Initial Entry

**4. Ongoing?**

Date	Location	User	Value	Reason
Dec-28-2020 17:13:08 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> YES	Initial Entry

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled  
Visit on Dec/28/2020

**Form:** RESPIRATORY TREATMENT - eCRF Audit Trail History

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

**Form Status:** Data Complete, Frozen

**Site No:** 1093

**Site Name:** (1093) Meridian Clinical Research

**Subject No:** 10931141

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 10:31

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**1. What is the treatment Identifier?**

Date	Location	User	Value	Reason
Dec-28-2020 17:13:17 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Done	Initial Entry

**2. Concomitant Non-drug Treatment Pre-specified:**

Date	Location	User	Value	Reason
Dec-28-2020 17:13:17 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Done	Initial Entry

**3. Treatment:**

Date	Location	User	Value	Reason
Dec-28-2020 17:13:17 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Done	Initial Entry

**4. Treatment:**

Date	Location	User	Value	Reason
Dec-28-2020 17:13:17 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Done	Initial Entry

**5. Start Date:**

Date	Location	User	Value	Reason
Dec-28-2020 17:13:17 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Done	Initial Entry

**6. Ongoing?**

090177e196ae2f53\Final\Final On: 01-Apr-2021 03:39 (GMT)

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled  
Visit on Dec/28/2020

**Form:** RESPIRATORY TREATMENT - eCRF Audit Trail History

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

**Form Status:** Data Complete, Frozen

**Site No:** 1093

**Site Name:** (1093) Meridian Clinical Research

**Subject No:** 10931141

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 10:31

Date	Location	User	Value	Reason
Dec-28-2020 17:13:17 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Done	Initial Entry

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled  
Visit on Dec/28/2020

**Form:** ILLNESS DETAILS - eCRF Audit Trail History

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

**Form Status:** Data Complete

**Site No:** 1093

**Site Name:** (1093) Meridian Clinical Research

**Subject No:** 10931141

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 10:31

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**1. Category of Clinical Event:**

Date	Location	User	Value	Reason
Dec-28-2020 17:13:44 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> POTENTIAL COVID-19 ILLN ESS	Initial Entry

**2. Was a diagnosis obtained for Potential COVID-19 Illness?**

Date	Location	User	Value	Reason
Jan-27-2021 09:59:06 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Salim Bouguermouh (b) (4)	Query 1: Closed	Response satisfies query
Jan-27-2021 08:15:02 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Answered	THIS QUALIFIES AS AN AE, AS SUBJECT WAS HOSPITALIZED FOR IT. MEDICAL RECORDS ARE STILL BEING MAINTANED.
Jan-06-2021 21:44:53 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Salim Bouguermouh (b) (4)	Query 1: Opened	Clin: Per Prot Sect 8.3.7., potential COVID-19 related UPPER RESPIRATORY INFECTION does not qualify as AE and please should be documented ONLY on the ILLNESS DETAILS CRF form (already entered) and should not be captured on the AE CRF page.

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**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled  
Visit on Dec/28/2020

**Form:** ILLNESS DETAILS - eCRF Audit Trail History

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

**Form Status:** Data Complete

**Site No:** 1093

**Site Name:** (1093) Meridian Clinical Research

**Subject No:** 10931141

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 10:31

Dec-28-2020 17:13:44 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> YES <i>Respiratory Illness Diagno sis:</i>  UPPER RESPIRATORY INFECTION  Date of Diagnosis:  Dec/26/2020	Initial Entry
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**3. Toxicity Grade:**

Date	Location	User	Value	Reason
Dec-28-2020 17:13:44 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> 3	Initial Entry

090177e196ae2f53\Final\Final On: 01-Apr-2021 03:39 (GMT)



**Header Text:** c4591001**Visit:** POT\_COVID\_ILL 1 - Unscheduled  
Visit on Dec/28/2020**Form:** ILLNESS DETAILS - SEVERE - eCRF Audit Trail History**Form Version:** 17-Jul-2020 21:55**Form Status:** Data Complete, Frozen**Site No:** 1093**Site Name:** (1093) Meridian Clinical Research**Subject No:** 10931141**Subject Initials:** ---**Generated By:** (b) (4)**Generated Time (GMT):** 29-Mar-2021 10:31[Back to Form](#)**1. Category of Clinical Event:**

Date	Location	User	Value	Reason
Feb-16-2021 08:40:32 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Applicable	Initial Entry
Feb-16-2021 08:40:08 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b>	Initial Entry
Dec-28-2020 17:14:02 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Done	Initial Entry

**2. Subcategory of Clinical Event:**

Date	Location	User	Value	Reason
Feb-16-2021 08:40:32 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Applicable	Initial Entry
Feb-16-2021 08:40:08 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b>	Initial Entry
Dec-28-2020 17:14:02 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Done	Initial Entry

**3. Was a diagnosis obtained?**

Date	Location	User	Value	Reason
Feb-16-2021 08:40:32 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Applicable	Initial Entry
Feb-16-2021 08:40:08 (UTC-06:00) Central	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b>	Initial Entry

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled  
Visit on Dec/28/2020

**Form:** ILLNESS DETAILS - SEVERE - eCRF Audit Trail History

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

**Form Status:** Data Complete, Frozen

**Site No:** 1093

**Site Name:** (1093) Meridian Clinical Research

**Subject No:** 10931141

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 10:31

Time (US & Canada)		(b) (4), (b) (6)		
Dec-28-2020 17:14:02 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Done	Initial Entry

**4. Toxicity Grade:**

Date	Location	User	Value	Reason
Feb-16-2021 08:40:32 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Applicable	Initial Entry
Feb-16-2021 08:40:08 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b>	Initial Entry
Dec-28-2020 17:14:02 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Done	Initial Entry

090177e196ae2f53\Final\Final On: 01-Apr-2021 03:39 (GMT)

**Header Text:** c4591001**Visit:** POT\_COVID\_ILL 1 - Unscheduled  
Visit on Dec/28/2020**Form Version:** 15-Sep-2020 21:51**Site No:** 1093**Subject No:** 10931141**Generated By:** (b) (4)**Form:** LOCAL LABORATORY DATA - REPEATING  
CHEMISTRY - eCRF Audit Trail History**Form Status:** Data Complete, Frozen**Site Name:** (1093) Meridian Clinical Research**Subject Initials:** ---**Generated Time (GMT):** 29-Mar-2021 10:31[Back to Form](#)**1. Lab Panel:**

Date	Location	User	Value	Reason
Dec-28-2020 17:14:17 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Done	Initial Entry

**2. Laboratory Name and Address**

Date	Location	User	Value	Reason
Dec-28-2020 17:14:17 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Done	Initial Entry

**3. Collection Date:**

Date	Location	User	Value	Reason
Dec-28-2020 17:14:17 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Done	Initial Entry

**4. Specimen Type:**

Date	Location	User	Value	Reason
Dec-28-2020 17:14:17 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Done	Initial Entry

**5.a**

Date	Location	User	Value	Reason
Dec-28-2020 17:14:17 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Sponsor-Defined Identifier:</b> Not Done <b>Test::</b> Not Done	Initial Entry

Header Text: c4591001

Visit: POT\_COVID\_ILL 1 - Unscheduled  
Visit on Dec/28/2020

Form: LOCAL LABORATORY DATA - REPEATING  
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Site No: 1093

Site Name: (1093) Meridian Clinical Research

Subject No: 10931141

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:31

			Result::	Not Done
			Not Done::	Not Done
			Lab Normal Range:	Not Done

5.a Sponsor ID:

Date	Location	User	Value	Reason
Dec-28-2020 17:14:17 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> Not Done	Initial Entry

5.a Test:

Date	Location	User	Value	Reason
Dec-28-2020 17:14:17 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> Not Done	Initial Entry

5.a Result:

Date	Location	User	Value	Reason
Dec-28-2020 17:14:17 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> Not Done	Initial Entry

5.a Not Done:

Date	Location	User	Value	Reason
Dec-28-2020 17:14:17 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> Not Done	Initial Entry

5.a LNMT

Date	Location	User	Value	Reason
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090177e196ae2f53\Final\Final On: 01-Apr-2021 03:39 (GMT)

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled  
Visit on Dec/28/2020

**Form:** LOCAL LABORATORY DATA - REPEATING  
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**Form Status:** Data Complete, Frozen

**Site No:** 1093

**Site Name:** (1093) Meridian Clinical Research

**Subject No:** 10931141

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 10:31

Dec-28-2020 17:14:17 (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.b**

Date	Location	User	Value	Reason
Dec-28-2020 17:14:17 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Sponsor-Defined Identifier:</b> Not Done <b>Test::</b> Not Done <b>Result::</b> Not Done <b>Not Done::</b> Not Done <b>Lab Normal Range:</b> Not Done	Initial Entry

090177e196ae2f53\Final\Final On: 01-Apr-2021 03:39 (GMT)

Header Text: c4591001

Visit: POT\_COVID\_ILL 1 - Unscheduled  
Visit on Dec/28/2020

Form: LOCAL LABORATORY DATA - REPEATING  
CHEMISTRY - eCRF Audit Trail History

Form Version: 15-Sep-2020 21:51

Form Status: Data Complete, Frozen

Site No: 1093

Site Name: (1093) Meridian Clinical Research

Subject No: 10931141

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:31

5.b Sponsor ID:

Date	Location	User	Value	Reason
Dec-28-2020 17:14:17 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> Not Done	Initial Entry

5.b Test:

Date	Location	User	Value	Reason
Dec-28-2020 17:14:17 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> Not Done	Initial Entry

5.b Result:

Date	Location	User	Value	Reason
Dec-28-2020 17:14:17 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> Not Done	Initial Entry

5.b Not Done:

Date	Location	User	Value	Reason
Dec-28-2020 17:14:17 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> Not Done	Initial Entry

5.b LNMT

Date	Location	User	Value	Reason
Dec-28-2020 17:14:17 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> Not Done	Initial Entry

5.c

Date	Location	User	Value	Reason
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090177e196ae2f53\Final\Final On: 01-Apr-2021 03:39 (GMT)

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled  
Visit on Dec/28/2020

**Form Version:** 15-Sep-2020 21:51

**Site No:** 1093

**Subject No:** 10931141

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

**Form:** LOCAL LABORATORY DATA - REPEATING  
CHEMISTRY - eCRF Audit Trail History

**Form Status:** Data Complete, Frozen

**Site Name:** (1093) Meridian Clinical Research

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 10:31

Dec-28-2020 17:14:17 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Sponsor-Defined Identifier:</b> Not Done <b>Test::</b> Not Done <b>Result::</b> Not Done <b>Not Done::</b> Not Done <b>Lab Normal Range:</b> Not Done	Initial Entry
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090177e196ae2f53\Final\Final On: 01-Apr-2021 03:39 (GMT)

Header Text: c4591001

Visit: POT\_COVID\_ILL 1 - Unscheduled  
Visit on Dec/28/2020

Form: LOCAL LABORATORY DATA - REPEATING  
CHEMISTRY - eCRF Audit Trail History

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Form Status: Data Complete, Frozen

Site No: 1093

Site Name: (1093) Meridian Clinical Research

Subject No: 10931141

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:31

5.c Sponsor ID:

Date	Location	User	Value	Reason
Dec-28-2020 17:14:17 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> Not Done	Initial Entry

5.c Test:

Date	Location	User	Value	Reason
Dec-28-2020 17:14:17 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> Not Done	Initial Entry

5.c Result:

Date	Location	User	Value	Reason
Dec-28-2020 17:14:17 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> Not Done	Initial Entry

5.c Not Done:

Date	Location	User	Value	Reason
Dec-28-2020 17:14:17 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> Not Done	Initial Entry

5.c LNMT

Date	Location	User	Value	Reason
Dec-28-2020 17:14:17 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> Not Done	Initial Entry

5.d

Date	Location	User	Value	Reason
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090177e196ae2f53\Final\Final On: 01-Apr-2021 03:39 (GMT)



**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled  
Visit on Dec/28/2020

**Form Version:** 15-Sep-2020 21:51

**Site No:** 1093

**Subject No:** 10931141

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

**Form:** LOCAL LABORATORY DATA - REPEATING  
CHEMISTRY - eCRF Audit Trail History

**Form Status:** Data Complete, Frozen

**Site Name:** (1093) Meridian Clinical Research

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 10:31

Dec-28-2020 17:14:17 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Sponsor-Defined Identifier:</b> Not Done <b>Test::</b> Not Done <b>Result::</b> Not Done <b>Not Done::</b> Not Done <b>Lab Normal Range:</b> Not Done	Initial Entry
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**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled  
Visit on Dec/28/2020

**Form:** LOCAL LABORATORY DATA - REPEATING  
CHEMISTRY - eCRF Audit Trail History

**Form Version:** 15-Sep-2020 21:51

**Form Status:** Data Complete, Frozen

**Site No:** 1093

**Site Name:** (1093) Meridian Clinical Research

**Subject No:** 10931141

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 10:31

**5.d Sponsor ID:**

Date	Location	User	Value	Reason
Dec-28-2020 17:14:17 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Done	Initial Entry

**5.d Test:**

Date	Location	User	Value	Reason
Dec-28-2020 17:14:17 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Done	Initial Entry

**5.d Result:**

Date	Location	User	Value	Reason
Dec-28-2020 17:14:17 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Done	Initial Entry

**5.d Not Done:**

Date	Location	User	Value	Reason
Dec-28-2020 17:14:17 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Done	Initial Entry

**5.d LNMT**

Date	Location	User	Value	Reason
Dec-28-2020 17:14:17 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Done	Initial Entry

**5.e**

Date	Location	User	Value	Reason
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090177e196ae2f53\Final\Final On: 01-Apr-2021 03:39 (GMT)

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled  
Visit on Dec/28/2020

**Form Version:** 15-Sep-2020 21:51

**Site No:** 1093

**Subject No:** 10931141

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

**Form:** LOCAL LABORATORY DATA - REPEATING  
CHEMISTRY - eCRF Audit Trail History

**Form Status:** Data Complete, Frozen

**Site Name:** (1093) Meridian Clinical Research

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 10:31

Dec-28-2020 17:14:17 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Sponsor-Defined Identifier:</b> Not Done <b>Test::</b> Not Done <b>Result::</b> Not Done <b>Not Done::</b> Not Done <b>Lab Normal Range:</b> Not Done	Initial Entry
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**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled  
Visit on Dec/28/2020

**Form:** LOCAL LABORATORY DATA - REPEATING  
CHEMISTRY - eCRF Audit Trail History

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**Form Status:** Data Complete, Frozen

**Site No:** 1093

**Site Name:** (1093) Meridian Clinical Research

**Subject No:** 10931141

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 10:31

**5.e Sponsor ID:**

Date	Location	User	Value	Reason
Dec-28-2020 17:14:17 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Done	Initial Entry

**5.e Test:**

Date	Location	User	Value	Reason
Dec-28-2020 17:14:17 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Done	Initial Entry

**5.e Result:**

Date	Location	User	Value	Reason
Dec-28-2020 17:14:17 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Done	Initial Entry

**5.e Not Done:**

Date	Location	User	Value	Reason
Dec-28-2020 17:14:17 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Done	Initial Entry

**5.e LNMT**

Date	Location	User	Value	Reason
Dec-28-2020 17:14:17 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Done	Initial Entry

**5.f**

Date	Location	User	Value	Reason
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090177e196ae2f53\Final\Final On: 01-Apr-2021 03:39 (GMT)

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled  
Visit on Dec/28/2020

**Form Version:** 15-Sep-2020 21:51

**Site No:** 1093

**Subject No:** 10931141

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

**Form:** LOCAL LABORATORY DATA - REPEATING  
CHEMISTRY - eCRF Audit Trail History

**Form Status:** Data Complete, Frozen

**Site Name:** (1093) Meridian Clinical Research

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 10:31

Dec-28-2020 17:14:17 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Sponsor-Defined Identifier:</b> Not Done <b>Test::</b> Not Done <b>Result::</b> Not Done <b>Not Done::</b> Not Done <b>Lab Normal Range:</b> Not Done	Initial Entry
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Header Text: c4591001

Visit: POT\_COVID\_ILL 1 - Unscheduled  
Visit on Dec/28/2020

Form: LOCAL LABORATORY DATA - REPEATING  
CHEMISTRY - eCRF Audit Trail History

Form Version: 15-Sep-2020 21:51

Form Status: Data Complete, Frozen

Site No: 1093

Site Name: (1093) Meridian Clinical Research

Subject No: 10931141

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:31

5.f Sponsor ID:

Date	Location	User	Value	Reason
Dec-28-2020 17:14:17 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> Not Done	Initial Entry

5.f Test:

Date	Location	User	Value	Reason
Dec-28-2020 17:14:17 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> Not Done	Initial Entry

5.f Result:

Date	Location	User	Value	Reason
Dec-28-2020 17:14:17 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> Not Done	Initial Entry

5.f Not Done:

Date	Location	User	Value	Reason
Dec-28-2020 17:14:17 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> Not Done	Initial Entry

5.f LNMT

Date	Location	User	Value	Reason
Dec-28-2020 17:14:17 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> Not Done	Initial Entry

5.g

Date	Location	User	Value	Reason
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090177e196ae2f53\Final\Final On: 01-Apr-2021 03:39 (GMT)

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled  
Visit on Dec/28/2020

**Form Version:** 15-Sep-2020 21:51

**Site No:** 1093

**Subject No:** 10931141

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

**Form:** LOCAL LABORATORY DATA - REPEATING  
CHEMISTRY - eCRF Audit Trail History

**Form Status:** Data Complete, Frozen

**Site Name:** (1093) Meridian Clinical Research

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 10:31

Dec-28-2020 17:14:17 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Sponsor-Defined Identifier:</b> Not Done <b>Test::</b> Not Done <b>Result::</b> Not Done <b>Not Done::</b> Not Done <b>Lab Normal Range:</b> Not Done	Initial Entry
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**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled  
Visit on Dec/28/2020

**Form:** LOCAL LABORATORY DATA - REPEATING  
CHEMISTRY - eCRF Audit Trail History

**Form Version:** 15-Sep-2020 21:51

**Form Status:** Data Complete, Frozen

**Site No:** 1093

**Site Name:** (1093) Meridian Clinical Research

**Subject No:** 10931141

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 10:31

**5.g Sponsor ID:**

Date	Location	User	Value	Reason
Dec-28-2020 17:14:17 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Done	Initial Entry

**5.g Test:**

Date	Location	User	Value	Reason
Dec-28-2020 17:14:17 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Done	Initial Entry

**5.g Result:**

Date	Location	User	Value	Reason
Dec-28-2020 17:14:17 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Done	Initial Entry

**5.g Not Done:**

Date	Location	User	Value	Reason
Dec-28-2020 17:14:17 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Done	Initial Entry

**5.g LNMT**

Date	Location	User	Value	Reason
Dec-28-2020 17:14:17 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Done	Initial Entry

090177e196ae2f53\Final\Final On: 01-Apr-2021 03:39 (GMT)



**Header Text:** c4591001**Visit:** POT\_COVID\_ILL 1 - Unscheduled  
Visit on Dec/28/2020**Form:** LOCAL LABORATORY DATA - REPEATING Hematology -  
eCRF Audit Trail History**Form Version:** 15-Sep-2020 21:55**Form Status:** Data Complete, Frozen**Site No:** 1093**Site Name:** (1093) Meridian Clinical Research**Subject No:** 10931141**Subject Initials:** ---**Generated By:** (b) (4)**Generated Time (GMT):** 29-Mar-2021 10:31[Back to Form](#)**1. Lab Panel:**

Date	Location	User	Value	Reason
Dec-28-2020 17:14:30 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Done	Initial Entry

**2. Laboratory Name and Address**

Date	Location	User	Value	Reason
Dec-28-2020 17:14:30 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Done	Initial Entry

**3. Collection Date:**

Date	Location	User	Value	Reason
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**4. Specimen Type:**

Date	Location	User	Value	Reason
Dec-28-2020 17:14:30 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Done	Initial Entry

**5.a**

Date	Location	User	Value	Reason
Dec-28-2020 17:14:30 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Sponsor-Defined Identifier:</b> Not Done <b>Test::</b> Not Done	Initial Entry

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled  
Visit on Dec/28/2020

**Form:** LOCAL LABORATORY DATA - REPEATING Hematology -  
eCRF Audit Trail History

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

**Form Status:** Data Complete, Frozen

**Site No:** 1093

**Site Name:** (1093) Meridian Clinical Research

**Subject No:** 10931141

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 10:31

			<b>Result::</b>	Not Done
				ne
			<b>Not Done::</b>	Not Done
				ne
			<b>Lab Normal Range:</b>	Not Done
				ne

**5.a Sponsor ID:**

Date	Location	User	Value	Reason
Dec-28-2020 17:14:30 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Done	Initial Entry

**5.a Test:**

Date	Location	User	Value	Reason
Dec-28-2020 17:14:30 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Done	Initial Entry

**5.a Result:**

Date	Location	User	Value	Reason
Dec-28-2020 17:14:30 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Done	Initial Entry

**5.a Not Done:**

Date	Location	User	Value	Reason
Dec-28-2020 17:14:30 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Done	Initial Entry

**5.a LNMT**

Date	Location	User	Value	Reason
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090177e196ae2f53\Final\Final On: 01-Apr-2021 03:39 (GMT)

**Header Text:** c4591001  
**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit on Dec/28/2020  
**Form:** LOCAL LABORATORY DATA - REPEATING Hematology - eCRF Audit Trail History  
**Form Version:** 15-Sep-2020 21:55  
**Form Status:** Data Complete, Frozen  
**Site No:** 1093  
**Site Name:** (1093) Meridian Clinical Research  
**Subject No:** 10931141  
**Subject Initials:** ---  
**Generated By:** (b) (4)  
**Generated Time (GMT):** 29-Mar-2021 10:31

Dec-28-2020 17:14:30 (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.b**

Date	Location	User	Value	Reason
Dec-28-2020 17:14:30 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Sponsor-Defined Identifier:</b> Not Done <b>Test::</b> Not Done <b>Result::</b> Not Done <b>Not Done::</b> Not Done <b>Lab Normal Range:</b> Not Done	Initial Entry

090177e196ae2f53\Final\Final On: 01-Apr-2021 03:39 (GMT)

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled  
Visit on Dec/28/2020

**Form:** LOCAL LABORATORY DATA - REPEATING Hematology -  
eCRF Audit Trail History

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

**Form Status:** Data Complete, Frozen

**Site No:** 1093

**Site Name:** (1093) Meridian Clinical Research

**Subject No:** 10931141

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 10:31

**5.b Sponsor ID:**

Date	Location	User	Value	Reason
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**5.b Test:**

Date	Location	User	Value	Reason
Dec-28-2020 17:14:30 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Done	Initial Entry

**5.b Result:**

Date	Location	User	Value	Reason
Dec-28-2020 17:14:30 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Done	Initial Entry

**5.b Not Done:**

Date	Location	User	Value	Reason
Dec-28-2020 17:14:30 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Done	Initial Entry

**5.b LNMT**

Date	Location	User	Value	Reason
Dec-28-2020 17:14:30 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Done	Initial Entry

**5.c**

Date	Location	User	Value	Reason
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090177e196ae2f53\Final\Final On: 01-Apr-2021 03:39 (GMT)

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled  
Visit on Dec/28/2020

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

**Site No:** 1093

**Subject No:** 10931141

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

**Form:** LOCAL LABORATORY DATA - REPEATING Hematology -  
eCRF Audit Trail History

**Form Status:** Data Complete, Frozen

**Site Name:** (1093) Meridian Clinical Research

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 10:31

Dec-28-2020 17:14:30 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Sponsor-Defined Identifier:</b> Not Done <b>Test::</b> Not Done <b>Result::</b> Not Done <b>Not Done::</b> Not Done <b>Lab Normal Range:</b> Not Done	Initial Entry
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**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled  
Visit on Dec/28/2020

**Form:** LOCAL LABORATORY DATA - REPEATING Hematology -  
eCRF Audit Trail History

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

**Form Status:** Data Complete, Frozen

**Site No:** 1093

**Site Name:** (1093) Meridian Clinical Research

**Subject No:** 10931141

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 10:31

**5.c Sponsor ID:**

Date	Location	User	Value	Reason
Dec-28-2020 17:14:30 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Done	Initial Entry

**5.c Test:**

Date	Location	User	Value	Reason
Dec-28-2020 17:14:30 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Done	Initial Entry

**5.c Result:**

Date	Location	User	Value	Reason
Dec-28-2020 17:14:30 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Done	Initial Entry

**5.c Not Done:**

Date	Location	User	Value	Reason
Dec-28-2020 17:14:30 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Done	Initial Entry

**5.c LNMT**

Date	Location	User	Value	Reason
Dec-28-2020 17:14:30 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Done	Initial Entry

**5.d**

Date	Location	User	Value	Reason
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090177e196ae2f53\Final\Final On: 01-Apr-2021 03:39 (GMT)

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled  
Visit on Dec/28/2020

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

**Site No:** 1093

**Subject No:** 10931141

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

**Form:** LOCAL LABORATORY DATA - REPEATING Hematology -  
eCRF Audit Trail History

**Form Status:** Data Complete, Frozen

**Site Name:** (1093) Meridian Clinical Research

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 10:31

Dec-28-2020 17:14:30 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Sponsor-Defined Identifier:</b> Not Done <b>Test::</b> Not Done <b>Result::</b> Not Done <b>Not Done::</b> Not Done <b>Lab Normal Range:</b> Not Done	Initial Entry
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**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled  
Visit on Dec/28/2020

**Form:** LOCAL LABORATORY DATA - REPEATING Hematology -  
eCRF Audit Trail History

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

**Form Status:** Data Complete, Frozen

**Site No:** 1093

**Site Name:** (1093) Meridian Clinical Research

**Subject No:** 10931141

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 10:31

**5.d Sponsor ID:**

Date	Location	User	Value	Reason
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**5.d Test:**

Date	Location	User	Value	Reason
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**5.d Result:**

Date	Location	User	Value	Reason
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**5.d Not Done:**

Date	Location	User	Value	Reason
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**5.d LNMT**

Date	Location	User	Value	Reason
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**5.e**

Date	Location	User	Value	Reason
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090177e196ae2f53\Final\Final On: 01-Apr-2021 03:39 (GMT)



**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled  
Visit on Dec/28/2020

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

**Site No:** 1093

**Subject No:** 10931141

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

**Form:** LOCAL LABORATORY DATA - REPEATING Hematology -  
eCRF Audit Trail History

**Form Status:** Data Complete, Frozen

**Site Name:** (1093) Meridian Clinical Research

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 10:31

Dec-28-2020 17:14:30 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Sponsor-Defined Identifier:</b> Not Done <b>Test::</b> Not Done <b>Result::</b> Not Done <b>Not Done::</b> Not Done <b>Lab Normal Range:</b> Not Done	Initial Entry
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**Header Text:** c4591001

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

**Site No:** 1093

**Subject No:** 10931141

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**Form Status:** Data Complete, Frozen

**Site Name:** (1093) Meridian Clinical Research

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 10:31

**5.e Sponsor ID:**

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**5.e Test:**

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**5.e Result:**

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Dec-28-2020 17:14:30 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Done	Initial Entry

**5.e Not Done:**

Date	Location	User	Value	Reason
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**5.e LNMT**

Date	Location	User	Value	Reason
Dec-28-2020 17:14:30 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Done	Initial Entry

**5.f**

Date	Location	User	Value	Reason
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090177e196ae2f53\Final\Final On: 01-Apr-2021 03:39 (GMT)

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**Site Name:** (1093) Meridian Clinical Research

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Dec-28-2020 17:14:30 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Sponsor-Defined Identifier:</b> Not Done <b>Test::</b> Not Done <b>Result::</b> Not Done <b>Not Done::</b> Not Done <b>Lab Normal Range:</b> Not Done	Initial Entry
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**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled  
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**Form:** LOCAL LABORATORY DATA - REPEATING Hematology -  
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**5.f Sponsor ID:**

Date	Location	User	Value	Reason
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**5.f Test:**

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Dec-28-2020 17:14:30 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Done	Initial Entry

**5.f Result:**

Date	Location	User	Value	Reason
Dec-28-2020 17:14:30 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Done	Initial Entry

**5.f Not Done:**

Date	Location	User	Value	Reason
Dec-28-2020 17:14:30 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Done	Initial Entry

**5.f LNMT**

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Dec-28-2020 17:14:30 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Done	Initial Entry

**5.g**

Date	Location	User	Value	Reason
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**Site No:** 1093

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**Form:** LOCAL LABORATORY DATA - REPEATING Hematology -  
eCRF Audit Trail History

**Form Status:** Data Complete, Frozen

**Site Name:** (1093) Meridian Clinical Research

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**Generated Time (GMT):** 29-Mar-2021 10:31

Dec-28-2020 17:14:30 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Sponsor-Defined Identifier:</b> Not Done <b>Test::</b> Not Done <b>Result::</b> Not Done <b>Not Done::</b> Not Done <b>Lab Normal Range:</b> Not Done	Initial Entry
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Header Text: c4591001

Visit: POT\_COVID\_ILL 1 - Unscheduled  
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Form: LOCAL LABORATORY DATA - REPEATING Hematology -  
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Date	Location	User	Value	Reason
Dec-28-2020 17:14:30 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> Not Done	Initial Entry

5.g Test:

Date	Location	User	Value	Reason
Dec-28-2020 17:14:30 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> Not Done	Initial Entry

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Date	Location	User	Value	Reason
Dec-28-2020 17:14:30 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> Not Done	Initial Entry

5.g Not Done:

Date	Location	User	Value	Reason
Dec-28-2020 17:14:30 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> Not Done	Initial Entry

5.g LNMT

Date	Location	User	Value	Reason
Dec-28-2020 17:14:30 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> Not Done	Initial Entry

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Date	Location	User	Value	Reason
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090177e196ae2f53\Final\Final On: 01-Apr-2021 03:39 (GMT)

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled  
Visit on Dec/28/2020

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

**Site No:** 1093

**Subject No:** 10931141

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

**Form:** LOCAL LABORATORY DATA - REPEATING Hematology -  
eCRF Audit Trail History

**Form Status:** Data Complete, Frozen

**Site Name:** (1093) Meridian Clinical Research

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 10:31

Dec-28-2020 17:14:30 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Sponsor-Defined Identifier:</b> Not Done <b>Test::</b> Not Done <b>Result::</b> Not Done <b>Not Done::</b> Not Done <b>Lab Normal Range:</b> Not Done	Initial Entry
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**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled  
Visit on Dec/28/2020

**Form:** LOCAL LABORATORY DATA - REPEATING Hematology -  
eCRF Audit Trail History

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

**Form Status:** Data Complete, Frozen

**Site No:** 1093

**Site Name:** (1093) Meridian Clinical Research

**Subject No:** 10931141

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 10:31

**5.h Sponsor ID:**

Date	Location	User	Value	Reason
Dec-28-2020 17:14:30 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Done	Initial Entry

**5.h Test:**

Date	Location	User	Value	Reason
Dec-28-2020 17:14:30 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Done	Initial Entry

**5.h Result:**

Date	Location	User	Value	Reason
Dec-28-2020 17:14:30 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Done	Initial Entry

**5.h Not Done:**

Date	Location	User	Value	Reason
Dec-28-2020 17:14:30 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Done	Initial Entry

**5.h LNMT**

Date	Location	User	Value	Reason
Dec-28-2020 17:14:30 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Done	Initial Entry

**5.i**

Date	Location	User	Value	Reason
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090177e196ae2f53\Final\Final On: 01-Apr-2021 03:39 (GMT)



**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled  
Visit on Dec/28/2020

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

**Site No:** 1093

**Subject No:** 10931141

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

**Form:** LOCAL LABORATORY DATA - REPEATING Hematology -  
eCRF Audit Trail History

**Form Status:** Data Complete, Frozen

**Site Name:** (1093) Meridian Clinical Research

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 10:31

Dec-28-2020 17:14:30 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Sponsor-Defined Identifier:</b> Not Done <b>Test::</b> Not Done <b>Result::</b> Not Done <b>Not Done::</b> Not Done <b>Lab Normal Range:</b> Not Done	Initial Entry
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Header Text: c4591001

Visit: POT\_COVID\_ILL 1 - Unscheduled  
Visit on Dec/28/2020

Form: LOCAL LABORATORY DATA - REPEATING Hematology -  
eCRF Audit Trail History

Form Version: 15-Sep-2020 21:55

Form Status: Data Complete, Frozen

Site No: 1093

Site Name: (1093) Meridian Clinical Research

Subject No: 10931141

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:31

[Back to Form](#)

**5.i Sponsor ID:**

Date	Location	User	Value	Reason
Dec-28-2020 17:14:30 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Done	Initial Entry

**5.i Test:**

Date	Location	User	Value	Reason
Dec-28-2020 17:14:30 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Done	Initial Entry

**5.i Result:**

Date	Location	User	Value	Reason
Dec-28-2020 17:14:30 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Done	Initial Entry

**5.i Not Done:**

Date	Location	User	Value	Reason
Dec-28-2020 17:14:30 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Done	Initial Entry

**5.i LNMT**

Date	Location	User	Value	Reason
Dec-28-2020 17:14:30 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Done	Initial Entry

**5.j**

Date	Location	User	Value	Reason
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090177e196ae2f53\Final\Final On: 01-Apr-2021 03:39 (GMT)

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled  
Visit on Dec/28/2020

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

**Site No:** 1093

**Subject No:** 10931141

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

**Form:** LOCAL LABORATORY DATA - REPEATING Hematology -  
eCRF Audit Trail History

**Form Status:** Data Complete, Frozen

**Site Name:** (1093) Meridian Clinical Research

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 10:31

Dec-28-2020 17:14:30 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Sponsor-Defined Identifier:</b> Not Done <b>Test::</b> Not Done <b>Result::</b> Not Done <b>Not Done::</b> Not Done <b>Lab Normal Range:</b> Not Done	Initial Entry
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**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled  
Visit on Dec/28/2020

**Form:** LOCAL LABORATORY DATA - REPEATING Hematology -  
eCRF Audit Trail History

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

**Form Status:** Data Complete, Frozen

**Site No:** 1093

**Site Name:** (1093) Meridian Clinical Research

**Subject No:** 10931141

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 10:31

**5.j Sponsor ID:**

Date	Location	User	Value	Reason
Dec-28-2020 17:14:30 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Done	Initial Entry

**5.j Test:**

Date	Location	User	Value	Reason
Dec-28-2020 17:14:30 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Done	Initial Entry

**5.j Result:**

Date	Location	User	Value	Reason
Dec-28-2020 17:14:30 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Done	Initial Entry

**5.j Not Done:**

Date	Location	User	Value	Reason
Dec-28-2020 17:14:30 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Done	Initial Entry

**5.j LNMT**

Date	Location	User	Value	Reason
Dec-28-2020 17:14:30 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Done	Initial Entry

090177e196ae2f53\Final\Final On: 01-Apr-2021 03:39 (GMT)

**Header Text:** c4591001**Visit:** POT\_COVID\_ILL 1 - Unscheduled  
Visit on Dec/28/2020**Form:** VITAL SIGNS - COVID - eCRF Audit Trail History**Form Version:** 15-Sep-2020 21:52**Form Status:** Data Complete, Frozen**Site No:** 1093**Site Name:** (1093) Meridian Clinical Research**Subject No:** 10931141**Subject Initials:** ---**Generated By:** (b) (4)**Generated Time (GMT):** 29-Mar-2021 10:31[Back to Form](#)**1. Date:**

Date	Location	User	Value	Reason
Dec-28-2020 17:14:51 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Done	Initial Entry

**2.a**

Date	Location	User	Value	Reason
Dec-28-2020 17:14:51 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Record Identifier::</b> Not Done <b>Systolic::</b> Not Done <b>Diastolic::</b> Not Done <b>Respiratory Rate in r</b> <b>espirations/minute:</b> Not Done <b>Heart Rate in beats/m</b> <b>inute:</b> Not Done	Initial Entry

**2.a Record Identifier:**

Date	Location	User	Value	Reason
Dec-28-2020 17:14:51 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Done	Initial Entry

**2.a Systolic:**

Date	Location	User	Value	Reason
Dec-28-2020 17:14:51 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Done	Initial Entry

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled  
Visit on Dec/28/2020

**Form:** VITAL SIGNS - COVID - eCRF Audit Trail History

**Form Version:** 15-Sep-2020 21:52

**Form Status:** Data Complete, Frozen

**Site No:** 1093

**Site Name:** (1093) Meridian Clinical Research

**Subject No:** 10931141

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 10:31

**2.a Diastolic:**

Date	Location	User	Value	Reason
Dec-28-2020 17:14:51 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Done	Initial Entry

**2.a Respiratory Rate in respirations/minute:**

Date	Location	User	Value	Reason
Dec-28-2020 17:14:51 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Done	Initial Entry

**2.a Heart Rate in beats/minute:**

Date	Location	User	Value	Reason
Dec-28-2020 17:14:51 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Done	Initial Entry

090177e196ae2f53\Final\Final On: 01-Apr-2021 03:39 (GMT)

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled  
Visit on Dec/28/2020

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

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

**Form Status:**

**Site No:** 1093

**Site Name:** (1093) Meridian Clinical Research

**Subject No:** 10931141

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 10:31

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Date	Location	User	Value	Reason
Feb-16-2021 08:41:25 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Form Created	

Header Text: c4591001

Visit: POT\_COVID\_ILL 1 - Unscheduled  
Visit on Dec/28/2020

Form: VITAL SIGNS - PULSE OX ROOM AIR - eCRF Audit Trail  
History

Form Version: 15-Sep-2020 21:54

Form Status: Data Complete

Site No: 1093

Site Name: (1093) Meridian Clinical Research

Subject No: 10931141

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:31

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**I. Date:**

Date	Location	User	Value	Reason
Feb-16-2021 08:41:25 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Jan/19/2021	Initial Entry
Feb-16-2021 08:41:00 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b>	Initial Entry
Dec-28-2020 17:15:02 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Done	Initial Entry

**2.a**

Date	Location	User	Value	Reason
Feb-16-2021 08:41:25 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Record Identifier::</b> Not Done <b>Oxygen Saturation</b> 85.0 :	Initial Entry
Feb-16-2021 08:41:00 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Record Identifier::</b> Not Done <b>Oxygen Saturation</b> :	Initial Entry
Dec-28-2020 17:15:02 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Record Identifier::</b> Not Done <b>Oxygen Saturation</b> Not Done :	Initial Entry

**2.a Record Identifier:**

Date	Location	User	Value	Reason
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090177e196ae2f53\Final\Final On: 01-Apr-2021 03:39 (GMT)



**Header Text:** c4591001  
**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit on Dec/28/2020  
**Form:** VITAL SIGNS - PULSE OX ROOM AIR - eCRF Audit Trail History  
**Form Version:** 15-Sep-2020 21:54  
**Form Status:** Data Complete  
**Site No:** 1093  
**Site Name:** (1093) Meridian Clinical Research  
**Subject No:** 10931141  
**Subject Initials:** ---  
**Generated By:** (b) (4)  
**Generated Time (GMT):** 29-Mar-2021 10:31

Dec-28-2020 17:15:02 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Done	Initial Entry
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**2.a SPO2 Pulse Oximetry %**

Date	Location	User	Value	Reason
Feb-16-2021 08:41:25 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> 85.0	Initial Entry
Feb-16-2021 08:41:00 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b>	Initial Entry
Dec-28-2020 17:15:02 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Done	Initial Entry

090177e196ae2f53\Final\Final On: 01-Apr-2021 03:39 (GMT)

**Header Text:** c4591001**Visit:** POT\_COVID\_ILL 1 - Unscheduled  
Visit on Dec/28/2020**Form:** OXYGENATION PARAMETERS - eCRF Audit Trail History**Form Version:** 06-Jul-2020 21:52**Form Status:** Data Complete, Frozen**Site No:** 1093**Site Name:** (1093) Meridian Clinical Research**Subject No:** 10931141**Subject Initials:** ---**Generated By:** (b) (4)**Generated Time (GMT):** 29-Mar-2021 10:31[Back to Form](#)**1. Date Time of Assessment:**

Date	Location	User	Value	Reason
Feb-16-2021 08:37:40 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Applicable	Initial Entry
Feb-16-2021 08:37:23 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b>	Initial Entry
Dec-28-2020 17:15:14 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Done	Initial Entry

**2. Arterial Blood Gases PaO2 (mmHg):**

Date	Location	User	Value	Reason
Feb-16-2021 08:37:40 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Applicable	Initial Entry
Feb-16-2021 08:37:23 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b>	Initial Entry
Dec-28-2020 17:15:14 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Done	Initial Entry

**3. FiO2 (Fraction of Inhaled Oxygen):**

Date	Location	User	Value	Reason
Feb-16-2021 08:37:40 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Applicable	Initial Entry
Feb-16-2021 08:37:23 (UTC-06:00) Central	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b>	Initial Entry

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled  
Visit on Dec/28/2020

**Form:** OXYGENATION PARAMETERS - eCRF Audit Trail History

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

**Form Status:** Data Complete, Frozen

**Site No:** 1093

**Site Name:** (1093) Meridian Clinical Research

**Subject No:** 10931141

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 10:31

Time (US & Canada)		(b) (4), (b) (6)		
Dec-28-2020 17:15:14 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Done	Initial Entry

**Header Text:** c4591001**Visit:** POT\_COVID\_ILL 1 - Unscheduled  
Visit on Dec/28/2020**Form:** CONCOMITANT MEDICATIONS - VASOPRESSORS -  
eCRF Audit Trail History**Form Version:** 06-Jul-2020 21:55**Form Status:** Data Complete, Frozen**Site No:** 1093**Site Name:** (1093) Meridian Clinical Research**Subject No:** 10931141**Subject Initials:** ---**Generated By:** (b) (4)**Generated Time (GMT):** 29-Mar-2021 10:31[Back to Form](#)**1. What is the medication identifier?**

Date	Location	User	Value	Reason
Dec-28-2020 17:15:26 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Done	Initial Entry

**2. Category:**

Date	Location	User	Value	Reason
Dec-28-2020 17:15:26 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Done	Initial Entry

**3. Concomitant Medications Pre-specified:**

Date	Location	User	Value	Reason
Dec-28-2020 17:15:26 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Done	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
Dec-28-2020 17:15:26 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Done	Initial Entry

**5. Start Date:**

Date	Location	User	Value	Reason
Dec-28-2020 17:15:26 (UTC-06:00) Central	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Done	Initial Entry

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled  
Visit on Dec/28/2020

**Form:** CONCOMITANT MEDICATIONS - VASOPRESSORS -  
eCRF Audit Trail History

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

**Form Status:** Data Complete, Frozen

**Site No:** 1093

**Site Name:** (1093) Meridian Clinical Research

**Subject No:** 10931141

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 10:31

Time (US & Canada)		(b) (4), (b) (6)		
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**6. Ongoing?**

Date	Location	User	Value	Reason
Dec-28-2020 17:15:26 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Done	Initial Entry

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled  
Visit on Dec/28/2020

**Form:** IMAGING - eCRF Audit Trail History

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

**Form Status:** Data Complete, Frozen

**Site No:** 1093

**Site Name:** (1093) Meridian Clinical Research

**Subject No:** 10931141

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 10:31

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**1. Date of Assessment:**

Date	Location	User	Value	Reason
Dec-28-2020 17:15:38 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Done	Initial Entry

**2. Location of Assessment:**

Date	Location	User	Value	Reason
Dec-28-2020 17:15:38 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Done	Initial Entry

**3. Type of Imaging Exam:**

Date	Location	User	Value	Reason
Dec-28-2020 17:15:38 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Done	Initial Entry

**4. Assessment:**

Date	Location	User	Value	Reason
Dec-28-2020 17:15:38 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Done	Initial Entry

090177e196ae2f53\Final\Final On: 01-Apr-2021 03:39 (GMT)

**Header Text:** c4591001

**Visit:** POT\_COVID\_CONVA 1 -  
Unscheduled Visit on Feb/11/2021

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

**Site No:** 1093

**Subject No:** 10931141

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

**Form:** DATE OF VISIT - ILLNESS CONVALESCENT - eCRF  
Audit Trail History

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

**Site Name:** (1093) Meridian Clinical Research

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 10:31

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**1. Date of Visit**

Date	Location	User	Value	Reason
Feb-16-2021 08:36:19 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Feb/11/2021	Initial Entry

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

Date	Location	User	Value	Reason
Feb-16-2021 08:36:19 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> COVID_A1	Initial Entry

090177e196ae2f53\Final\Final On: 01-Apr-2021 03:39 (GMT)

**Header Text:** c4591001

**Visit:** POT\_COVID\_CONVA 1 -  
Unscheduled Visit on Feb/11/2021

**Form:** ELECTRONIC SAMPLE TRACKING -  
IMMUNOGENICITY - eCRF Audit Trail History

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

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

**Site No:** 1093

**Site Name:** (1093) Meridian Clinical Research

**Subject No:** 10931141

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 10:31

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**1. Data Origin**

Date	Location	User	Value	Reason
Feb-16-2021 08:36:28 (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-16-2021 08:36:28 (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-03-2021 08:51:39 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Answer Auto Query
Mar-02-2021 14:48:20 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Reissued:Candidate	DM: Requesting CRA/Triad assistance
Mar-02-2021 08:11:53 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Answered	BARCODE WILL BE UPDATED WHEN AVAILABLE.
Mar-02-2021 00:22:36 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Reissued:Opened	DM 1: Per the response "WAITING FOR BARCODE TO BECOME AVAILABLE." please verify and update Bar code once it will be

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**Header Text:** c4591001**Visit:** POT\_COVID\_CONVA 1 -  
Unscheduled Visit on Feb/11/2021**Form Version:** 22-Apr-2020 21:03**Site No:** 1093**Subject No:** 10931141**Generated By:** (b) (4)**Form:** ELECTRONIC SAMPLE TRACKING -  
IMMUNOGENICITY - eCRF Audit Trail History**Form Status:** Data Complete, Frozen, Verified**Site Name:** (1093) Meridian Clinical Research**Subject Initials:** ---**Generated Time (GMT):** 29-Mar-2021 10:31

				available. Thank you.
Mar-01-2021 17:12:48 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Answered	WAITING FOR BARCODE TO BECOME AVAILABLE.
Feb-17-2021 07:09:29 (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-16-2021 08:36:28 (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-16-2021 08:36:28 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> YES Date of Collection:  Feb/11/2021	Initial Entry

**5.a**

Date	Location	User	Value	Reason
Mar-03-2021 08:51:39 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Sample ID: BSHLV7	Initial Entry

**5.a Sample ID**

Date	Location	User	Value	Reason
Mar-03-2021 08:51:39 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> BSHLV7	Initial Entry

**Header Text:** c4591001

**Visit:** POT\_COVID\_CONVA 1 -  
Unscheduled Visit on Feb/11/2021

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

**Site No:** 1093

**Subject No:** 10931141

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

**Form:** ELECTRONIC SAMPLE TRACKING -  
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**Form Status:** Data Complete, Frozen, Verified

**Site Name:** (1093) Meridian Clinical Research

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**5.b**

Date	Location	User	Value	Reason
Mar-03-2021 08:51:53 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Sample ID:</b> BSHLV8	Initial Entry

**5.b Sample ID**

Date	Location	User	Value	Reason
Mar-03-2021 08:51:53 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> BSHLV8	Initial Entry

**5.c**

Date	Location	User	Value	Reason
Mar-03-2021 08:52:53 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Sample ID:</b> BJ88JJ	Initial Entry

**5.c Sample ID**

Date	Location	User	Value	Reason
Mar-03-2021 08:52:53 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> BJ88JJ	Initial Entry

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**Header Text:** c4591001

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

**Site No:** 1093

**Subject No:** 10931141

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

**Form:** ADVERSE EVENT REPORT - Audit Trail

**Form Status:**

**Site Name:** (1093) Meridian Clinical Research

**Subject Initials:** ---

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Date	Location	User	Value	Reason
Dec-28-2020 17:16:40 (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:** 1093

**Subject No:** 10931141

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

**Form:** ADVERSE EVENT REPORT - Audit Trail

**Form Status:**

**Site Name:** (1093) Meridian Clinical Research

**Subject Initials:** ---

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Date	Location	User	Value	Reason
Dec-28-2020 17:18:17 (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: 1093

Subject No: 10931141

Generated By: (b) (4)

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Status: Data Complete, Frozen

Site Name: (1093) Meridian Clinical Research

Subject Initials: ---

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**1. Category:**

Date	Location	User	Value	Reason
Dec-28-2020 17:16:40 (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
Dec-28-2020 17:16:40 (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
Dec-28-2020 17:16:40 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> URINARY TRACT INFECTION	Initial Entry

**4. Start Date Time:**

Date	Location	User	Value	Reason
Dec-28-2020 17:16:40 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Dec/26/2020 UNK:UNK	Initial Entry

**5. Is the adverse event still ongoing?**

Date	Location	User	Value	Reason
Feb-25-2021 23:00:23 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 2: Closed	Response satisfies query
Feb-24-2021 08:20:31 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 2: Answered	Transcription Error

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**Header Text:** c4591001**Visit:** Logs - Unscheduled**Form Version:** 22-Apr-2020 21:02**Site No:** 1093**Subject No:** 10931141**Generated By:** (b) (4)**Form:** ADVERSE EVENT REPORT - eCRF Audit Trail History**Form Status:** Data Complete, Frozen**Site Name:** (1093) Meridian Clinical Research**Subject Initials:** ---**Generated Time (GMT):** 29-Mar-2021 10:31

Feb-24-2021 08:20:31 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO End Date Time:  Dec/28/2020 UNK:UNK	Transcription Error
Feb-23-2021 20:40:22 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 2: Opened	Clinical End date for event UTI is 31Dec20; however, SAE report end date for both URI/UTI is 28Dec20. Please review, harmonize reporting and update UTI end date where applicable
Feb-16-2021 08:43:55 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO End Date Time:  Dec/31/2020 UNK:UNK	Transcription Error
Jan-05-2021 03:17:18 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Closed	Response satisfies query
Jan-04-2021 14:24:34 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Answered	ENTRY UPDATED
Dec-29-2020 22:35:15 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Opened	DM: Please complete item # 6 and 9. Thank you.
Dec-28-2020 17:16:40 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> YES	Initial Entry

**6. Toxicity Grade:**

Date	Location	User	Value	Reason
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Header Text: c4591001

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Subject Initials: ---

Generated By: (b) (4)

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Jan-04-2021 14:24:23 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> 1	Initial Entry
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**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-23-2021 18:23:46 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Closed	Response satisfies query
Feb-10-2021 15:47:44 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Answered	Transcription Error
Feb-10-2021 15:47:44 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> YES Is this serious event associ- ated with congenital anom- aly or birth defect?  NO  Did this serious event resul- t in death?  NO  Did this serious event requ- ire or prolong hospitalizati- on?  YES  Did this serious event resul- t in persistent or significant disability/incapacity?	Transcription Error

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**Subject No:** 10931141

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

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			NO  Is this serious event life threatening?  NO  Other medically important serious event  NO	
Feb-10-2021 02:58:07 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 2: Deleted	Query can be addressed internally
Feb-04-2021 06:36:10 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 2: Candidate	For AE URINARY TRACT INFECTION: Response to "Is the adverse event serious?" is 'No' but "Serious Adverse Event Number" is present.
Feb-03-2021 23:31:59 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Opened	Clinical Serious status for event UTI is NO; however, in SAE report UTI is reported as a serious event, on a separate event tab (rather than reported in narrative). Please review UTI serious criteria status; harmonize reporting, and

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Form Status: Data Complete, Frozen

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				update where required
Dec-28-2020 17:16:40 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO	Initial Entry

**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
Dec-28-2020 17:16:40 (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
Jan-04-2021 14:24:23 (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>  GYNOCOLOGY	Initial Entry

**10. Latest Action Taken with Study Treatment:**

Date	Location	User	Value	Reason
Dec-28-2020 17:16:40 (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
Dec-28-2020 17:16:40 (UTC-06:00) Central	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> YES	Initial Entry

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Header Text: c4591001

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Subject No: 10931141

Generated By: (b) (4)

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Form Status: Data Complete, Frozen

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Subject Initials: ---

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Time (US & Canada)

(b) (4), (b) (6)

12. Was a Non-Drug Treatment given?

Date	Location	User	Value	Reason
Dec-28-2020 17:16:40 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> NO	Initial Entry

13. What was the outcome of this adverse event?:

Date	Location	User	Value	Reason
Feb-16-2021 13:34:35 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Closed	Response satisfies query
Feb-16-2021 08:43:35 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Answered	Transcription Error
Feb-16-2021 08:43:35 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> RECOVERED/RESOLVED	Transcription Error
Feb-11-2021 12:59:51 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Opened	SAE RECON:AER#2021107150,outcome was reported as RECOVERED/RESOLVED to Safety DB however, recorded as RECOVERING/RESOLVING on AE CRF. Please confirm correct outcome. If safety update is required, please submit a follow-up form.
Dec-28-2020 17:16:40	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> RECOVERING/	Initial Entry

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**Header Text:** c4591001

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**Form Status:** Data Complete, Frozen

**Site No:** 1093

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**Subject Initials:** ---

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

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(UTC-06:00)  
Central Time (US  
& Canada)

(b) (4), (b) (6)

RESOLVING

**14. Did the adverse event cause the subject to be discontinued from the study?**

Date	Location	User	Value	Reason
Dec-28-2020 17:16:40 (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
Feb-04-2021 06:36:10 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> 2021107150	Initial Entry

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Subject No: 10931141

Generated By: (b) (4)

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**1. Category:**

Date	Location	User	Value	Reason
Dec-28-2020 17:18:17 (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
Dec-28-2020 17:18:17 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> 2	Initial Entry

**3. Adverse Event:**

*(If possible specify diagnosis, not individual symptoms)*

Date	Location	User	Value	Reason
Mar-03-2021 12:43:12 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 2: Closed	Response satisfies query
Mar-02-2021 08:11:29 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 2: Answered	ENTRY HAS BEEN ADDED
Feb-23-2021 20:43:20 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 2: Reissued:Opened	Clinical- Pardon typo; SAE report states subject received influenza vaccine on 04Oct20; please report on Vaccine log
Feb-10-2021 15:30:17 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 2: Answered	IMPOSSIBLE FOR SUBJECT TO HAVE RECIEVED SHOT ON

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**Subject No:** 10931141

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

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				04OCT2021, AS IT IS ONLY 10FEB2021.
Feb-10-2021 08:15:48 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 2: Opened	Clinical - SAE report (2021107150) states subject received Influenza vaccine on 04Oct21; please report on Vaccine log
Jan-05-2021 04:17:23 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Hayley Wyper (b) (4)	Query 1: Closed	Response satisfies query
Jan-04-2021 15:17:38 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Answered	ENTRY UPDATED.
Jan-04-2021 14:41:07 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Hayley Wyper (b) (4)	Query 1: Reissued:Opened	CLINQUERY: Adverse event entry is currently marked as 'no' for serious. If subject's hospitalisation meets serious criteria please review that entry. AE would then stay in AE listing.
Jan-04-2021 14:26:09 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Answered	SAME EVEN AS CAPTURED IN COV ILL FOLDER, HOWEVER, SUBJECT WAS HOSPITALIZED. UNSURE OF AE SHOULD BE ERASED.
Jan-04-2021 05:28:21	ACV0PFEINFP6000	Hayley Wyper	Query 1: Opened	CLINQUERY:

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Header Text: c4591001

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Generated By: (b) (4)

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(UTC-06:00) Central Time (US & Canada)		(b) (4)		Event appears to be captured in the COV ILL folder. If same event, duplicate within AE listing is not necessary. Please review
Dec-28-2020 17:18:17 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> UPPER RESPIRATORY I NFECTIO	Initial Entry

4. Start Date Time:

Date	Location	User	Value	Reason
Feb-23-2021 18:25:47 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Closed	Response satisfies query
Feb-18-2021 02:33:32 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 2: Closed	Response satisfies query
Feb-17-2021 17:32:34 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 2: Answered	Transcription Error
Feb-17-2021 17:32:34 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Dec/26/2020 UNK:UNK	Transcription Error
Feb-16-2021 21:24:02 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 2: Opened	SAE RECON: AER#2021107150 ,onset date was recorded as 26Dec2020 in Safety database however, recorded as 25Dec2020 on AE CRF. Please confirm correct Onset Date.If safety update is required,

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**Header Text:** c4591001**Visit:** Logs - Unscheduled**Form Version:** 22-Apr-2020 21:02**Site No:** 1093**Subject No:** 10931141**Generated By:** (b) (4)**Form:** ADVERSE EVENT REPORT - eCRF Audit Trail History**Form Status:** Data Complete, Frozen**Site Name:** (1093) Meridian Clinical Research**Subject Initials:** ---**Generated Time (GMT):** 29-Mar-2021 10:31

				please submit a ffup SAE form
Feb-10-2021 15:51:05 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Answered	Transcription Error
Feb-10-2021 15:51:05 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Dec/25/2020 UNK:UNK	Transcription Error
Feb-04-2021 00:33:02 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Opened	CLINICAL Event start date is 26Dec20; however, Covid illness visit reports symptoms began 25Dec20. Please review, harmonize reporting, and update where applicable
Dec-28-2020 17:18:17 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Dec/26/2020 UNK:UNK	Initial Entry

**5. Is the adverse event still ongoing?**

Date	Location	User	Value	Reason
Feb-10-2021 15:54:25 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO End Date Time: Dec/28/2020 UNK:UNK	Transcription Error
Jan-04-2021 23:42:00 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Closed	Response satisfies query
Jan-04-2021 14:25:29 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Answered	ENTRY UPDATED

**Header Text:** c4591001**Visit:** Logs - Unscheduled**Form Version:** 22-Apr-2020 21:02**Site No:** 1093**Subject No:** 10931141**Generated By:** (b) (4)**Form:** ADVERSE EVENT REPORT - eCRF Audit Trail History**Form Status:** Data Complete, Frozen**Site Name:** (1093) Meridian Clinical Research**Subject Initials:** ---**Generated Time (GMT):** 29-Mar-2021 10:31

Dec-29-2020 22:35:37 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Opened	DM: Please complete item # 6 and 9. Thank you.
Dec-28-2020 17:18:17 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> YES	Initial Entry

**6. Toxicity Grade:**

Date	Location	User	Value	Reason
Feb-23-2021 18:25:00 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Closed	Response satisfies query
Feb-10-2021 15:52:38 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Answered	SEVERITY IS STILL 1 PER PI
Feb-03-2021 23:41:27 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Opened	Clinical Severity grade for SAE is 1. Please review severity to confirm or update this mild severity
Jan-04-2021 14:25:18 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> 1	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-23-2021 20:41:37 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 7: Closed	during 2 day Hosp; sufficient test window



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**Site No:** 1093

**Subject No:** 10931141

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

**Form:** ADVERSE EVENT REPORT - eCRF Audit Trail History

**Form Status:** Data Complete, Frozen

**Site Name:** (1093) Meridian Clinical Research

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Feb-23-2021 18:27:03 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 6: Closed	Response satisfies query
Feb-10-2021 15:51:48 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 7: Answered	Transcription Error
Feb-10-2021 15:51:48 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 6: Answered	Transcription Error
Feb-10-2021 15:51:48 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> YES Is this serious event asso ciated with congenital an omaly or birth defect?  NO  Did this serious event res ult in death?  NO  Did this serious event re quire or prolong hospital ization?  YES  Did this serious event res ult in persistent or signifi cant disability/incapacity ?  NO  Is this serious event life t hreatening?	Transcription Error

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**Header Text:** c4591001**Visit:** Logs - Unscheduled**Form Version:** 22-Apr-2020 21:02**Site No:** 1093**Subject No:** 10931141**Generated By:** (b) (4)**Form:** ADVERSE EVENT REPORT - eCRF Audit Trail History**Form Status:** Data Complete, Frozen**Site Name:** (1093) Meridian Clinical Research**Subject Initials:** ---**Generated Time (GMT):** 29-Mar-2021 10:31

			NO  Other medically important serious event  NO	
Feb-10-2021 08:14:07 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 7: Opened	Clinical SAE report (2021107150) includes negative COVID test [thank you]; please update with the test DATE.
Feb-09-2021 14:15:10 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Giselle Castillo (b) (4)	Query 5: Closed	Response satisfies query
Feb-04-2021 06:35:34 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 4: Deleted	Close Auto Query
Feb-03-2021 23:37:36 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 6: Opened	Clinical Serious criteria for event are Hosp and Medically Important/Significant; however, SAE report serious criterion is Hosp. Please review, harmonize reporting and update where applicable.
Feb-02-2021 10:36:41 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 5: Answered	SAE REPORT WILL BE SUBMITTED.
Feb-02-2021 05:32:18 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Giselle Castillo (b) (4)	Query 5: Opened	CLINICAL_ If the event meets seriousness criteria (ie, hospitalization), please submit the

**Header Text:** c4591001**Visit:** Logs - Unscheduled**Form Version:** 22-Apr-2020 21:02**Site No:** 1093**Subject No:** 10931141**Generated By:** (b) (4)**Form:** ADVERSE EVENT REPORT - eCRF Audit Trail History**Form Status:** Data Complete, Frozen**Site Name:** (1093) Meridian Clinical Research**Subject Initials:** ---**Generated Time (GMT):** 29-Mar-2021 10:31

				SAE report per protocol requirements as per protocol section 8.3.7. Thanks.
Jan-30-2021 20:17:45 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 3: Closed	Response satisfies query
Jan-29-2021 14:27:23 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 4: Candidate	For AE UPPER RESPIRATORY INFECTION: Response to "Is the adverse event serious?" is 'Yes' but "Serious Adverse Event Number" is blank.
Jan-29-2021 14:27:23 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 3: Answered	Transcription Error
Jan-29-2021 14:27:23 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> 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	Transcription Error

**Header Text:** c4591001

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			?  NO  Is this serious event life t hreatening?  NO  Other medically importa nt serious event  YES	
Jan-29-2021 12:08:28 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) [REDACTED]	Query 3: Opened	Clinical Event status is Not serious; however, COVID illness visit reports hospitalization on 26Dec20. Please clarify if hospitalized or not, and update in the correct location
Jan-08-2021 05:16:46 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) [REDACTED]	Query 2: Closed	event downgraded TO NON SERIOUS
Jan-06-2021 14:23:02 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 2: Answered	Transcription Error
Jan-06-2021 14:23:02 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) [REDACTED]	<b>Data Entry:</b> NO	Transcription Error

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Form Status: Data Complete, Frozen

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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
Jan-06-2021 06:20:02 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 2: Opened	SAE RECON:UPPER RESPIRATORY INFECTION(Onset date:26Dec2020) is not reported to Safety database but marked serious on AE CRF. Confirm seriousness and report to Pfizer immediately. If this event is not serious, downgrade the event on AE CRF
Jan-05-2021 21:10:11 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Deleted	Query can be addressed internally
Jan-04-2021 15:16:44 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Candidate	For AE UPPER RESPIRATORY INFECTION: Response to "Is the adverse event serious?" is 'Yes' but "Serious Adverse Event Number" is blank.
Jan-04-2021 15:16:44 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> YES Is this serious event associ	Transcription Error

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**Site Name:** (1093) Meridian Clinical Research

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			<p>ated with congenital anomaly or birth defect?</p> <p>NO</p> <p>Did this serious event result in death?</p> <p>NO</p> <p>Did this serious event require or prolong hospitalization?</p> <p>YES</p> <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>YES</p>	
Dec-28-2020 17:18:17 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO	Initial Entry

**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
Dec-28-2020 17:18:17 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO	Initial Entry

Header Text: c4591001

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Generated By: (b) (4)

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Form Status: Data Complete, Frozen

Site Name: (1093) Meridian Clinical Research

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9. Is this event related to study treatment:

Date	Location	User	Value	Reason
Jan-04-2021 14:25:18 (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  If Other, specify:  VIRAL	Initial Entry

10. Latest Action Taken with Study Treatment:

Date	Location	User	Value	Reason
Dec-28-2020 17:18:17 (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
Dec-28-2020 17:18:17 (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
Dec-28-2020 17:18:17 (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
Feb-11-2021 12:57:59	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Closed	Response satisfies query

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

**Form:** ADVERSE EVENT REPORT - eCRF Audit Trail History

**Form Status:** Data Complete, Frozen

**Site Name:** (1093) Meridian Clinical Research

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 10:31

(UTC-06:00) Central Time (US & Canada)				
Feb-10-2021 16:04:37 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 2: Closed	Close Auto Query
Feb-10-2021 16:04:37 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Answered	Transcription Error
Feb-10-2021 16:04:37 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> RECOVERED/RESOLVED	Transcription Error
Feb-10-2021 15:54:25 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 2: Opened	For AE UPPER RESPIRATORY INFECTION: Response to "What was the outcome of this adverse event?" is 'Recovering/Resolving' but AE End Date/Time is present.
Feb-10-2021 03:08:35 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Opened	SAE RECON:AER#2021107150,outcome was reported as RECOVERED/RESOLVED to Safety DB however, recorded as RECOVERING/RESOLVING on AE CRF. Please confirm correct outcome. If safety update is required, please submit a follow-up form.
Dec-28-2020 17:18:17 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> RECOVERING/RESOLVING	Initial Entry

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**Header Text:** c4591001

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

**Form:** ADVERSE EVENT REPORT - eCRF Audit Trail History

**Form Status:** Data Complete, Frozen

**Site Name:** (1093) Meridian Clinical Research

**Subject Initials:** ---

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**14. Did the adverse event cause the subject to be discontinued from the study?**

Date	Location	User	Value	Reason
Dec-28-2020 17:18:17 (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
Feb-04-2021 06:35:34 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> 2021107150	Initial Entry

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**Header Text:** c4591001

**Visit:** Logs - Unscheduled

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

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

**Form Status:**

**Site No:** 1093

**Site Name:** (1093) Meridian Clinical Research

**Subject No:** 10931141

**Subject Initials:** ---

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

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Date	Location	User	Value	Reason
Mar-02-2021 08:11:14 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Form Created	

Header Text: c4591001

Visit: Logs - Unscheduled

Form: CONCOMITANT MEDICATIONS - NON STUDY VACCINATIONS - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Frozen, Verified

Site No: 1093

Site Name: (1093) Meridian Clinical Research

Subject No: 10931141

Subject Initials: ---

Generated By: (b) (4)

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**1. What is the medication identifier?**

Date	Location	User	Value	Reason
Mar-02-2021 08:11:14 (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
Mar-02-2021 08:11:14 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> VACCINATIONS	Initial Entry

**3. Concomitant Medications Pre-specified:**

Date	Location	User	Value	Reason
Mar-02-2021 08:11:14 (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
Mar-02-2021 08:11:14 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> INFLUENZA VACCINE	Initial Entry

**5. Date:**

Date	Location	User	Value	Reason
Mar-02-2021 08:11:14 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Oct/4/2020	Initial Entry

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**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:** 1093

**Site Name:** (1093) Meridian Clinical Research

**Subject No:** 10931141

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 10:31

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**1. Date of Completion/Discontinuation/Death :**

Date	Location	User	Value	Reason
Nov-12-2020 08:28:08 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Nov/11/2020	Initial Entry

**2. Phase of Disposition:**

Date	Location	User	Value	Reason
Nov-12-2020 08:28:08 (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
Nov-12-2020 08:28:08 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> COMPLETED	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

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***1. Date of Visit***

Date	Location	User	Value	Reason
Feb-24-2021 08:23:23 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Feb/19/2021	Initial Entry

**Header Text:** c4591001**Visit:** Potential ReVax Initial Contact -  
Unscheduled**Form Version:** 10-Dec-2020 02:25**Site No:** 1093**Subject No:** 10931141**Generated By:** (b) (4)**Form:** FURTHER VACCINATION CONFIRMATION - eCRF Audit  
Trail History**Form Status:** Data Complete, Frozen**Site Name:** (1093) Meridian Clinical Research**Subject Initials:** ---**Generated Time (GMT):** 29-Mar-2021 10:31[Back to Form](#)***1. Select appropriate response - Is participant willing to return for Vaccination 3?***

Date	Location	User	Value	Reason
Feb-24-2021 08:23:46 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Feb-24-2021 08:23:32 (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-24-2021 08:23:32 (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 local/national recommendations and confirmed to have received only placebo at Vaccination 1/2	Initial Entry

**Header Text:** c4591001

**Visit:** Disposition - Unscheduled

**Form:** TREATMENT UNBLINDED - eCRF Audit Trail History

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

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

**Site No:** 1093

**Site Name:** (1093) Meridian Clinical Research

**Subject No:** 10931141

**Subject Initials:** ---

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

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**1. Date Treatment Unblinded :**

Date	Location	User	Value	Reason
Feb-24-2021 08:23:46 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Feb/19/2021	Initial Entry

**2. Primary Reason for Unblinding:**

Date	Location	User	Value	Reason
Feb-24-2021 08:23:46 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> ASSESS ELIGIBILITY FOR ADDITIONAL VACCINATIO N	Initial Entry

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**Header Text:** c4591001

**Visit:** V101\_VAX3

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

**Site No:** 1093

**Subject No:** 10931141

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

**Form:** DATE OF VISIT - eCRF Audit Trail History

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

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*I. Date of Visit*

Date	Location	User	Value	Reason
Feb-24-2021 08:24:01 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Feb/23/2021	Initial Entry



**Header Text:** c4591001

**Visit:** V101\_VAX3

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

**Site No:** 1093

**Subject No:** 10931141

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

**Form:** INFORMED CONSENT - FURTHER VACCINATION -  
eCRF Audit Trail History

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

**Site Name:** (1093) Meridian Clinical Research

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 10:31

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**I. Consent Was:**

Date	Location	User	Value	Reason
Feb-24-2021 08:24:14 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> OBTAINED Date Written Consent Obtain ed  Feb/23/2021	Initial Entry

**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:** 1093

**Site Name:** (1093) Meridian Clinical Research

**Subject No:** 10931141

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 10:31

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**1. Date of Completion/Discontinuation/Death :**

Date	Location	User	Value	Reason
Feb-24-2021 08:25:19 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Feb/23/2021	Initial Entry

**2. Phase of Disposition:**

Date	Location	User	Value	Reason
Feb-24-2021 08:25:19 (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
Feb-24-2021 08:25:19 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> COMPLETED	Initial Entry

090177e196ae2f53\Final\Final On: 01-Apr-2021 03:39 (GMT)

**Header Text:** c4591001

**Visit:** V101\_VAX3

**Form:** LAB URINALYSIS - PREGNANCY TEST - eCRF Audit Trail History

**Form Version:** 20-Feb-2021 02:14

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

**Site No:** 1093

**Site Name:** (1093) Meridian Clinical Research

**Subject No:** 10931141

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 10:31

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**1. Lab Panel:**

Date	Location	User	Value	Reason
Feb-24-2021 08:25:38 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Applicable	Initial Entry

**2. Lab Sub-Panel:**

Date	Location	User	Value	Reason
Feb-24-2021 08:25:38 (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
Feb-24-2021 08:25:38 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Applicable	Initial Entry

**4. Laboratory Name and Address (Derived)**

Date	Location	User	Value	Reason
Feb-24-2021 08:25:38 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Applicable	Initial Entry

**5. Specimen Type:**

Date	Location	User	Value	Reason
Feb-24-2021 08:25:38 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Applicable	Initial Entry

**6.a**

090177e196ae2f53\Final\Final On: 01-Apr-2021 03:39 (GMT)

Header Text: c4591001

Visit: V101\_VAX3

Form: LAB URINALYSIS - PREGNANCY TEST - eCRF Audit Trail History

Form Version: 20-Feb-2021 02:14

Form Status: Data Complete, Frozen, Verified

Site No: 1093

Site Name: (1093) Meridian Clinical Research

Subject No: 10931141

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:31

Date	Location	User	Value	Reason
Feb-24-2021 08:25:38 (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	Initial Entry

6.a Sponsor ID:

Date	Location	User	Value	Reason
Feb-24-2021 08:25:38 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Applicable	Initial Entry

6.a Test:

Date	Location	User	Value	Reason
Feb-24-2021 08:25:38 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Applicable	Initial Entry

6.a Result:

Date	Location	User	Value	Reason
Feb-24-2021 08:25:38 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Applicable	Initial Entry

6.a Not Done:

Date	Location	User	Value	Reason
Feb-24-2021 08:25:38 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Applicable	Initial Entry

090177e196ae2f53\Final\Final On: 01-Apr-2021 03:39 (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:** 1093**Site Name:** (1093) Meridian Clinical Research**Subject No:** 10931141**Subject Initials:** ---**Generated By:** (b) (4)**Generated Time (GMT):** 29-Mar-2021 10:31[Back to Form](#)**1. Data Origin**

Date	Location	User	Value	Reason
Feb-24-2021 08:25:55 (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-24-2021 08:25:55 (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
Feb-24-2021 16:53:02 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Feb-24-2021 08:25:55 (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-24-2021 08:25:55 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> YES Date of Collection:  Feb/23/2021	Initial Entry

**5.a**

Date	Location	User	Value	Reason
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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: 1093

Site Name: (1093) Meridian Clinical Research

Subject No: 10931141

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:31

Feb-24-2021 16:53:02 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Sample ID:</b> BSHLWV	Initial Entry
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5.a Sample ID

Date	Location	User	Value	Reason
Feb-24-2021 16:53:02 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> BSHLWV	Initial Entry

5.b

Date	Location	User	Value	Reason
Feb-24-2021 16:53:12 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Sample ID:</b> BSHLWT	Initial Entry

5.b Sample ID

Date	Location	User	Value	Reason
Feb-24-2021 16:53:12 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> BSHLWT	Initial Entry

5.c

Date	Location	User	Value	Reason
Feb-24-2021 17:03:25 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Sample ID:</b> BJ88GS	Initial Entry

5.c Sample ID

Date	Location	User	Value	Reason
Feb-24-2021 17:03:25 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> BJ88GS	Initial Entry

090177e196ae2f53\Final\Final On: 01-Apr-2021 03:39 (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:** 1093

**Site Name:** (1093) Meridian Clinical Research

**Subject No:** 10931141

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 10:31

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**1. Data Origin**

Date	Location	User	Value	Reason
Feb-24-2021 08:26:10 (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-24-2021 08:26:10 (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-24-2021 16:51:16 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Feb-24-2021 08:26:10 (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-24-2021 08:26:10 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> YES Date of Collection:  Feb/23/2021	Initial Entry

**5.a**

Date	Location	User	Value	Reason
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090177e196ae2f53\Final\Final On: 01-Apr-2021 03:39 (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:** 1093

**Site Name:** (1093) Meridian Clinical Research

**Subject No:** 10931141

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 10:31

Feb-24-2021 16:51:16 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Sample ID:</b> BJ88GV	Initial Entry
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**5.a Sample ID**

Date	Location	User	Value	Reason
Feb-24-2021 16:51:16 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> BJ88GV	Initial Entry



Header Text: c4591001

Visit: V101\_VAX3

Form: VACCINATION - eCRF Audit Trail History

Form Version: 10-Dec-2020 02:26

Form Status: Data Complete, Frozen, Verified

Site No: 1093

Site Name: (1093) Meridian Clinical Research

Subject No: 10931141

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:31

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**1. Was there a temporary delay of vaccination?**

Date	Location	User	Value	Reason
Feb-24-2021 08:26:35 (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
Feb-24-2021 08:26:35 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> BNT162b2	Initial Entry

**3. Formulation:**

Date	Location	User	Value	Reason
Feb-24-2021 08:26:35 (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
Feb-24-2021 08:26:35 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Feb/23/2021 14:27	Initial Entry

**5. Anatomical Location:**

Date	Location	User	Value	Reason
Feb-24-2021 08:26:35 (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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090177e196ae2f53\Final\Final On: 01-Apr-2021 03:39 (GMT)

Header Text: c4591001

Visit: V101\_VAX3

Form Version: 10-Dec-2020 02:26

Site No: 1093

Subject No: 10931141

Generated By: (b) (4)

Form: VACCINATION - eCRF Audit Trail History

Form Status: Data Complete, Frozen, Verified

Site Name: (1093) Meridian Clinical Research

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 10:31

Feb-24-2021 08:26:35 (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
Feb-24-2021 08:26:35 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> INTRAMUSCULAR	Initial Entry

**8. Actual Dose:**

Date	Location	User	Value	Reason
Feb-24-2021 08:26:35 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> 30.0	Initial Entry

**9. Unit:**

Date	Location	User	Value	Reason
Feb-24-2021 08:26:35 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> ug	Initial Entry

**10. Timeframe Subject Was Observed**

Date	Location	User	Value	Reason
Feb-24-2021 08:26:35 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> 30 MINUTES	Initial Entry

**11. Was the subject observed for at least the protocol specified observation period after investigational product administration?**

Date	Location	User	Value	Reason
Feb-24-2021 08:26:35 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> YES	Initial Entry

090177e196ae2f53\Final\Final On: 01-Apr-2021 03:39 (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:** 1093

**Site Name:** (1093) Meridian Clinical Research

**Subject No:** 10931141

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 10:31

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**1. Subject Status**

Date	Location	User	Value	Reason
Nov-12-2020 08:28:08 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> FOLLOW-UP	Initial Entry
Sep-22-2020 15:36:55 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> ENROLLED/RANDOMIZED	Initial Entry
Sep-22-2020 15:35:26 (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
Nov-12-2020 08:28:08 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> Nov/11/2020	Initial Entry
Sep-22-2020 15:36:55 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> Sep/22/2020	Initial Entry
Sep-22-2020 15:35:26 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> Sep/22/2020	Initial Entry

090177e196ae2f53\Final\Final On: 01-Apr-2021 03:39 (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, Verified

**Site No:** 1093

**Site Name:** (1093) Meridian Clinical Research

**Subject No:** 10931141

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 10:31

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*1. Casebook Signature*

Date	Location	User	Value	Reason
Oct-28-2020 15:21:41 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Click Here to Enable	Initial Entry